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FDA Interim Hiring and Retention Assessment

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LIST OF EXHIBITS

ACRONYMS

ACRONYM	MEANING
AO	Administrative Officer
APS	Alternative Pay Structure
ATLAS	Applicant Tracking Lifecycle Analysis Solution
BIIS	Business Intelligence Information System
BsUFA	Biosimilar User Fee Act
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
DE	Delegated Examining
DEU	Delegated Examining Unit
DHA	Direct Hire Authority
EHCM	Enterprise Human Capital Management
EOD	Entrance on Duty
EVP	Employee Value Proposition
FDA	Food and Drug Administration
FDARA	FDA Reauthorization Act
FEVS	Federal Employee Viewpoint Survey
FTE	Full-time Equivalency
FY	Fiscal Year
GP	General Physician
GS	General Schedule
HC	Human Capital
HHS	Department of Health and Human Services
HR	Human Resources
HRIS	Human Resources Information System
HRIT	Human Resources Information Technology
KSA	Knowledge, Skills, and Abilities
MCO	Mission Critical Occupation
OC	Office of the Commissioner
OHCM	Office of Human Capital Management
OHR	Office of Human Resources
OM	Office of Management
OO	Office of Operations
OPM	U.S. Office of Personnel Management
OTS	Office of Talent Solutions
PD	Position Description
PDUFA	Prescription Drug User Fee Act
PM	Program Manager
PMAP	Performance Management Appraisal Program
RPA	Robotic Process Automation
SME	Subject Matter Expert
SMO	Senior Management Officer
SOP	Standard Operating Procedure
SST	Scientific Staffing Team
STEM	Science, Technology, Engineering, and Mathematics
TSO	Talent Strategy Officer

1. EXECUTIVE SUMMARY

1.1 Background

FDA's Hiring Challenge

The Food and Drug Administration (FDA) has the monumental task of building and cultivating a world-class workforce to provide oversight to one of the most highly regulated food and drug markets in the world. Given the increasing speed of medical and scientific advancements, FDA must compete with the private sector and academia to attract and hire top talent with the proper backgrounds and levels of experience; many times, this requires attracting candidates from disciplines that have unique and specialized skills. Moreover, the Agency needs to do so swiftly and effectively.

In addition to the external talent development challenges created by rapid scientific advancements and market forces, FDA has also faced internal challenges. FDA has experienced a long history of protracted hiring timeframes with inefficient human resources (HR) processes, a disparate collection of Human Resources Information Systems (HRIS) and applications that are not integrated, an underdeveloped infrastructure and operating model, poor data curation and data management that impacts data quality and validity, ineffective workload management, and varying levels of competencies within the HR staff.[1] FDA also uses a complex set of hiring and pay authorities (e.g., Title 5 [including Direct Hire Authority (DHA)], Title 38, Title 42, 21st Century Cures Act hiring flexibilities) that has the potential to create hiring efficiencies and improve hiring effectiveness. This diverse range of authorities, many of which are similar, have nuanced differences that can make the authorities confusing to effectively use.[2] In addition, because most of these authorities are delegated to the "Executive Agency" level (i.e., the Department of Health and Human Services [HHS] versus FDA), additional layers of guidance or restrictions can be imposed that may unintentionally limit their effectiveness for FDA.

The combination of these challenges impacts the degree of collaboration among groups that rely on each other to recruit, hire, and retain a world-class workforce. In addition, a recent Office of Personnel Management (OPM) audit uncovered significant issues with FDA's delegated examining (DE) activities. The Agency is also fighting against time regarding succession planning, with almost half of its senior leaders eligible for retirement in Fiscal Year (FY) 2020.[3]

User Fee Commitments

FDA is authorized to collect user fees from sponsors and applicants to help expedite the development, review, and approval processes of human drug and biologics. The passage of the 2017 FDA Reauthorization Act (FDARA) and the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II commitment letters assert that FDA must perform continuous assessments—by an independent contractor with the appropriate expertise—of its hiring processes as well as its hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in hiring human drug and biologics review program staff.[4]

Scope

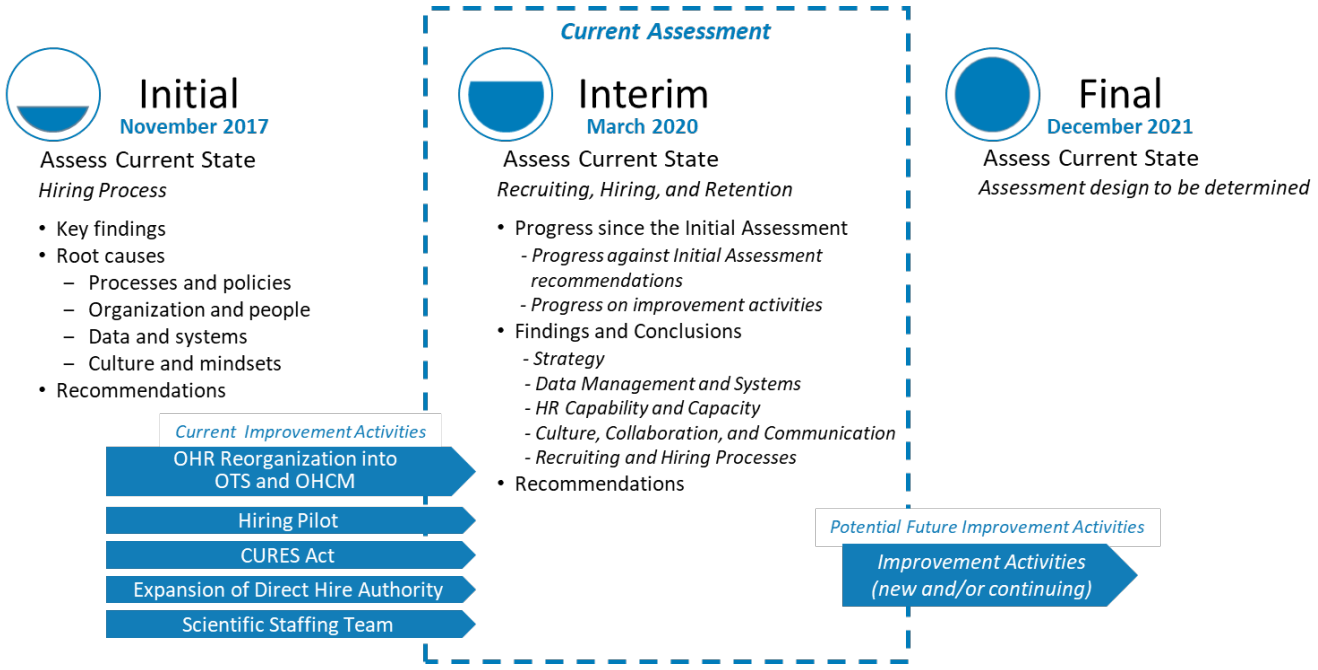
In response to the PDUFA VI and BsUFA II commitment letters, FDA has committed to conducting a series of three assessments of the recruiting, hiring, and retention of its human drug and biologics review program staff: an Initial Assessment (completed in November 2017), an Interim Assessment (summarized in this report), and a Final Assessment (scheduled for late 2021). Specifically, the scope of this Interim Assessment is

[1] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[2] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.
[3] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.
[4] Sources: FDA Reauthorization Act of 2017 (FDARA), FDA.gov; PDUFA VI Commitment Letter FY2018 to FY2022, FDA.gov; BsUFA II Commitment Letter, FDA.gov.

limited to the human drug and biologics review program staff located in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) and, from a service delivery perspective, the Agency's HR Organization (now comprised of the Office of Talent Solutions [OTS] and the Office of Human Capital Management [OHCM]) within the Office of the Commissioner's (OC) Office of Operations (OO). Data collection, analysis, evaluation, reporting, and documentation (including policies, procedures, and HR activities) only apply to the organizations and functions studied and do not extend to other Centers or organizational units beyond those mentioned. Booz Allen worked with FDA to define the time parameters of the Interim Assessment as the start of FY2017 (October 1, 2016)—which directly followed the end of the Initial Assessment's data collection phase—through the end of FY2019 (September 30, 2019).

As the second of three assessments, the Interim Assessment is intended to report on progress since the Initial Assessment (including progress on recommendations from the Initial Assessment and effectiveness of five identified improvement activities: Scientific Talent Recruiting Staff [STRS] Hiring Pilot, OHR reorganization, 21st Century Cures Act, Scientific Staffing Team [SST], and expanded DHA), define the current state, and recommend improvements for FDA's recruiting, hiring, and retention of scientific, technical, professional, and administrative staff involved in the human drug and biologics review programs. Where possible, this report compares data from the Initial Assessment to yield a more comprehensive view of the impact and sustainability of results versus examining a single point in time. However, while the Initial Assessment was intended to establish a baseline for the FDA's hiring state, inadequate access and maintenance of data limited the ability for equivalent comparisons. Exhibit 1 provides a frame of reference for this study design.

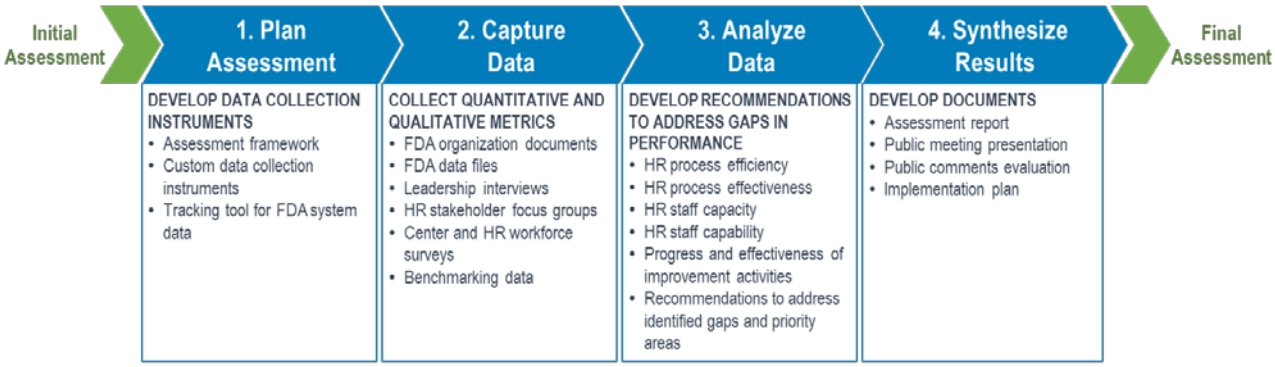
Exhibit 1: Study Design



Methodology

Booz Allen developed and applied a four-step methodology that guided the team through the assessment. Exhibit 2 and the subsequent narrative summarize each step.

Exhibit 2: Interim Assessment Methodology



Step 1: Plan Assessment. *Details were planned in coordination with FDA—specifying how and when data will be collected and curated, as well as the analyses designed to address assessment objectives.*

To appropriately address the complex and multifunctional nature of the Interim Assessment requirements, our team explored four discrete but interconnected focus areas for evaluation: HR process efficiency, HR process effectiveness, HR staff capacity, and HR staff capability. These four focus areas (defined further in Supplement Exhibit S-1) formed the basis of this assessment's research design and helped to target our efforts to conduct an objective and comprehensive assessment. The team then developed a comprehensive Data Collection Plan to support consistency in data collection technique. Part of this plan included designing and developing customized data collection instruments (e.g., interview and focus group protocols, surveys).

Step 2: Capture Data. *Data collection activities were designed to efficiently garner complete, accurate, and useful data while minimizing the burden on FDA employees providing the data.*

Using a multi-method data collection approach enabled the team to gather quantitative and qualitative data via objective (e.g., data from HR systems) and subjective methods (e.g., focus groups, interviews, surveys) covering the Interim Assessment time period of FY2017 through FY2019. Having a rich set of data from each source is critical to conducting a valuable multi-method evaluation. Unfortunately, limited availability of reliable data and discrepancies in the data files created a lack of confidence in the veracity of some of the quantitative data. The assessment team used multiple data collection methods to develop findings based on available data and perspectives (see Supplement Exhibit S-2 for more details). Exhibit 3 displays the data collected via each method during the Interim Assessment.

Exhibit 3: Data Collection By The Numbers

Step 3: Analyze Data. *Data were organized using appropriate methodologies to interpret the results and develop insightful, actionable recommendations; input and validation from FDA stakeholders was incorporated, as appropriate.*

Booz Allen conducted quantitative analyses by first compiling, formatting, and reviewing the data, which included identifying and resolving potential data challenges (e.g., missing data, data discrepancies). The team used descriptive statistics—such as means (averages) frequencies (number counts, percentages), and crosstabs (e.g., breakouts of certain variables across groups)—to characterize and summarize the results. The team used inferential statistics (e.g., correlations) in instances where it was helpful to investigate the relationship among variables.

Booz Allen conducted qualitative data analyses by categorizing individual comments (i.e., interview and focus group feedback and open-ended survey responses) into themes. To control for evaluator bias and to maintain consistency, an assessment leader trained the team on the analysis procedures, conducted regular joint reviews, and maintained oversight throughout the qualitative analysis process. The resultant list of themes represents the most prominent sentiments expressed for each item. In addition, the team identified any other relevant patterns (e.g., theme differences across interviews and focus groups).

Finally, when sufficient data were available to compare Initial Assessment and Interim Assessment results, the team also performed the analyses appropriate to the data type (e.g., qualitative comparisons of similar results, quantitative analyses of identical survey items).

Step 4: Synthesize Results. *A set of findings and conclusions were generated, leading to a comprehensive assessment report documenting progress since the Initial Assessment, evaluating the current state, and recommending improvements.*

Based on the analyses of multi-method data, the assessment team generated data-driven findings. Booz Allen then drew inferences across one or more related findings—based on the synthesis of relevant themes and complementary information that pointed to the most substantive takeaways—and encapsulated these points into conclusions. Finally, based on a critical review of the conclusions, the team developed actionable recommendations to address the gaps identified in the assessment and to provide a path forward for FDA.

The findings, conclusions, and recommendations presented in this report will be published for public comment. Once public comments are received, Booz Allen will work with FDA on an implementation plan to act on the recommendations to address identified gaps.

Considerations and Limitations

This study's design was intended to provide as much rigor as possible so that FDA and external stakeholders can be confident that the conclusions and recommendations are defensible and actionable. Yet, as with other organizational research, certain data collection and analysis factors can impact results. In this particular study, the reader is urged to consider the following factors, which influenced the assessment:

Assessing Current State

- The assessment team's ability to make unconditional determinations of process efficiency and effectiveness, as well as assess staff capability, workload distribution, and resource requirements, was reduced due to the limited availability of reliable data and information.
- In instances where FDA maintains the same data in multiple places or ways, the assessment team prioritized data drawn from the system of record as the more credible data source to increase confidence in data accuracy.
- The team's analysis of FDA data files was limited by issues (e.g., data discrepancies, data gaps) with how FDA captures and maintains some data and how FDA produces some reports and queries drawn from the system of record; these data management issues can impact the quality and veracity of the data findings.

- The team conducted interviews and focus groups, which are useful methods for generating rich information given the open-ended format of questions and the ability of the facilitator to probe on responses. However, recognizing that themes can be biased by group composition (e.g., participants self-selecting to participate, the dynamics that occur in group settings), the assessment team minimized these biases by inviting a broad range of participants, encouraging all participants to speak in the sessions, and reporting the more dominant perspectives in the thematic analyses.
- The team established and provided definitions for recruiting, hiring, and retention during the study. However, it is possible that participants responded to questions (in surveys, focus groups, and interviews) based on their own frames of reference for these terms as well as the distinctions among the terms. As a result, some findings may be impacted by differing definitions.

Assessing Changes Over Time

- The team performed comparisons across the Initial Assessment and the Interim Assessment where possible; however, the team was limited in the comparisons that it could perform because records from the Initial Assessment that were available to FDA did not include comprehensive objective data and procedural documentation. As an example, for the Initial Assessment, "observed" timeframes for each process stage of the traditional Title 5 hiring process were based solely on stakeholder interviews rather than objective data.[5]

In addition, at times in the report, the team references taking a more enterprise-wide view, such as to employ a more strategic focus or to promote inter-Center consistency. While the context of this study is the human drug and biologics review program staff, who reside in CDER and CBER, the team presented enterprise-wise recommendations that FDA may choose to apply across the Agency overall.

Definitions of Recruiting, Hiring, and Retention

While the Initial Assessment focused only on the hiring function, for the Interim Assessment, the scope was expanded to include recruiting, hiring, and retention functions. Each of these was addressed as a unique function. However, certain topics spanned functions; in these instances, the assessment team presented the topic in the most relevant section. For the purposes of this assessment, the following definitions were developed in partnership with FDA and used in all surveys.

Recruiting: FDA's process of finding potential candidates who may be qualified to fill positions at the Agency and attracting qualified candidates to apply. The term outreach is also sometimes used to describe this process.

Hiring: FDA's process of reviewing applications, selecting candidates to interview, interviewing candidates, making hiring decisions, and extending initial (or tentative) job offers.[6] This study focuses less on the steps that occur after the initial job offer (e.g., security review, final offer, enter on duty) because the timing of those activities is driven more by FDA's Office of Security Operations and the candidates themselves, rather than the HR workforce.

Retention: FDA's strategies, programs, and other actions to keep employees motivated and focused so they elect to remain employed and fully productive for the benefit of the Agency. Examples include student loan repayment programs, retention allowances, flexible work schedules, telework, changes in duty station, professional development opportunities, employee networking and affinity groups, and diversity and inclusion programs.

FDA HR Staff

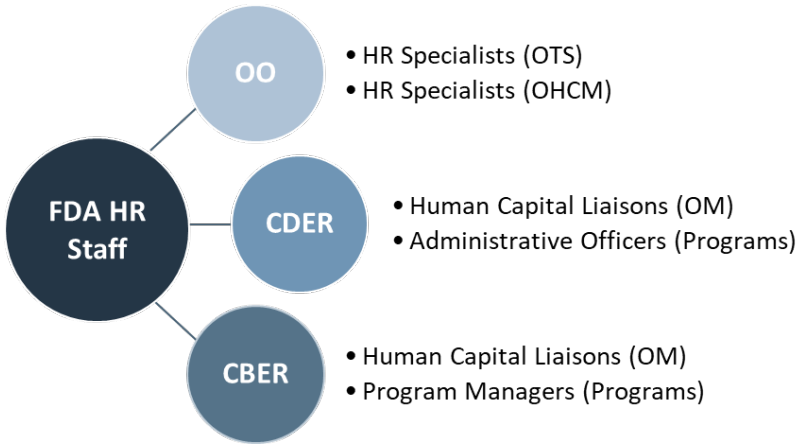
HR staff are aligned to the Agency's HR Organization (i.e., OTS and OHCM within OO) as well as within each Center (i.e., within its Office of Management (OM) and its program offices (Programs). Depending on their

[5] Source: Revamping the Hiring Process 09.15.2017, OTS.

[6] Note: In the surveys, the hiring process stages were categorized as classification, job analysis, interview and selection, and onboarding.

organizational alignment and role, HR staff often perform different, yet complementary, work related to HR recruiting, hiring, and retention functions. Exhibit 4 presents the groupings of staff who typically engage in HR activities and are fundamental to this assessment.

Exhibit 4: FDA HR Staff



FDA Stakeholders Impacted by Recruiting, Hiring, and Retention Activities

FDA stakeholders embedded in and impacted by HR processes and activities include FDA and Center/Office leadership, HR senior leadership, hiring managers, managers of HR staff, and human drug and biologics review program staff in CDER and CBER. Exhibit 5 presents a high-level overview of these stakeholders.

Exhibit 5: Relevant FDA HR Stakeholders

TERM	SPECIFIC ROLES	DEFINITION
FDA and Center/ Office Leadership	• *OC Chief Operating Officer* • *OC Office of Equal Employment Opportunity Director* • *CDER/CBER Center Directors* • *CDER/CBER Executive Officers* • *CDER/CBER Office Directors*	FDA Executives with FDA-wide oversight as well as Center/Office Leadership involved in overseeing the human drug and biologics review programs.
HR Senior Leadership	• *OTS/OHCM Senior Leadership* • *CDER/CBER OM HR Leadership* • *OTS/OHCM Directors*	Leaders involved in overseeing FDA's HR functions.
Hiring Managers	• *CDER/CBER Hiring Managers*	Managers involved in staffing decisions to hire human drug and biologics review program staff.
Managers of HR Staff[7]	• *OTS Division Directors and Branch Chiefs* • *OHCM Team Leads* • *CDER/CBER OM Managers* • *CDER Senior Management Officers* • *CBER Managers of Program Managers (PM)*	Managers involved in overseeing the work of staff performing the applicable HR functions.
HR Staff	• *HR Specialists* • *Classifiers* • *Employee Engagement Staff* • *CDER/CBER OM Human Capital Liaisons* • *CDER Administrative Officers (AO)* • *CBER PMs*	Staff involved in performing the applicable HR functions, including HR professionals working in OTS, OHCM, CDER, and CBER.
Human Drug and Biologics Review Program Staff	• *All employees in CDER and CBER*	Human drug and biologics review program staff, including professional, scientific, technical, and administrative employees.

[7] Note: For spacing purposes, this role is referred to as "HR Managers" in some charts and graphs.

1.2 Summary of Progress Since the Initial Assessment

The previous Initial Assessment report, published in 2017, presented three major hiring-related recommendations for improvement that resulted in the implementation of the Hiring Pilot. See Section 2.1 for more detail on progress against these Initial Assessment recommendations.

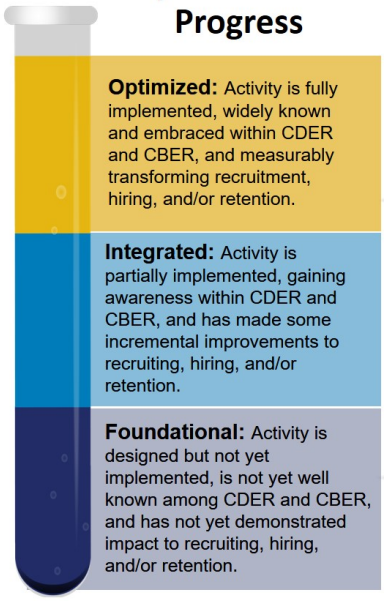
1. Develop and launch a controlled pilot to test a completely new and redesigned hiring process.
2. Rigorously and continuously evaluate performance and iterate on the process design based on pilot findings; capture insights related to how best to leverage and scale the process, with the ultimate goal of identifying a dramatically improved process that could be rolled out across the entire Agency.
3. Initiate an assessment of the technologies available, leveraging emerging business requirements from the pilot, to identify a fit-for-purpose solution.

Following the Initial Assessment, FDA defined the Hiring Pilot as an improvement activity and also identified four additional improvement activities.

It is worth recognizing that an Office of Personnel Management (OPM) audit of FDA's human capital (HC) management from May 2018 through June 2018 (report delivered in December 2018) uncovered significant issues with FDA's delegated examining (DE) activities. This resulted in mandatory and immediate remediation actions that diverted OTS resources from the improvement activities identified in the Initial Assessment.

Exhibit 6 provides our version of a maturity model, intended to provide a *rough estimation* of implementation of each improvement activity for the purposes of visualizing progress. Booz Allen created the levels of implementation—Foundational, Integrated, and Optimized—and their definitions and based estimated progress on the aggregation of findings and conclusions in this report. Items in blue represent accomplishments that have resulted in integrated effectiveness for that particular activity; items in grey depict high-level goals that could help the activity reach optimal effectiveness. Summaries of each improvement activity and its progress can be found in Section 2.2 of this report.

Exhibit 6: Implementation Progress of Improvement Activities



❑ *Representative activities to help obtain optimal effectiveness (aligned to select recommendations in this Interim Assessment)*

☑ Representative accomplishments resulting in integrated effectiveness

STRS Hiring Pilot

- ❑ *Improve data management and reporting capabilities (**R-4**, **R-6**) tied to outcome/success measures (**R-17**)*
- ❑ *Expand system integrations (**R-5**)*
- ❑ *Increase pilot communication products (**R-12**)*
- ❑ *Create a centralized knowledge management repository for pilot documentation and communications (**R-15**)*
- ☑ Demonstrated reduced time-to-hire with certain parameters through its streamlined process
- ☑ Demonstrated time-savings through the use of shared certificates
- ☑ Introduced applicant tracking with the ATLAS system
- ☑ Created a new Talent Strategy Officer role to improve communications with hiring managers

OHR Reorganization

- ❑ *Design a well-coordinated organizational strategic plan (**R-2**)*
- ❑ *Create a stakeholder engagement strategy (**R-11**) and tactical communication products (**R-12**)*
- ❑ *Foster a collaborative, customer-centric culture (**R-10**) and reframe roles (**R-7**)*
- ❑ *Develop workload management processes and tools (**R-8**)*
- ☑ Instituted new levels of management focused on the Centers
- ☑ Separated pre-employment activities from employee experience services
- ☑ Centralized dedicated teams with functional expertise to enhance quality control and scalability for critical or specialized hiring components
- ☑ Enhanced HR employee accountability with new HR performance management action plans

21st Century Cures Act

- ❑ *Create a strategic stakeholder engagement strategy (**R-11**) along with a detailed communication plan (**R-13**) and tactical communication products (**R-12**) regarding FDA's procedures and use of Cures*
- ❑ *Define outcome/success measures (**R-17**) tied to specific hiring goals and targets (**R-3**)*
- ☑ Made 47 appointments across CDER and CBER (data through Sept 30, 2019)
- ☑ Delivered mandated FDA Workforce Planning Report, Recruiting and Retention Plan, and Recommendations to Congress
- ☑ Implemented governance structure, including a HR Cures Working Group and Steering Committee
- ☑ Designed and implemented new Alternative Pay Structure (APS)

Scientific Staffing Team

- ❑ *Create a strategic stakeholder engagement strategy (**R-11**) and tactical communication products (**R-12**) with a collaborative, customer-centric culture (**R-10**)*
- ❑ *Identify outcome/success measures (**R-17**) tied to specific hiring goals/targets (**R-3**)*
- ☑ Generated a unified FDA recruitment brand and presence at external events
- ☑ Launched new FDA social media presence for recruitment and outreach; increased online traffic
- ☑ Created 100+ external partnerships with government, professional associations, and academic institutions to develop a pipeline of highly qualified candidates with a focus on STEM talent
- ☑ Hosted 12+ academic visits on the White Oak campus in 2018 and 2019
- ☑ Introduced a recruiting effort for Veterans and persons with disabilities

Expansion of Direct Hire Authority

- ❑ *Create a detailed communication plan (**R-13**) and tactical communication products (**R-12**) regarding OPM requirements for and FDA's procedures and use of DHA*
- ❑ *Define outcome/success measures (**R-17**) tied to specific hiring goals and targets (**R-3**)*
- ☑ 100% of CBER Direct Hires and 30% of CDER Direct Hires in FY2019 were associated with the authority's expanded positions

1.3 Crosswalk of Conclusions and Recommendations

The body of the report details the study's 26 findings (based on the data), 10 conclusions (based on syntheses of the findings), and 17 recommendations (based on the conclusions) that are also accessible via the following links for easy reference by the reader:

1. Strategy (Findings and Conclusions; Recommendations)
2. Data Management and Systems (Findings and Conclusions; Recommendations)
3. HR Staff Capability and Capacity (Findings and Conclusions; Recommendations)
4. Culture, Collaboration, and Communication (Findings and Conclusions; Recommendations)
5. Recruiting and Hiring Processes (Findings and Conclusions; Recommendations)

This section presents a high-level crosswalk of the study's conclusions and recommendations, which also demonstrates the interconnectedness across these recommendations. Some conclusions lead to multiple recommendations. And, some conclusions lead to one or more recommendation(s) previously tied to another conclusion; in these instances, a note indicates that the recommendation was stated elsewhere in the crosswalk tables.

Strategy

CONCLUSION	RECOMMENDATIONS
C1-1: FDA lacks an enterprise-wide systems approach to integrate and optimize recruiting, hiring, and retention functions; however, the Agency-level HR Organization and the Centers have made some noteworthy strategic efforts. **C1-2.** Despite perceptions of significant attrition problems, overall turnover at CDER and CBER is relatively low and staff are committed to working for the Agency; however, when turnover occurs, FDA lacks a strategic approach to quickly recover when they lose specialized talent.	**R-1:** Assess the strategic alignments among recruiting, hiring, and retention to identify and leverage their linkages with each other and across the talent management life cycle. **R-2:** Develop and implement an integrated human capital strategic plan that focuses on enterprise-wide, time-bound goals and actionable steps for achieving them. **R-3:** Integrate CDER's and CBER's hiring targets into a unified strategic hiring plan for the human drug and biologics review program staff to prioritize recruiting efforts.

Data Management and Systems

CONCLUSION	RECOMMENDATIONS
C2-1: Deficiencies in how FDA collects, manages, and maintains HR data result in inefficiencies and inhibit measurement of recruiting, hiring, and retention efforts. **C2-2:** FDA does not yet have the mature technology integration necessary to sustain data integrity, data access, and reporting agility in support of hiring, recruiting, and retention.	**R-4:** Put more uniformity and structure into data management and reporting practices for recruiting, hiring, and retention data. **R-5:** Compile an inventory and develop a map showing the linkages across major HRIS technologies used for recruiting, hiring, and retention for CDER and CBER. **R-6:** In conjunction with the review of existing HRIS technologies, FDA should consider employing additional technological solutions to enhance data management and reporting capabilities. **R-17:** Drive greater accountability for process improvement by documenting and regularly tracking outcome measures, such as customer-centric, key performance indicators (KPI) and success measures.

HR Staff Capability and Capacity

CONCLUSION	RECOMMENDATIONS
C3-1: Although the OHR reorganization established some important building blocks, FDA lacks a comprehensive organizational infrastructure for HR to enable consistent, high-quality service delivery. **C3-2:** FDA faces issues with both HR staff capability and capacity; moreover, FDA does not sufficiently track HR workload, distribution of work, nor HR staff competencies and performance to enable a complete understanding of the challenges and root causes of these issues.	**R-7:** Reframe the roles of OTS' HR staff aligned to CDER and CBER as "HR Business Partners." **R-8:** Establish a workload management process for assessing and distributing work across the HR workforce, leveraging reliable analytic tools. **R-9:** Hold managers of HR staff—across the Agency's HR Organization, CDER, and CBER—accountable for actively managing staff performance by establishing standardized PMAP goals.

Culture, Collaboration, and Communication

CONCLUSION	RECOMMENDATIONS
C4-1: Stakeholders overwhelmingly consider the hiring process to be inefficient and ineffective; improved communication and collaboration—in conjunction with process documentation and guidance—is widely viewed as key to making improvements.	**R-10:** Shift to a more collaborative, customer-centric culture. **R-11:** Establish a stakeholder engagement strategy to encourage two-way communications with the goal of increasing awareness and efficient adoption of recruiting and hiring process improvements. **R-12:** Create and disseminate tactical communication products that will help leaders, hiring managers, and HR staff perform their tasks related to recruiting, hiring, and retention. **R-13:** Disseminate communications plans to increase awareness and share critical information about the Cures Act and DHA to support strategic and consistent application of these hiring authorities. **R-14:** Reinvigorate standing meetings that occur between OTS and the Centers to improve effectiveness and encourage greater collaboration.

Recruiting and Hiring Processes

CONCLUSION	RECOMMENDATIONS
C5-1: FDA has been able to attract human drug and biologics review program staff; however, certain challenges (e.g., lack of a targeted approach to recruiting, questions about the sufficiency of the HR recruiting staff's capabilities) impact the speed and quality of the process. **C5-2:** As one indicator of hiring effectiveness, FDA new hires are qualified and able to perform well in their positions; however, stakeholders consider process documentation to be a persistent challenge hindering the efficiency and effectiveness of hiring, especially classification. **C5-3:** Based on limited available data, some of which are tracked manually, FDA is realizing process efficiencies via the Hiring Pilot, other hiring and compensation flexibilities (e.g., expanded DHA, 21st Century Cures Act, and Title 38), and demonstrated use of shared certificates; however, not all of these approaches are broadly and consistently implemented or measured across CDER and CBER.	**R-6:** In conjunction with the review of existing HRIS technologies, FDA should consider employing additional technological solutions to enhance data management and reporting capabilities. *(previously presented with another conclusion)* **R-8:** Establish a workload management process for assessing and distributing work across the HR workforce, leveraging reliable analytic tools. *(previously presented with another conclusion)* **R-13:** Disseminate communications plans to increase awareness and share critical information about the Cures Act and DHA to support strategic and consistent application of these hiring authorities. *(previously presented with another conclusion)* **R-15:** Streamline frequently used hiring processes and house the new hiring process maps in a centralized HR knowledge management repository. **R-16:** Resolve the classification backlog and develop SOPs to standardize the classification process. **R-17:** Drive greater accountability for process improvement by documenting and regularly tracking outcome measures, such as customer-centric, key performance indicators (KPI) and success measures. *(previously presented with another conclusion)*

2. PROGRESS SINCE THE INITIAL ASSESSMENT

As previously mentioned, the Initial Assessment report[8] presented three major hiring-related recommendations for improvement, which resulted in the implementation of the Hiring Pilot. Following the Interim Assessment, FDA identified the Hiring Pilot as an improvement activity and also identified four additional improvement activities.

2.1 Progress Against Initial Assessment Recommendations

Exhibit 7 presents the Initial Assessment recommendations (verbatim from the Initial Assessment report) and our team's alignment of the recommendations to the subsequent improvement activities that address them.

Exhibit 7: Initial Assessment Recommendations Aligned to FDA Improvement Activities

INITIAL ASSESSMENT RECOMMENDATIONS	RELATED IMPROVEMENT ACTIVITIES
1. The Agency should consider developing and launching a controlled pilot to test a completely new and redesigned hiring process. To ensure a meaningful experiment, the pilot should include an appropriate sample size of live hiring actions—most likely drawing from a mix of hiring needs across CDER and CBER. In addition, the pilot process should test several important elements, including the following:	Primarily addressed through: • Hiring Pilot
– An optimized, clean sheet process design focused on minimizing handoffs, eliminating unnecessary process steps, and reducing total time to hire	Partially addressed through: • Hiring Pilot
– Re-evaluation and use of flexibilities embedded in current hiring authorities and policies, including those related to employee performance, appraisal, training and development, attendance and leave, and benefits	Partially addressed through: • Expansion of DHA • 21st Century Cures Act • OHR Reorganization (Policy and Accountability Staff)
– Identification and use of new talent sources	Partially addressed through: • Scientific Staffing Team
– Targeted investments to build HR capabilities in communication, timeliness, and personal initiative—three core HR competencies with the greatest observed deficiencies	*Not yet addressed*
– Testing of reconfigured stakeholder positions, aimed at having HR provide a more sophisticated service to the centers and reducing the number of HR contacts a hiring manager must interact with throughout the process	*Not yet addressed*
– An enhanced effort to meet user requirements for enabling technologies (e.g., resume mining, virtual structured interviews, and automated qualifications), thereby supporting meaningful workflow tracking and streamlining time intensive steps	Minimally addressed through: • Hiring Pilot (e.g., Applicant Tracking Lifecyle Analysis Solution [ATLAS] workflow tracking)
2. Once the pilot is launched, the Agency should rigorously and continuously evaluate performance and iterate on the process design based on pilot findings. The evaluation should focus on a prospectively-defined set of performance measures tied to the five hallmarks of success (i.e., timeliness, accuracy, customer service, employee satisfaction, and quality). Additionally, the pilot team should actively capture insights related to how best to leverage and scale the process, with the ultimate goal of identifying a dramatically improved process that could be rolled out across the entire Agency.	Partially addressed through: • Hiring Pilot (evaluation and modification from Hiring Pilot Phase 1 to Hiring Pilot Phase 2)
3. Finally, given the centrality of improved data and systems to a long-term solution and the long lead times associated with technology procurement in the public sector, FDA should consider initiating an assessment of the technologies available, leveraging emerging business requirements from the pilot, to identify a fit for purpose solution.	Primarily tested through: • Hiring Pilot (e.g., ATLAS requirements analysis/ technology comparison)[9]

[8] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[9] Source: Applicant Tracking Workflow Technology Comparison 10.26.2017.

2.2 Implementation Progress of Improvement Activities

This section presents a high-level summary of implementation progress for the five identified improvement activities—STRS Hiring Pilot (Hiring Pilot), the OHR reorganization, 21st Century Cures Act, SST, and expanded DHA—as presented graphically in Exhibit 6 within the earlier Executive Summary (page 8). The later Findings and Conclusions section of this report addresses these improvement activities in more granularity.

2.2.1 STRS HIRING PILOT

In response to the Initial Assessment, the Hiring Pilot was deployed to select offices within CDER and CBER in a phased approach beginning in July 2018. Its first phase of testing (Phase 1) concluded in July 2019 and its second phase of testing (Phase 2) is scheduled to conclude in April 2020. Focused only on certain positions, the Hiring Pilot identified goals of (1) setting the new "gold standard" for FDA hiring practices, (2) reducing the average time-to-hire, (3) building cohesive, collaborative relationships with hiring managers and candidates, and (4) rapidly rolling out and scaling up new tools and approaches across the Agency.[10]

The Hiring Pilot has offered FDA the opportunity to test different approaches to addressing hiring process deficiencies. To support consistent implementation of the new approaches, FDA developed process documentation and guidance (e.g., process map, standard operating procedures (SOP), desk guides), as well as five new performance criteria (process timeliness, customer service, employee satisfaction, outcome quality, and process accuracy).[11] Based on extremely limited Hiring Pilot process data points, the Hiring Pilot gained efficiencies through its streamlined processes and use of shared certificates. However, after 15 months, key program elements are still not fully established (technology integration, data management and quality control, reliable performance outcome metrics, realized benefits by the Centers) and pilot participation is limited with mixed levels of satisfaction.

The Hiring Pilot's Applicant Tracking Lifecyle Analysis Solution (ATLAS) system has capabilities with the potential to improve the effectiveness and efficiency of the hiring workflow. For example, ATLAS features include enhanced hiring process visibility, improved stakeholder interactions, and integration with USAStaffing. ATLAS workflow management tracking functionality for hiring managers and leadership supports the potential for increased transparency, accountability, and quality control around time-to-fill metrics. However, such outcomes have not been realized. For example, Hiring Pilot data is currently being manually tracked because the reporting functionality, which is a critical aspect of the anticipated improvement of transparency, consistency, and quality control, is not yet implemented within the ATLAS system. In addition to reporting analytics, the technology is capable of other, potentially useful features that are not currently implemented (e.g., integration with classification and associated data metrics), thereby limiting its overall level of effectiveness. In addition, because outcome data are not yet available for two of the five performance criteria (outcome quality and process accuracy), it is not possible to assess all aspects of effectiveness.

The Hiring Pilot's implementation has demonstrated some incremental improvements to hiring; however, because of data limitations, it is not yet possible to determine whether these improvements are repeatable for groups outside the Pilot. Going forward, greater data curation and data management—tied to outcome/success measures—can help improve data integrity and provide the reliable information needed to drive business decisions for the Pilot and its future potential for broader impact (different hiring workflows, hiring flexibilities, organizational units, occupational series, additional technology integrations). Improved data integrity and larger test group data could help more accurately determine the benefits of the new process and improve confidence among the Centers in the measurement of success of the streamlined process. Housing and sharing pilot documentation and communication products through a centralized knowledge management repository could also help drive greater transparency and consistency among pilot

[10] Source: STRS Hiring Pilot Launch Presentation (Phase II), OTS.
[11] Source: STRS Hiring Pilot Launch Presentation (Phase II), OTS.

participants and HR staff. These types of next steps will help this improvement activity reach its optimal state of implementation and effectiveness.

2.2.2 OHR REORGANIZATION

The Initial Assessment emphasized the need for more dedicated focus on recruiting and hiring. [12] On July 9, 2018, OHR was reorganized into two separate offices to improve operational discipline and expertise in core HR areas and provide dedicated leadership focus.[13] Policy, sourcing, recruiting, and hiring functions were organized under the new OTS and aspects of the employee experience under the new OHCM (see Exhibit 8).

Exhibit 8: OHR Reorganization

**Note: While OHCM manages work-life retention programs, OTS manages monetary retention programs and incentives.*

Many of the services and structure of OHCM remained the same from the original organizational design (e.g., Employee and Labor Relations, Performance Management and Awards, Training and Development). Two exceptions were a new Management and Administrative Inquiries staff and a new Human Resources Information Technology (HRIT) branch (within the Division of Human Resources Systems) to focus support on the many HRIT initiatives underway, including ATLAS, a new electronic Performance Management Appraisal Program (PMAP) system, as well as a new ePortal HR employee interface.

OTS embarked on numerous structural realignments, including the creation of centralized dedicated teams with functional expertise (e.g., classification team, delegated examining unit (DEU), SST, policy and accountability staff) and new management levels focused on the Centers. OTS established a Hiring Reform Roadmap in 2018 with a number of proposed initiatives to deploy targeted process improvements, better accommodate demand, increase transparency, improve accountability and governance, ensure quality control, and sharpen communications and training.[14] Accomplishments to date include, but are not limited to, the launch of a Talent Academy for OTS-wide training, Hiring Pilot hiring manager training, targeted recruiting for Veterans and persons with disabilities, a Center-inclusive Scientific Staffing Working Group, a unified FDA recruiting branding campaign, and new performance management action plans for HR staff.

The OHR reorganization established foundational building blocks for a strategic, systematic approach to recruiting, hiring, and retention and have made incremental progress in establishing internal governance and operations. However, the assessment finds that Centers are generally unclear about the purpose and intended benefits of the OHR reorganization, and/or have not yet observed meaningful improvements. FDA

[12] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[13] Source: FDA Hiring and Retention Reforms Update 12.12.2018, OO.
[14] Source: FDA Hiring and Retention Reforms Update 12.12.2018, OO.

has not yet established a collaborative, customer-centric culture across HR stakeholders, which inhibit its ability to achieve lasting, transformational change. For example, the roles of OTS' HR staff are not sufficiently integrated with the Center's (e.g., as "HR Business Partners"), which creates an incomplete understanding and alignment to strategy and business operations and leads to transactional, uncoordinated interactions between parties. In addition, the lack of a well-coordinated strategic framework (e.g., organizational strategic plan, stakeholder engagement strategy, tactical communication products, and workload management processes and tools) inhibits the effectiveness of this improvement activity. Specifically, FDA is unable to monitor the effectiveness of the OHR reorganization over time, because measures such as timeliness of meeting organizational goals, employee satisfaction, customer satisfaction, and impact on customer goals (i.e., Center hiring targets) are not reliably integrated, tracked, and reported.

2.2.3 21ST CENTURY CURES ACT

The 21st Century Cures Act was enacted on December 13, 2016 and, among other features, provides HHS with "critical new authorities to help advance medical product innovation."[15]

Specifically, Section 3071 of the Cures Act expanded the scope of the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service to encompass biomedical product assessment experts and quadrupled the size of the Service, expanding its member limit from 500 to 2000.[16] HHS is currently updating regulations for FDA to use the expansion under Section 3071, and at the time of this report, there have been no FDA appointments under this expansion.

However, FDA has made use of Section 3072 of the Cures Act, which allows for the appointment of outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products."[17] Cures data in this report reflects those appointed under Section 3072.[18]

Regardless, the authority to set more competitive salary options (to a maximum of $400,000 annually)[19] should enable FDA to better compete with the private sector and academia as well as to boost external recruiting and strengthen retention of existing staff.

In January 2017, the Agency established an HR Cures Working Group and HR Cures Steering Committee, chaired by the FDA Commissioner, with representatives from across the Agency. The groups were tasked with developing an Alternative Pay Structure (APS), creating a streamlined hiring process, and producing guidelines for the Cures Act's consistent and proper use across the Agency. The groups conducted an environmental scan that included interviews with federal agencies with alternative pay systems and research on private sector practices. The scan led to the decision for a phased approach to implementation, with an initial focus on leadership positions and the refinement of policies and procedures over time.[20] Section 3072 of the Cures Act mandated an FDA Workforce Planning Report be submitted to Congress within 18 months of the Cures Act's enactment. This report was submitted ahead of schedule in May 2018.[21]

As described above, OTS has conducted foundational planning and initial implementation; however, its implementation progress has not yet reached optimal effectiveness. For example, to date, OTS has not defined outcome measures tied to specific Center goals and hiring targets to help determine the effectiveness of Cures hiring. Specifically, OTS is not yet able to evaluate effectiveness of Cures hiring over

[15] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.
[16] Source: 21st Century Cures Act Legislation, OTS.
[17] Source: Title 21: 21st Century Cures Act Positions, FDA.gov (https://www.fda.gov/about-fda/jobs-and-training-fda/title-21-21st-century-cures-act-positions).
[18] Source: Meeting Minutes from Discussion with OTS Director 2.24.2019, OTS.
[19] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.
[20] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.
[21] Source: Cures Workforce Planning Report to Congress 05.21.2018, OTS.

time in terms of the number and diversity of applicants (e.g., demographic, educational, career level); the number and diversity of hires; increases in the number and diversity of candidates and hires; or time-to-hire compared to other hiring authorities.

FDA has made 47 Cures appointments across CDER and CBER to date (4 percent of CDER's and CBER's 1,124 total gains in FY2018 and FY2019), and policy and procedures have been created, with plans to deploy them to Cures-eligible Centers in 2020.[22] Feedback from this assessment indicates that there is confusion within the Centers regarding the application of the 21st Century Cures Act and a high demand for policies and procedures as well as training. Creating a strong stakeholder engagement strategy, a detailed communication plan, and tactical communication products can help address such concerns from the Centers.

2.2.4 SCIENTIFIC STAFFING TEAM

In November 2018, the SST was established with a goal of cultivating a sustainable talent pipeline through external strategic partnerships with national institutions (e.g., professional associations, universities, government agencies) and a consolidated online presence.[23] Since its recent inception, SST's unified FDA recruitment branding campaign has resulted in a substantial increase of online traffic (as detailed in Supplement Exhibit S-3).[24,25] The team has also forged 100+ external partnerships, deployed a virtual recruiting effort for Veterans and persons with disabilities, and hosted over a dozen academic visits on campus. However, based on interviews and focus groups, Center staff expressed limited awareness of the SST's scope and impact as well as concerns of limited coordination with the Centers.

The SST has made incremental progress toward effectiveness; however, optimal effectiveness will require a more collaborative, customer-centric culture. Developing a strategic stakeholder engagement strategy and tactical communication products can help. In addition, outcome measures that are tied to specific Center goals and hiring targets can show impact. Potential measures include tracking the number of applicants and hires with direct linkages between their recruiting source and the SST recruiting initiative (e.g., academic recruiting event, online campaign), and the number of inquiries from each partnership organization.

2.2.5 EXPANSION OF TITLE 5 DIRECT HIRE AUTHORITY

DHA is a long-established hiring flexibility, under Title 5, intended to address a severe shortage of candidates or critical hiring need and permits the appointment of individuals without regard to competitive rating, ranking, or Veterans' preference for certain mission-critical occupations.[26] On October 11, 2018, OPM authorized a government-wide DHA expansion that included STEM positions in 14 specific occupational series, at grades 11-15, and Cybersecurity positions in four occupational series, at grades 12-15 (this is in contrast to the authority in the Cures Act, Section 3072, which did not restrict the appointments to specific occupational series but only to the type of work being performed).

This assessment focuses on the effectiveness of the expansion of positions under DHA, which offers FDA potential hiring efficiencies to a larger subset of positions. Data illustrate this improvement activity has begun to meet the criteria for the integrated level effectiveness through increased usage of DHA for CBER over the past year. In fact, CDER's FY2019 Personnel Action Plan[27] does prioritize the use of DHA for hiring certain positions. However, its use remains a small fraction of total human drug and biologics review program staff hires (12 percent of total gains for both CDER and CBER in FY2019). [28] Developing additional strategic goals

[22] Sources: 21st Century Cures Act and Alternative Pay System SOP 12.16.2019, OTS; Cures Communications and Engagement Briefing for Human Capital Managers 02.27.2020. OTS.
[23] Source: SST Background and Accomplishments, OTS.
[24] Note: FDA Jobs website data pulled from FDA's Angelfish Profiles; Twitter data collected from Twitter Analytics; LinkedIn data collected from Visitor Analytics.
[25] Sources: SST Social Media Dashboard 09.2018, OTS; SST Social Media Dashboard 09.2019, OTS.
[26] Source: FDA SOP (Direct Hire Authority), InsideFDA.gov.
[27] CDER Personnel Action Plan FY2019, CDER OM.
[28] Source: CBER-CDER Direct Hires from 10.01.2016 – 09.30.2019, EHCM.

for DHA, will help FDA establish a data-driven framework to determine what amount of additional progress is needed to realize optimal effectiveness. Once goals are identified, defining outcome measures that are tied to specific Center goals and hiring targets can help track the effectiveness of DHA over time. Potential measures include the number and diversity of applicants and hires, success in hiring high-priority or hard-to-fill positions, and time-to-hire compared to other hiring authorities. Interview and focus group feedback recognize DHA as helpful in hiring qualified people (see Supplement Exhibit S-4 and Supplement Exhibit S-5) but also highlight frustrations by hiring managers around lack of communications from OTS regarding OPM requirements for DHA and the perceived impact of such policies on the expediency of DHA hiring (see Supplement Exhibit S-6). Creating a detailed communications plan and tactical communication products can help address such concerns from hiring managers.

3. FINDINGS AND CONCLUSIONS

This section presents the assessment's findings and conclusions, derived from multiple data sources. Each section addresses 1) the definition and context for that topic, 2) expounds on the effectiveness of the improvement activities implemented since the Initial Assessment, 3) distinguishes information relevant to recruiting, hiring, and retention, and 4) details the findings and conclusions most pertinent for FDA's forward momentum. In addition, details relevant to the four focus areas of the assessment (HR Process Effectiveness, HR Process Efficiency, HR Staff Capability, and HR Staff Capacity) are also included.

3.1 Strategy

Hiring, combined with the related functions of recruiting and retention, is one of FDA's most significant organizational challenges. The confluence of numerous external and internal factors—FDA's reputation as the premiere pharmaceutical and medical device regulator, a competitive job market, prescriptive Federal Government hiring rules and regulations, requirements established by the HHS, FDA's own hiring practices, and FDA HR staff capabilities, among others—can have significant positive and negative impacts on the Agency's ability to attract, hire, and retain talented human drug and biologics review program staff. Moreover, there are clear downstream benefits of effective recruiting, hiring, and retention (e.g., engaged employees, productive employees, greater organizational outcomes) and weighty consequences of ineffective recruiting, hiring, and retention (e.g., missed opportunities to onboard talented experts to fulfill public health obligations, a tainted reputation, disengaged employees).

An integrated, holistic, systems-based approach to talent management will help FDA optimize its ability to recruit, hire, and retain human drug and biologics review program staff. Amidst all the pressures to improve these functions, it is important to drive toward creating strategic, risk-based solutions that fit within a larger "systems-based approach." Hiring is one critical piece of the talent management life cycle and, as such, hiring solutions work best when they are well integrated with workforce planning, recruiting, hiring, staff development, performance management, succession management, and retention. Holistic, integrative solutions can be mutually beneficial across multiple aspects of talent management and can increase the likelihood of addressing broader systemic issues while also realizing synergies and improving efficiency through increased alignment.

Comparison to Initial Assessment: The Initial Assessment did not include strategy as a major topic therefore we cannot assess progress from the Initial Assessment to the Interim Assessment. Given that the scope of the Interim Assessment expanded beyond the hiring function to include recruiting and retention, there is a new focus on taking an integrated approach across the three functions.

CONCLUSION

C1-1. FDA lacks an enterprise-wide systems approach to integrate and optimize recruiting, hiring, and retention functions; however, the Agency-level HR Organization and the Centers have made some noteworthy strategic efforts.

While it is paramount for Centers to take accountability for determining their recruiting strategies, there is not currently an enterprise-wide recruiting strategy that documents the linkages between Center-level (specifically CDER and CBER) and Agency-wide recruiting goals, guidance's, processes, and resources.

The investment in broad, coordinated efforts such as SST, the CDER Personnel Action Plan, and succession planning is a good indicator that FDA recognizes the value of employing strategic approaches. However, the fact that OTS, CDER OM, and CBER OM have large HR staff vacancy rates may be precluding them from more fully employing true strategic, integrative HR support for CDER and CBER. A more proactive investment of

time and existing resources will enable FDA to create a robust and integrated strategy that encapsulates an enterprise-wide approach for recruiting, hiring, and retaining human drug and biologics review program staff.

F1.1 FDA lacks a coordinated strategy that links Agency-level recruiting, hiring, and retention objectives with Center-level data, priorities, and targeted efforts.

FDA is successfully hiring qualified human drug and biologics review program staff, but the Agency has not yet developed integrated plans to optimize its recruiting, hiring, and retention functions. FDA can align multiple objectives (e.g., diversity goals, succession planning, maintaining mission-critical bench strength), enabling more effective coordination and economies of scale in its recruiting, hiring, and retention efforts. For example, in response to the Initial Assessment, FDA created a 2-year "Roadmap for Hiring Reform" in December 2018, to which FDA has employed numerous tactics that are intended to fundamentally address longstanding challenges and make lasting improvements.[29] These initiatives, which include establishing dedicated OTS support teams for recruiting and classification, employing initiatives to improve OTS staff performance (via performance plans and regular reviews), and piloting of the ATLAS system that is intended to increase hiring process transparency and accountability, establish initial cross-cutting programs and integration.

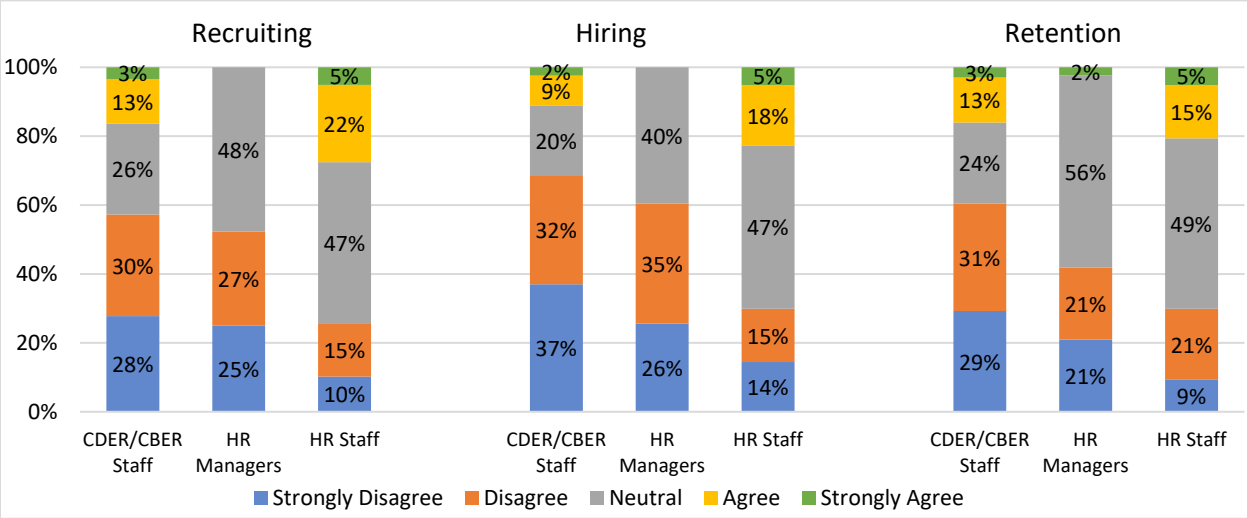
With regard to strategic planning, a legacy OHR Strategic Plan from FY2015–FY2018 incorporated key aspects of a comprehensive plan (e.g., shared vision, strategic priorities, goals and objectives, target metrics for accountability, implementation plan).[30] More recently, OTS created an FY2019 OTS Strategic Plan, with a high-level hiring strategy, goals, and tasks for the year, which provides a common foundation to set the group in a positive direction.[31] Incorporating additional critical components—that address alignment to business activities and benefits to stakeholders, allocation of resources, responsible parties and accountability, data-driven performance measures, and risk mitigation and management—will help guide future decision-making and foster greater transparency and accountability between the Agency's HR Organization (i.e., OTS and OHCM) and the Centers. For example, existing plans fall short of integrating elements such as anticipated attrition, targeted and prioritized positions to recruit and retain, detailed hiring targets and metrics, and guidance on consistent and appropriate use of hiring authorities, retention incentives, and other flexibilities.

F1.2 The consequences of not having an integrated strategy for recruiting, hiring, and retention include sub-optimal effectiveness of each function and insufficient plans to manage complex cross-functional dynamics, such as workforce gains and losses.

The consequences of not having a well-established, coordinated strategy include ineffective functions, incomplete understanding about the factors driving ineffectiveness, and a limited ability to take deliberate action that leads to improvements. As an example, survey respondents were asked whether the recruiting, hiring, and retention functions meet the needs of the Agency (see Exhibit 9). The patterns of responses from each group – CDER/CBER Staff, managers of HR staff, and HR staff – were similar across all three functions. Specifically, most CDER/CBER staff and managers of HR staff generally expressed unfavorable views (disagree or strongly disagree), while HR staff expressed more moderate or favorable views (neutral, agree, or strongly agree). Those who are most directly involved with service delivery (i.e., HR Staff) are slightly more optimistic than the other groups, which suggests that the intensity of reactions is more pronounced for those in customer roles (i.e., CDER/CBER staff).

[29] Source: FDA Hiring and Retention Reforms Update 12.12.2018, OO.
[30] Source: OHR Strategic Plan 2016-2018, OO.
[31] Source: OTS Strategic Plan FY2019, OTS.

Exhibit 9: Interim Surveys (All Respondents)—Overall Process Effectiveness[32]



Respondents: CDER and CBER staff (n=1805); HR Managers (n=52); HR Staff (n=120). Survey item: "Overall, I believe the FDA's current [recruiting process/hiring process/retention strategies] for human drug and biologics review program staff meets the needs of the Agency." A "Not Applicable" response option was also provided; those responses are not included in this analysis.

Another consequence of the lack of an integrated strategy is that predicting and managing complex dynamics that are impacted by multiple functions (i.e., recruiting, hiring, and retention) is more difficult. The dynamics of workforce gains and losses in CDER and CBER illustrates this point. CDER and CBER are able to successfully hire talent; however, the ongoing need to fill vacancies due to losses impedes the ability to maintain a qualified workforce in targeted areas (e.g., mission critical occupations (MCO), diverse populations) and make net gains in the workforce numbers.

For example, CDER and CBER are beginning to establish hiring targets and track progress for each FY (see Exhibit 10). CBER fell short of its hiring targets for FY2018 and FY2019 but came closer to meeting its target in FY2019. CDER did not have a hiring target for FY2018 but did establish and exceed the hiring target for FY2019 that was an integral part of its coordinated Personnel Action Plan.

Exhibit 10: CDER and CBER Hiring Data—Progress Against Hiring Targets[33]

CENTER	FY	HIRING TARGETS	ACTUAL HIRING	RESULT
CDER	FY2018	*Not available*	475	*Not available*
	FY2019	300	407	107 **above** target (26%)
CBER	FY2018	141	109	32 **below** target (29%)
	FY2019	152	134	18 **below** target (13%)

As CDER and CBER were completing these hiring actions, they were also experiencing losses (see Exhibit 11). Due to the ongoing cycle of gains (including new hires and transfers into the Center) and losses (including employees leaving FDA and transfers out of the Center), only a portion of the total number hired actually contributed to the Centers' workforce growth. In most years, only about one-third or fewer of the employees hired contributed to new workforce growth, while the rest of the hiring actions contributed to filling the vacancies left by the losses. See Supplement Exhibit S-7 for more detail about the diversity profile of the gains and losses (i.e., Veterans' Preference Eligible, Reported Disability, Female, Non-White).

[32] Sources: CDER/CBER Staff Survey, HR Workforce Manager Survey, HR Workforce Staff Survey.
[33] Sources: CBER Staffing Projections FY2018, Manual Reporting (Microsoft Access); CBER Staffing Projections FY2019, Manual Reporting (Microsoft Access); CDER Personnel Action Plan FY2019, CDER OM; FDA Personnel Data FY2016 to FY2019, BIIS.

Exhibit 11: CDER and CBER Hiring Data—Center Gains and Losses[34]

CENTER	FY	GAINS	LOSSES	PERCENTAGE OF GAINS NEEDED TO REPLACE LOSSES	PERCENTAGE OF GAINS CONTRIBUTING TO WORKFORCE GROWTH
CDER	FY2017	481	235	49%	51%
	FY2018	475	327	69%	31%
	FY2019	413	345	79%	21%
CBER	FY2017	93	61	66%	34%
	FY2018	109	84	77%	23%
	FY2019	127	85	65%	35%

F1.3 FDA has established some targeted initiatives, such as OTS' new dedicated SST and FDA's succession management plan, that serve as a preliminary Agency-level strategic framework for establishing a more comprehensive, integrated strategy.

Some initiatives—such as SST and succession management—related to FDA recruiting, hiring, and retention provide initial frameworks and approaches that can be leveraged when developing a more comprehensive cross-functional enterprise strategy. With regard to recruiting, OTS created a dedicated Scientific Staffing and Outreach branch with a goal of setting a foundation for more strategic and impactful recruiting results. This new structure included a new, dedicated SST to primarily focus on STEM recruitment and outreach and to align to other existing recruiting initiatives, such as Veterans Outreach and Retention, Pathways Program, and academic visits. The SST implemented several initiatives in late 2018 and 2019 with the goal of increasing interest among a greater number of applicants and developing a pipeline of highly qualified STEM-focused talent[35]. As a whole, FDA has hosted over a dozen academic visits in 2018 and 2019 and expanded FDA's external partnerships with 100+ government, professional associations, and academic institutions[36] (see Exhibit 12). Despite these accomplishments, interview and focus group themes indicated that many people are not yet familiar with SST. Others expressed uncertainty about the value of their service offerings and had not seen much coordination between SST and the Centers (see Supplement Exhibit S-8). Other data needed to assess the value of SST's efforts (e.g., applicants or hires linked to specific initiatives) were not available for this Interim Assessment.

Exhibit 12: OTS SST—External Strategic Partnerships[37]

	GOVERNMENT BODIES	PROFESSIONAL ASSOCIATIONS	ACADEMIC INSTITUTIONS	OTHER ORGANIZATIONS
September 2018 (FY2018)	16	10	26	3
September 2019 (FY2019)	22	15	54	9
Percentage Increase	38%	50%	108%	200%

With regard to hiring, although FDA does not have an enterprise level strategic plan for recruiting human drug and biologics review program staff, Centers have taken some steps in the right direction. For example, CDER's FY2019 Personnel Action Plan[38] considers dynamic and strategic factors, such as anticipated attrition, targeted utilization of hiring flexibilities (e.g., Hiring Pilot, DHA, Cures), prioritized hiring for certain positions and occupations, and specific targets for each Super Office. Additional recruiting strategies in the plan include a focused recruitment and outreach strategy for Cures and DHA and coordination between CDER and FDA recruitment and outreach staff.

[34] Source: FY2017 and FY2018 totals calculated from FDA Personnel Data FY2016 to FY2019, BIIS; FY2019 totals pulled from https://www.fda.gov/industry/prescription-drug-user-fee-amendments/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data.
[35] Sources: SST Strategic Partnerships 2019, OTS; SST Background and Accomplishments, OTS.
[36] Source: SST Activities 04.2018 to 09.2019, OTS.
[37] Sources: SST Social Media Dashboard 09.2018, OTS; SST Social Media Dashboard 09.2019, OTS.
[38] CDER Personnel Action Plan FY2019, CDER OM.

With regard to retention, FDA has enacted tactics that can contribute to staff retention, such as flexible work arrangements, student loan repayment, and (if successful) the authorities under the 21st Century Cures Act (see Finding F1.3 for more detail). In addition to the aforementioned targeted retention initiatives, FDA has developed foundational resources for Agency-wide succession planning—which generates important data and insights to inform and focus a retention strategy (e.g., specialized or hard-to-fill positions without robust succession pipeline). Specifically, FDA'S Succession Management Strategic Plan[39] and the CDER and CBER Workforce Profiles[40] provide useful models to be monitored, expanded, and customized as needed to improve FDA's ability to retain human drug and biologics review program staff. Specifically, FDA's Succession Management Strategic Plan outlines an approach for using workforce information, such as analyses of retirement eligibility status, average years worked past earliest retirement eligibility date, number of employees in a given position (i.e., "bench strength"), patterns of turnover, and Federal Employee Viewpoint Survey (FEVS) results, to help identify high-priority positions in need of succession plans.

Although some targeted retention initiatives and foundational resources related to succession planning have been developed and implemented, FDA has not yet created an integrated retention strategy to minimize the loss of specialized talent and to quickly recover when losses do occur. Elements of an integrated retention strategy include targeted objectives for inspiring human drug and biologics review program staff to stay with FDA, supported by tailored initiatives for increasing staff engagement, satisfaction, and performance. Absent of such a strategy, FDA's retention of these staff can be due more to happenstance than deliberate action. Retention rates can vacillate when there is no strong counterbalance to the external forces that can lure talented staff away, and unpredictable turnover can hinder organizational planning.

CONCLUSION

C1-2. Despite perceptions of significant attrition problems, overall turnover at CDER and CBER is relatively low and staff are committed to working for the Agency; however, when turnover occurs, FDA lacks a strategic approach to quickly recover when they lose specialized talent.

Broad-based losses of top talent to industry are not as prevalent as they may be perceived to be. Overall, attrition rates for CDER and CBER are markedly low compared to other government agencies and to the private sector. While this is the case broadly across CDER and CBER, during FY2017 through FY2019 there were some exceptions where certain occupations and organizational units showed higher attrition rates[41] than the Center's overall rates. CDER and CBER staff tend to stay or leave for predictable reasons, such as a commitment to the mission or the lure of greater compensation and/or career opportunities elsewhere. Staff are just as likely to explore opportunities elsewhere in the government as they are with industry.

While some trends emerge in regard to why staff leave, where they go, and what may incentivize them to stay (as detailed in the findings below), FDA will be most successful with retaining top talent if it remains mindful that people have different motivators at different times in their careers and may respond best to different retention strategies tailored to those different motivators. Moreover, some retention efforts can have unintended consequences by demotivating staff who were not offered incentives, which highlights the importance of clearly communicating processes and procedures to better prepare the workforce to understand and accept Agency decisions.

Furthermore, in interviews and focus groups, Center staff expressed concerns about turnover because it can have ripple effects for an entire team. For example, the remaining staff may experience workload increases and disruptions due to the vacant positions, long hiring times may lead to long-term vacancies, and staff may become burned out, all of which can result in additional turnover.

[39] Source: FDA Succession Management Plan FY2017 to FY2020, OO.
[40] Sources: CDER Workforce Analysis FY2016, 2017, 2018, CDER OM; CBER Workforce Analysis FY2018, CBER OM.
[41] Source: FDA Personnel Data FY2016 to FY2019, BIIS.

F1.4 Attrition rates for CDER and CBER are low compared to other government agencies; however, it remains a concern due to pockets of higher turnover, high rates of retirement eligibility, and the challenges of filling vacancies.

According to the CDER and CBER Workforce Analysis Profiles, CDER's attrition averages approximately 5 percent and CBER's attrition averages approximately 6 percent (see Exhibit 13).

Exhibit 13: Average CDER and CBER Attrition[42]

	FY2015	FY2016	FY2017	FY2018	AVERAGE
CDER	5.15%	4.81%	4.52%	5.80%	5.07%
CBER	6.80%	7.30%	4.90%	6.90%	6.48%

In comparison, according to the U.S. Bureau of Labor Statistics, the attrition rate across the Federal Government was more than 16 percent in 2016 and 2017.[43] Therefore, FDA's overall attrition is not considered to be high; however, there are pockets of higher attrition in certain occupations and offices . For example, in CBER occupations such as Toxicologist (20.6%) and Veterinary Medical Officer (22.2%) and the Office of Management (12.2%) are usually areas of concern. [44] While, CDER experiences higher rates of attrition in offices such as Office of Strategic Programs (10.4%) and occupations such as Regulatory Counsel (8%).[45] In addition, low rates of attrition can still be considered highly problematic due to the loss of specialized talent in MCOs.

Moreover, retirement eligibility rates are as high as 25–35 percent in some CDER and CBER Offices. More than 15 percent of the FDA workforce has reached their earliest retirement eligibility date, and an additional 14 percent will become eligible between 2020 and 2024 (see Supplement Exhibit S-9). In addition, FDA's Succession Management Strategic Plan[46] shows that retirement eligibility percentages vary across Centers and are consistently higher for leaders (e.g., GS-15, Senior Executive Service), the latter of which is likely due to a relationship between seniority and age. These increasingly high numbers of retirement eligibility may be a major reason that retirement is one of FDA's top reasons for attrition.

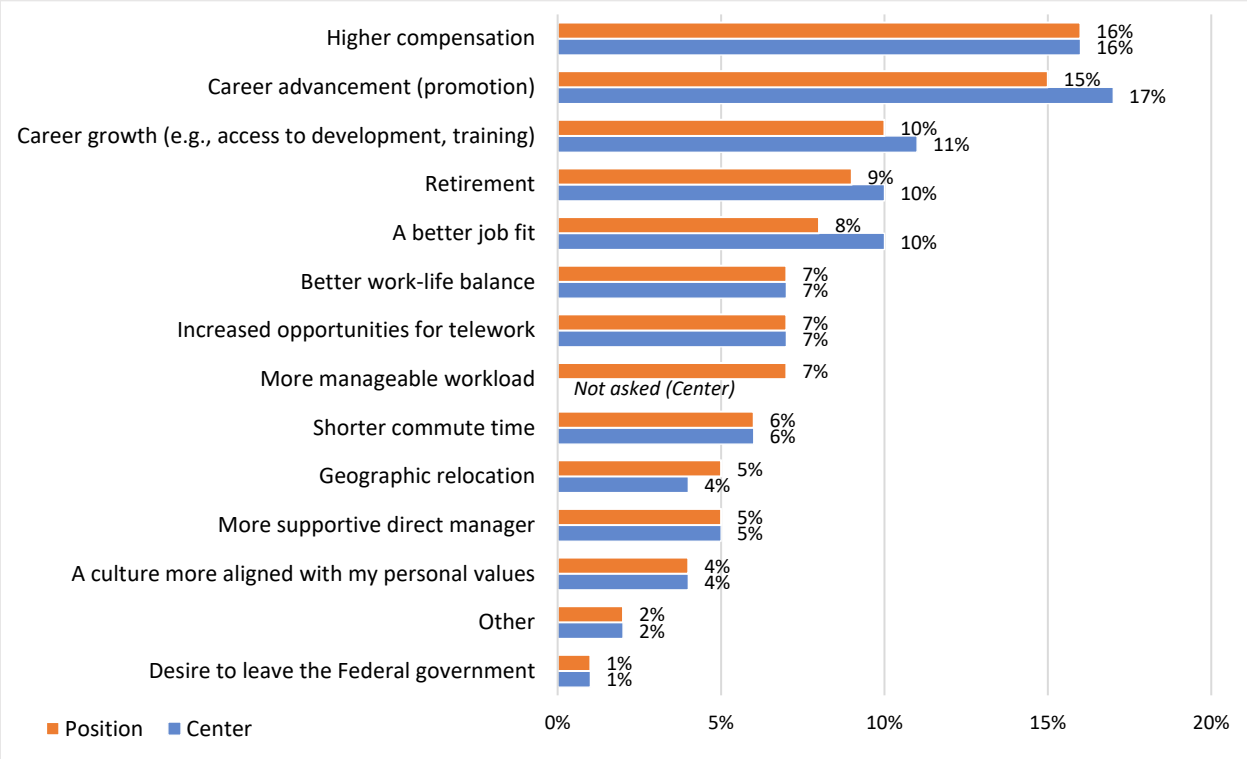
While turnover is not currently unusually high, retention is a major organizational concern. Specifically, interview and focus group participants stated that the primary concerns about retention are related to the challenges of turnover and the long time that is generally required to fill vacancies. While efforts are underway to fill vacancies, remaining staff often experience higher workloads as the office works to complete its responsibilities without a full workforce (see Supplement Exhibit S-10).

F1.5 The main reasons employees would leave CDER and CBER are retirement, opportunities for higher compensation, and greater potential for career advancement and career growth.

Survey data show the reasons CDER and CBER staff would consider leaving their current positions and Centers (see in Exhibit 14).

[42] Sources: CDER Workforce Analysis FY2016, CDER OM; CDER Workforce Analysis FY2017, CDER OM; CDER Workforce Analysis FY2018, InsideFDA.gov; CBER Workforce Analysis FY2018, InsideFDA.gov. Formula used to calculate attrition: total number of voluntary losses (e.g., retirement; resignation; and transfer) divided by the average onboard count during the FY.
[43] Source: Turnover Up as More Workers Quit the Federal Government 3.22.2018, Fedsmith.com (https://www.fedsmith.com/2018/03/22/turnover-workers-quit-federal-government/).
[44] Sources: CBER Workforce Analysis FY2018, InsideFDA.gov. Formula used to calculate attrition: total number of voluntary losses (e.g., retirement; resignation; and transfer) divided by the average onboard count during the FY.
[45] Sources: CDER Workforce Analysis FY2018, InsideFDA.gov; Formula used to calculate attrition: total number of voluntary losses (e.g., retirement; resignation; and transfer) divided by the average onboard count during the FY.
[46] Source: FDA Succession Management Plan FY2017 to FY2020.

Exhibit 14: CDER/CBER Staff Survey—Reasons Staff Would Consider Leaving their Position/Center[47]



Respondents: CDER and CBER staff. Number of responses= 5,956-7,057. This item type is Select All That Apply, so the response numbers count all selections provided by each group of survey participants.

Survey respondents reported that the top two reasons they would consider leaving their position and/or Center are higher compensation (16 percent for both position and Center) and career advancement (position: 15 percent; Center: 17 percent). Other top reasons include career growth (position: 10 percent; Center: 11 percent), retirement (position: 9 percent; Center: 10 percent), and better job fit (position: 8 percent; Center: 10 percent).

FDA exit survey responses (collected outside of this assessment) from CDER and CBER employees who left FDA between June 2016 and June 2019 corroborate these findings.[48] When asked why they were leaving FDA, the top two reasons for attrition were retirement and a better job opportunity, although it is unclear what factors make the new opportunities better than the FDA position employees were leaving (see Supplement Exhibit S-11). Other top reasons employees left included family and personal reasons, better pay and benefits, ineffective leadership, and lack of management support. Exit survey data further shows some CDER and CBER employees leaving FDA gave the highest unfavorable responses about their satisfaction with career development opportunities (36 percent Somewhat Disagree or Strongly Disagree) and salary (28 percent Somewhat Disagree or Strongly Disagree). While not the mathematical majority, the dissatisfied percentages represent large enough proportions to warrant attention. In comparison, responses were more favorable for the training received, their willingness to work at FDA again, and their willingness to recommend FDA as a good place to work (72, 74, and 77 percent Somewhat Agree or Strongly Agree, respectively) (see Supplement Exhibit S-12).[49]

Similarly, interview and focus group themes express that staff are attracted to jobs that provide better compensation, promotion opportunities, and work flexibilities (see Supplement Exhibit S-13). The CDER/CBER

[47] Source: CDER/CBER Staff Survey.
[48] Source: FDA Exit Survey Data. Number of respondents varies by survey item (n=344-357).
[49] Source: FDA Exit Survey Data. Number of respondents varies by survey item (n=344-357).

Staff Survey's open-ended survey item also showed that staff believe negative perceptions about promotion (e.g., inconsistencies, lack of transparency) can increase the risk of turnover (see Supplement Exhibit S-14).

F1.6 When considering a job search, CDER and CBER staff are most interested in staying with FDA as an employer; if they do look elsewhere, it is nearly evenly split between the private sector (including pharmaceutical firms) and other government agencies.

The CDER/CBER Staff Survey showed that staff who considered changing jobs in the past 6 months are most interested in another position within FDA, including another Center, an Office within their current Center, or a Sub-Office within their Super Office (see Exhibit 15).

Exhibit 15: CDER/CBER Staff Survey—Where Staff Considered Looking for Positions, by FDA Tenure[50]

	FDA Tenure					
In the past 6 months, how often have you considered looking for another position in:	Less than 2 years	2 years up to 5 years	5 years up to 10 years	10 years up to 15 years	15 years up to 20 years	More than 20 years
Another FDA Center	1.74	2.03	2.13	2.00	1.91	1.84
Another Office within your FDA Center	1.80	2.22	2.32	2.26	2.00	1.86
Another Sub-Office within your Super Office (CDER only)	1.69	2.03	2.11	1.94	1.70	1.66
A pharmaceutical firm	1.50	1.80	1.87	1.81	1.73	1.58
Other private industry (non-pharmaceutical)	1.44	1.66	1.76	1.70	1.76	1.56
Clinical practice (e.g., hospital, private practice)	1.32	1.26	1.25	1.25	1.26	1.14
Academia	1.37	1.42	1.26	1.38	1.35	1.33
Another government agency	1.73	1.80	1.84	1.81	1.86	1.65
A not-for-profit organization	1.40	1.40	1.49	1.46	1.53	1.37

Respondents: CDER and CBER staff (responses vary by item; n=1,651-1,758). Averages are based on a 1-4 scale: 1=Never; 2=Occasionally; 3=Sometimes; 4=Frequently.

Other potential employers that CDER and CBER staff have considered include pharmaceutical firms, other government agencies, and other private industry (non-pharmaceutical) positions. In general, staff with tenure between two and 15 years considered looking for another position more often than staff with less than two years and more than 15 years with FDA. That said, most indicated that, in the past six months, they have only occasionally or never considered changing jobs.

FDA exit survey data from CDER and CBER respondents who left FDA between June 2016 and June 2019[51] were nearly consistent with these survey results. There was a fairly even split between exiting staff going to the private sector (44 percent) and another government agency (39 percent) (see Supplement Exhibit S-15).

F1.7 The top reasons people stay at FDA include both intrinsic motivators (e.g., a commitment to the work and mission support from one's manager and team) as well as extrinsic motivators (e.g., salary increases, student loan repayment); to mitigate the risk of attrition, Centers sometimes offer retention incentives, which can be beneficial but can also have unintended consequences, such as pay inequities.

Understanding retention (why people *stay*) is a more complex and indirect topic to investigate than attrition (why people *leave*). Nevertheless, the ability to discern and leverage FDA's strengths in keeping employees committed, satisfied, and motivated is critically important for informing retention strategy. This finding presents results from several sources to help shed light on why employees want to stay with FDA.

[50] Source: CDER/CBER Staff Survey.

[51] Sources: FDA Exit Survey Data (n=355. However, the analysis excluded 106 respondents who left for retirement to focus the on those leaving FDA for other employment. Remaining n=249.).

A retention analysis (conducted by FDA prior to and separate from this mandated assessment effort) tracked staff hired into CDER and CBER from outside FDA in FY2016 to determine how many left FDA by the end of FY2019. The retention rate reflects the percentage of staff in each Center who remained after each FY. Exhibit 16 shows CDER retained 87 percent of staff, and CBER retained 90 percent of staff after three years.

Exhibit 16: Retention Patterns for Employees Hired in FY2016

CDER	HIRED IN FY2016	REMAINED AFTER FY2016	REMAINED AFTER FY2017	REMAINED AFTER FY2018	REMAINED AFTER FY2019
Staff	427	420	404	383	370
Losses	n/a	7	16	21	13
Retention	n/a	98%	95%	90%	87%
CBER	**HIRED IN FY2016**	**REMAINED AFTER FY2016**	**REMAINED AFTER FY2017**	**REMAINED AFTER FY2018**	**REMAINED AFTER FY2019**
Staff	84	82	80	78	76
Losses	n/a	2	2	2	2
Retention	n/a	98%	95%	93%	90%

This high rate of actual retention for CDER and CBER staff *staying with FDA* is not consistent with the CDER and CBER staff survey results on how long they *intend to stay* in their current Office. Exhibit 17 shows that, on average, nearly half of respondents intend to stay between two and ten years (26 percent intend to stay for two to five years; 22 percent intend to stay for 5 to 10 years). One potential explanation for this disparity is that some staff may intend to leave their Office for another position within FDA, which does disrupt the Office, but is not a loss for FDA overall. This comparison also suggests that staff may actually stay longer in their positions than they predict. In addition, these results present an opportunity for FDA to focus specific retention efforts for staff with two to five years of tenure, recognizing that many of them may be considering other employment options.

Exhibit 17: CDER/CBER Staff Survey—Heat Chart on Intention to Stay in Current Office, by FDA Tenure[52]

	FDA Tenure						
How long do you intend to stay employed within your current Office?	**All Tenure Levels**	Less than 2 years	2 years up to 5 years	5 years up to 10 years	10 years up to 15 years	15 years up to 20 years	More than 20 years
No more than 6 months	**8%**	6%	7%	9%	8%	8%	9%
6 months up to 2 years	**19%**	13%	19%	22%	19%	20%	24%
2 years up to 5 years	**26%**	29%	30%	24%	20%	30%	26%
5 years up to 10 years	**22%**	26%	22%	21%	21%	21%	18%
10 years up to 15 years	**8%**	6%	7%	7%	15%	4%	8%
15 years up to 20 years	**6%**	4%	4%	6%	9%	11%	3%
More than 20 years	**11%**	17%	12%	9%	8%	5%	12%

Respondents: CDER and CBER staff (number of responses varies by item; n=1,758-1,787).

Interview and focus group participants expressed that staff stay with the Agency because of a commitment to the work and mission and the workplace amenities on FDA's campus such as the Childcare Center and the outdoor farmer's market. FDA also offers several other Work Life programs focused on providing employees a positive work experience such as Employee Assistance, Nursing Mothers, and Bring Your Child to Work Day.[53] In addition, strategies used to retain employees include compensation (e.g., salary increase, retention bonus/allowance, career advancement opportunity) and other financial incentives (e.g., student loan repayment), but some believe these retention strategies are not used to their fullest strategic potential (see Supplement Exhibit S-16).

[52] Source: CDER/CBER Staff Survey.

[53] Source: Source: Work Life Programs Home Page 6.15.2018, inside.fda.gov (http://inside.fda.gov:9003/EmployeeResources/FDAUniversity/WorkLife/default.htm).

A correlation analysis of survey questions yielded similar findings (see Exhibit 18). Results showed that when new hires' responses were more positive on questions related to their engagement with FDA, they also intended to stay longer in their position at FDA. Overall, the strength of the correlation is moderate. The correlation scores ranked by strength (strongest first) provide an indication of what factors most influence a new hire to stay with FDA. The strongest correlation was with job fit (r = 0.42), followed by the belief that one made the right decision to join FDA (r = 0.39). Other, more moderate correlations are feeling supported to achieve career goals (r = 0.36), having meaningful conversations with managers about FDA career (r = 0.35), identifying with FDA core values (r = 0.33), and a willingness to recommend FDA as a great place to work (r = 0.33). These results reflect a common principle of employee management—that the first-line supervisor is critical to an employee's job experience—and offer insights that could be leveraged in retention planning.

Exhibit 18: Correlations Between Organizational Factors and New Hire Intention to Stay in Position[54]

CDER/CBER STAFF SURVEY ITEMS FOR NEW HIRES	CORRELATION WITH HOW LONG STAFF INTEND TO STAY IN THEIR POSITION
This job is a good fit for me	r = 0.42
I feel I made the right decision to join FDA	r = 0.39
I feel supported to achieve my career goals at FDA	r = 0.36
I have had a meaningful conversation(s) with my manager about my career aspirations at FDA	r = 0.35
I identify with FDA's values and core behaviors	r = 0.33
I would recommend FDA as a great place to work	r = 0.33

Respondents: CDER and CBER new hires (number of responses varies by item; n=1,787-1,866). Survey items related to new hire engagement correlated with the survey item: "How long do you intend to stay employed within your current Office?" Correlations were calculated using Pearson's Correlation Coefficient, and results are presented as "r = X".

However, FDA does use a strategic approach in defining the criteria for offering retention incentives. Specifically, employees in restricted occupations or functions that have been identified as difficult to fill in the past or likely to be difficult to fill in the future are eligible to receive categorical (group) retention incentives. Categorical retention incentives are offered based on business cases that include recent attrition data for the occupation and grade levels covered in the group-specific recruitment efforts.[55] For example, CDER is using the 21st Century Cures Act as a retention incentive through conversions and salary increases for existing employees (e.g., providing pay adjustments based on market salary data or other pay equity considerations) (see Supplement Exhibit S-17). As detailed in Exhibit 41 in the Hiring section (Finding F5.10), the Centers' use of the 21st Century Cures Act hiring and compensation flexibilities as a retention incentive has included converting existing talent to Cures' positions and providing associated salary increases.

Furthermore, data from the FEVS Employee Engagement and General Satisfaction Indices show that while CDER and CBER exceed government-wide levels, there is room for improvement (see Supplement Exhibits S-18 and S-19). Engagement and satisfaction in CDER are 4 to 11 percent higher than CBER, FDA, and government-wide levels. Engagement in CBER generally aligns with FDA levels and is 6 to 10 percent higher than government-wide levels. Information about employee engagement and general satisfaction is a critical consideration when formulating engagement and retention strategies. Understanding and building on these patterns—especially the strengths and opportunities they reveal—can help FDA be more deliberate and strategic in its approach to engagement and retention of top talent and mitigate the impact of unintended consequences. For example, CDER's consistently higher scores can help FDA identify internal and best practices that can be leveraged across Centers to enhance engagement and retention of all human drug and biologics review program staff. In addition, annual Workforce Analysis Profiles track critical information for the Centers and for FDA overall. Elements of these reports provide insights and metrics, including retirement eligibility, FEVS scores, and attrition patterns for MCOs as well as diversity categories.

[54] Source: CDER/CBER Staff Survey.
[55] Source: Guiding Principles – Categorical (Group) Retention Incentives, OTS.

3.2 Data Management and Systems

FDA's recruiting and hiring challenges are compounded by data management issues. Some issues center around data quality issues, such as reliance on homegrown approaches for manually tracking data (e.g., Access databases, Excel spreadsheets) and not reconciling manually tracked data with the appropriate system of record (e.g., the Enterprise Human Capital Management [EHCM] system). Other issues involve inefficient data management practices, resulting in unnecessary time loss to run analyses or respond to data calls. Still other issues stem from reactive rather than forward-looking data collection protocols, which hinder proper measurement of near-term and long-term impacts of various recruiting, hiring, and retention initiatives.

Furthermore, the lack of an integrated HRIS hampers FDA's ability to take an enterprise-wide view of the status of the recruiting and hiring workload, progress against recruiting and hiring goals, and transparency across stakeholders and different steps of the process. Furthermore, the lack of integration introduces quality control issues given that seemingly conflicting data may be pulled from various systems. While federal regulations will probably keep FDA tethered to certain governmentwide systems (e.g., USA Staffing), better integration among the multiple systems will provide FDA better data integrity, easier and quicker access to data, greater agility with report generation, and more reliable resources for making data-driven decisions.

Comparison to Initial Assessment: Since the Initial Assessment, challenges with data quality, data management practices, and system integration continue to impede FDA's access to the comprehensive, reliable information needed to make proactive data-driven decisions, monitor progress of its improvement initiatives, and improve efficiency and accountability issues. Relevant results from the Initial Assessment Report[56] include:

- Key Finding: *Inconsistent data tracking does not support process transparency and execution accountability*.
- Root Cause (Data & Systems): *Current data tracking metrics are insufficient to enable effective accountability and end-to-end management of the process.*
- Root Cause (Data & Systems): *IT systems are not consistently integrated, user friendly, or supportive of an efficient, effective hiring process.*

CONCLUSION

C2-1. Deficiencies in how FDA collects, manages, and maintains HR data result in inefficiencies and inhibit measurement of recruiting, hiring, and retention efforts.

FDA lacks an outcomes approach to data management to address issues associated with data quality, inefficiency, and the reactionary nature of data capture. To note, the dispersed infrastructure for HR data collection and analysis adds to the complexity. OHCM maintains an HRIT unit that manages many of the HR systems of record. This unit concurrently serves as a customer to external entities (e.g., the Department, OPM) and as a service provider to internal entities (e.g., Centers). Meanwhile, other HR data are collected at the Center level, either using formal or informal processes. Furthermore, some Centers have independently developed their own tools for tracking HR data. This dispersed infrastructure, varied data management processes, and dispersion of tools means there is no one single, reliable source for all HR data. These data are vitally important for measuring the success of recruiting and hiring efforts and for maintaining compliance with applicable HR regulations.

[56] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.

F2.1 The lack of complete and detailed datasets related to FDA recruiting, hiring, and retention prevented several analyses for this Interim Assessment from being conducted as planned.

Several analyses planned for this Interim Assessment were limited because of incomplete or unavailable system data:

- Incomplete hiring process data (e.g., raw data from Initial Assessment, timing of Title 5 process steps related to classification, package creation, vacancy posting, interviews, and offer stages) prevented the evaluation of process times for the traditional Title 5 process, comparison with the Hiring Pilot, and assessment of changes since the Initial Assessment.
- Unavailable recruitment outcomes data (e.g., numbers of applicants from specific sources; data tracking interactions with potential candidates) prevented assessment of the effectiveness of recruitment strategies and sources.
- Unavailable information on performance management (e.g., performance ratings by occupation, competency models, position descriptions) prevented integrating perceptions of HR staff capability with official documentation.
- Incomplete workforce data (e.g., numbers and organization alignment of HR staff, numbers of vacancies by center, position management data) prevented comprehensive, objective evaluation of workload distribution and HR servicing ratios.

CONCLUSION

C2-2. FDA does not yet have the mature technology integration necessary to sustain data integrity, data access, and reporting agility in support of hiring, recruiting, and retention.

FDA lacks an integrated HRIS that would provide efficient access to a consistent set of data from multiple systems (e.g., USA Staffing, eClass, ATLAS) that are necessary to track and manage HR processes and actions and to maintain a comprehensive repository of hiring and workforce data. Instead, the HR workforce relies on several different data systems, including decentralized workbooks that are created separately in different organizations and manually maintained. Relying on these disjointed data systems can lead to HR process inefficiencies stemming from manual processes, redundant data entry, incomplete or contradictory data, errors, and delays in support of CDER and CBER. While FDA is piloting a new system (ATLAS) that may address some of these challenges, it will not completely fulfill FDA's need for a comprehensive, fully integrated HRIS.

F2.2 FDA's current ATLAS system has the potential to improve the effectiveness and efficiency of the hiring workflow, but the system alone will not address all the technology requirements.

FDA's HR work is hindered by insufficient technology resources. In survey responses, nearly half of CDER and CBER hiring managers and managers of HR staff (49 and 51 percent, respectively) reported that they need access to a reliable IT system that provides easy access to the status of hiring actions (see Supplement Exhibit S-20). In addition, stakeholders in interviews and focus groups highlighted issues such as manual data entry and system limitations as root causes that add to their workload. Participants also believed that not having a centralized data location impacts the effectiveness of future technological improvement efforts and that without a centralized data location it will be difficult to create a system that can effectively reduce the workload (see Supplement Exhibit S-21).

FDA is taking steps in the right direction by employing strategies to make greater use of technological solutions for the management, tracking, and reporting of hiring data. For example, FDA recently developed a workflow tracking system called ATLAS as part of with the Hiring Pilot. ATLAS was built to improve the effectiveness and efficiency of the hiring workflow by including increased transparency between stakeholders, time-to-fill tracking, increased accountability, and quality control. However, ATLAS offers only a partial solution to address some of the hiring technology challenges because the system does not currently

apply to recruiting (i.e., it does not include an applicant tracking component), does not apply to classification and position management, and does not yet offer reporting capabilities for hiring managers and leadership.

Accordingly, interview and focus group feedback indicated conflicting opinions about the potential benefits of ATLAS given the reality of the current state of its implementation. Stakeholders acknowledged that ATLAS has helped enhance process visibility and improve stakeholder interactions; however, its effectiveness is limited by the lack of technological infrastructure for HR data throughout FDA (e.g., data gaps, multiple systems, outdated technology) (see Supplement Exhibit S-22). In addition, with its focus specifically on the Hiring Pilot, it is not yet implemented broadly enough to replace the manual, homegrown data capture and reporting tools currently employed within the Centers' Program Offices.

3.3 HR Staff Capability and Capacity

Developing a clear understanding and plan to manage the dynamics of HR staff capacity and capability is critical to enabling FDA to maintain the right *number* of HR staff to manage the workload and to know that they have the right *skills and capabilities* to sufficiently recruit, hire, and retain qualified human drug review program staff. Because staff responsible for performing HR work are distributed across several organizations, including OTS, OHCM, CDER/CBER OM, and CDER/CBER Programs, FDA faces challenges with monitoring and managing HR staff capability and capacity, which is directly related to the quality, timeliness, and consistency of HR service delivery. In addition, a heavy workload and stated need for more resources (e.g., policy guidance, integrated HRIS, training) challenges HR staff capacity and capability. Furthermore, stakeholders, including hiring managers, express dissatisfaction with HR staff capability.

FDA's reorganization of its HR functions is an important step in the right direction for providing a structure to better manage HR staff capacity and capability, thereby supporting improved service delivery. The division of responsibilities between OTS and OHCM supplied additional leadership and direction to improve management and guidance related to these critical functions. The reorganization also included increased resources and specialization within the HR workforce to better manage the workload. However, since the reorganization, OTS and OHCM has been hampered by high vacancies, turnover, and process changes that have yet to stabilize, which is keeping the organizational structure from achieving optimal effectiveness. Having the benefit of a well-defined HR organizational structure will help equip HR staff to handle the volume of HR work and enable them to effectively integrate recruiting, hiring, and retention functions.

Comparison to Initial Assessment: Since the Initial Assessment, FDA's HR staff continues to operate in a decentralized fashion, which perpetuates several of the challenges identified in the Initial Assessment. However, the OHR reorganization did establish a new structure and plans to clarify the policies, procedures, and other guidance that are beginning to address these issues. Relevant results from the Initial Assessment Report[57] include:

- Key Finding: *The organizational structure is characterized by a proliferation of shadow HR positions and a geographic division between centralized HR and center-based stakeholders.*
- Key Finding: *A significant skill gap, combined with a lack of training, hinders efficient and accurate execution of the process.*
- Root Cause (Organization and People): *Organizational structure limits ability to execute an efficient process.*
- Root Cause (Organization and People): *Inadequate resources (FTEs) exist to execute process accurately and efficiently.*
- Root Cause (Organization and People): *Unclear and variable roles and responsibilities amongst stakeholders create confusion and redundancy.*
- Root Cause (Organization and People): *Skill gaps and inadequate training inhibit successful hiring process.*

[57] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.

CONCLUSION

C3-1. Although the OHR reorganization established some important building blocks, FDA lacks a comprehensive organizational infrastructure for HR to enable consistent, high-quality service delivery.

Because HR staff, who play various roles in hiring human drug and biologics review program staff, are distributed across FDA, there is no integrated performance and development structure to support their skill development and manage performance. This then impacts their ability to provide consistent quality delivery of HR services. The lack of a consistent set of competency requirements inhibits HR staff from building common behavioral expectations, training protocols and standard proficiency requirements for the critical knowledge, skills, and abilities (KSA) needed for the work. In addition, without adequate guidelines, processes, and tools for how best to quantify, distribute, share, and prioritize the workload, FDA is less equipped to make informed decisions about the resources needed to manage the work and equitably balance and redistribute the workload as needed, especially during absences and surges.

F3.1 With the OHR reorganization, OTS centralized expertise in Classification, DE, and Policy and Accountability into their own organizational units; however, success is limited because OTS maintains a large backlog of classification work, is not fully staffed, and has not yet updated all critical HR policies and procedures.

As a result of the OHR reorganization, classification and DE were centralized to better accommodate demand and efficiency of position description (PD) management and to strengthen DEU competencies and compliance (to note, HHS currently has 100 percent review oversight of all DE activities). OPM also provided DE training for all DEU HR staff. In addition, Policy and Accountability staff were centralized to improve hiring accountability and governance, first by reviewing and prioritizing HR policies that require action (e.g., updates).[58]

Themes from interview and focus group sessions with HR leadership and OTS classifiers reflect that there have been improvements in classification and the distribution of workload due to the new centralized structure of certain HR service units. However, OTS continues to maintain a backlog of 2,231 classification cases, impacting the effectiveness of its newly centralized business model.[59] Without information on classification processing time and the complexity of these classification cases, it is not possible to calculate a reliable estimate of time required for OTS to work through the backlog; however, the backlog is certainly a major investment of OTS resources and may also be slowing down progress of the ongoing CDER and CBER hiring actions. Nine of the 25 additional resources approved by the Working Capital Fund Counsel were identified as classification resources to help address the backlog of work and efficiency of classification/ position management services.[60]

Turnover and redistribution of HR staff (including internal movement between OHR and the Centers), as well as resource vacancies to support the new organizational structure, has resulted in gaps in support delaying the potential effectiveness of the OHR reorganization. The following data[61] summarize these personnel gaps and churn following the OHR reorganization on July 9, 2018 from the legacy OHR organization to the newly structured OTS and OHCM:

- **Gains**: A total of 58 personnel gains into OTS and OHCM (including transfers from other FDA Centers/Offices, other federal agencies, and new federal hires).

[58] Source: FDA Hiring and Retention Reforms Update 12.12.2018, OO.
[59] Source: Classification Backlog 01.10.2020, Human Resources Employment Processing System.
[60] Source: OTS Working Capital Fund Counsel Budget Request FY2020, OTS.
[61] Source: FDA Personnel Data FY2016 to FY2019, BIIS.

- **Losses**: A total of 44 personnel losses (including transfers to other FDA Centers/Offices, transfers to other federal agencies, other HHS Operating Divisions, other federal agencies, resignations, retirements, and involuntary losses).
- **Vacancies**: There remain 30 full-time equivalency (FTE) and three contractor vacancies within OTS (13 percent of their workforce) and nine FTE vacancies within OHCM (8 percent of their workforce).[62]
- **Additional Resource Requests**: OTS requested 52 additional FTE from the Working Capital Fund Counsel for FY2020 and was approved for 25 FTE. Currently, 22 of those 25 vacancies have been filled.[63] OTS also requested two additional FTE from the User Fee Council, which were both approved and filled.[64]

The Initial Assessment identified policies and process documentation as pain points for FDA. Since then, some changes have taken place, such as the establishment of a new Policy Working Group and the issuance of new or revised procedures and guidance, which included three SOPs, six HR Bulletin/Advisories, and three Guidance Memos. [65] Additional documents have been drafted and are pending review and approval. However, realized impact has been minimal to stakeholders, with interview and focus group feedback from Center staff (including Center leadership, HR leadership, HC liaisons within the Centers, hiring managers, HR staff, and managers of HR staff) and HR leadership within OTS and OHCM indicating that policies and processes continue to be a key pain point.

Interview and focus group feedback highlighted that the effectiveness of the OHR reorganization is limited by staffing changes as well as limited transparency and documentation of policy, processes, and services (see Supplement Exhibit S-23). OTS and OHCM currently maintain the official HR policies and process documentation on the Intranet, but many Centers maintain their own content and individualized processes both on the Intranet and SharePoint. In short, there are a substantial number of resources that contain differing information, and SOPs and guidelines are currently in multiple places within FDA's "InsideFDA.gov" intranet site instead of a centralized HR knowledge management repository. Some available resources contain broken or outdated web links and numerous documents simply refer to guidance issued by OPM/HHS without further FDA-specific guidance, culminating in confusion and misinformation between OTS and the Centers, which contributes toward poor quality control of hiring actions.[66]

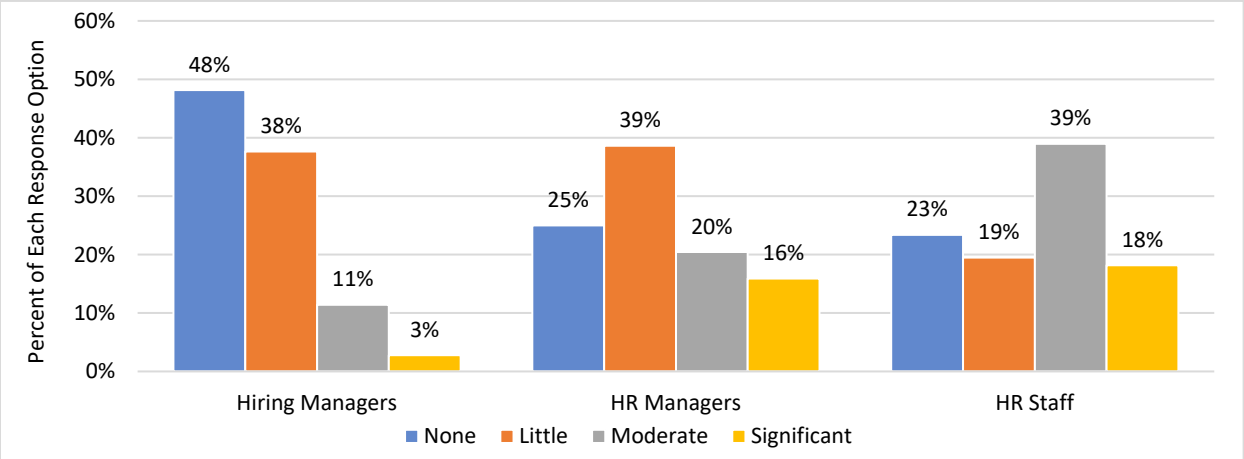
As a response to these challenges, the concept of a "Hiring Manager Portal"[67] is currently being developed by OTS and OHCM as a one-stop resource for all FDA hiring managers to learn FDA's hiring policies, processes, educational materials, forms, and status of actions. Initial research conducted by OTS inventoried HR materials across the enterprise that would potentially feed into the portal. Concurrently, OHCM is in the development phase for a new HR Employee Portal (ePortal) to serve as a one-stop interface and information aggregation point for all FDA employees. The ePortal will contain FDA employee data, FDA HR policies, procedures, and quick access to all HR information systems. The development of ePortal is underway with a tentative launch in Fall 2020, as the authoritative and official resource for HR information, may incorporate the concept of the Hiring Manager Portal.

Opinions about the degree to which the OHR reorganization impacted recruiting, hiring, and retention noticeably varied (see Exhibit 19). Based on the modal (most common) responses, Center Hiring Managers noted no improvements (48 percent), managers of HR staff noted little improvement (39 percent), and HR staff noted moderate improvement (39 percent). These results show a greater sense of optimism from those who provide HR services than from those who receive HR services. In addition, hiring managers may need

[62] Source: OTS Org Chart 2019, OTS.
[63] Source: OTS Working Capital Fund Counsel Budget Request FY2020, OTS.
[64] Source: Meeting Minutes from Discussion with OTS Director 2.24.2019, OTS.
[65] Source: Meeting Minutes from Discussion with OTS's Director of Policy and Accountability Staff 3.06.2020, OTS
[66] Sources: FDA SOPs, InsideFDA.gov; FDA Hiring and Retention Reforms Update 12.12.2018, OO.
[67] Source: FDA HRIT ePortal Presentation 08.06.2019, OHCM.

more experience with the changes generated by the OHR reorganization before it can impact their overall satisfaction with the recruiting and hiring functions.

Exhibit 19: Interim Surveys (All Respondents)—Improved Overall Satisfaction with Recruiting and Hiring Due to the OHR Reorganization[68]



Respondents: HR Staff (n=91); HR Managers (n=48); Center (CDER and CBER Hiring Managers only; n=354). Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to support provided by the Agency's HR Organization (formerly the Office of Human Resources [OHR]) to the Centers, in terms of timeliness, accuracy, quality, and your overall satisfaction?" A "Don't Know" response option was also provided; those responses are not included in this analysis.

F3.2 Although some new training and performance management resources are available for OTS staff; FDA lacks a unified framework to manage the work of all HR staff, including competency models, performance standards, training and development, and workload management.

OTS has taken steps to improve HR capabilities. OTS created the Talent Academy in 2018 as a best practice effort that began as part of the Hiring Pilot and has now been expanded to all of OTS. Talent Academy training includes technical courses on DEU Certification, Basic Staffing and Placement, DHA, and Pay Setting, as well as soft skills training such as asking powerful questions and customer service. OTS has also created standardized performance goals in July 2018, and OTS staff updated their PMAPs to align with these goals.[69]

As shown in Exhibit 20, FDA has not made progress in other areas identified in the Initial Assessment (e.g., well-documented and clearly understood processes, programs, strategic priorities; performance metrics to guide the performance and accountability of HR staff across the Agency). The distributed nature of FDA's recruiting, hiring, and retention activities hamper efforts to manage the performance of staff across OTS, OHCM, CDER, and CBER who perform this work. For example, there is no enterprise-wide system to track and coordinate job applicant workflow as it changes hands among multiple parties in both the Agency's HR Organization and the Centers. In addition, FDA lacks the foundational infrastructure, such as competency models and training plans, to support the management and development of HR staff supporting the recruiting, hiring, and retention of human drug and biologics review program staff.

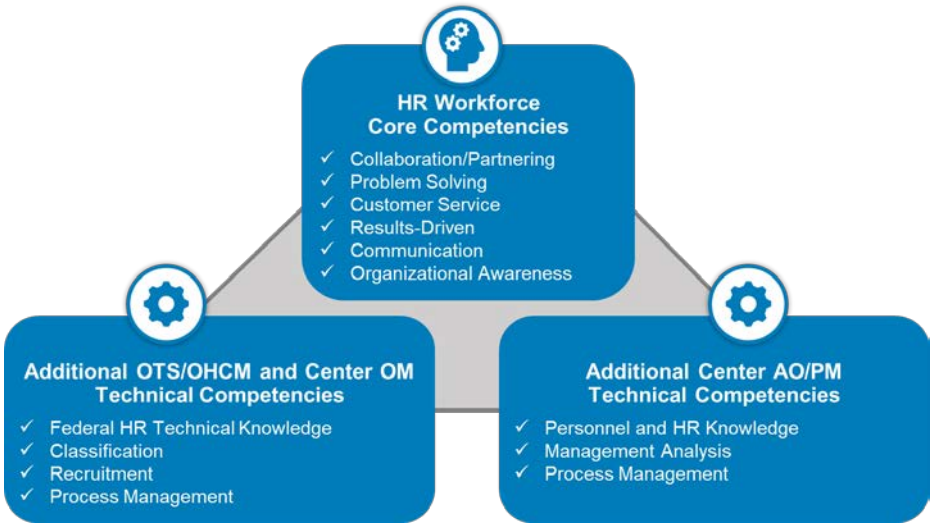
[68] Sources: HR Workforce Staff Survey, HR Workforce Manager Survey, CDER/CBER Staff Survey.
[69] Source: OPM Audit Remediation Activities 10.30.2019, OTS.

Exhibit 20: Initial and Interim Comparison—Progress Related to HR Staff Capability and Capacity

INITIAL ASSESSMENT RESULTS[70]	INTERIM ASSESSMENT RESULTS	PROGRESS
• Inconsistent performance goals, Service Level Agreements (SLA), or enforcement of expectations undermines accountability throughout process. • HR staff key performance indicators did not have meaningful targets. • Hiring managers reported that HR staff are not held accountable for their actions. • HR specialists[71] noted that lack of timely responses from hiring managers hinders their ability to efficiently complete the hiring process. • Lack of process accountability measures reinforces the sense that parties are solely responsible for "their part" of the hiring process.	• OTS established standard **performance goals** and established **Talent Academy** for all its staff members (see Finding F3.2). • **ATLAS system was designed** to increase transparency, time-to-fill tracking and reporting analytics for hiring managers and leadership, increased accountability, and quality control (see Finding F2.2). • **Similar to Initial results, themes** were expressed for issues with **HR staff timeliness and accountability** (see Supplement Exhibit S-24).	Some progress

For example, FDA has not developed a competency model with consistent core competencies for HR staff—regardless of their organizational alignment—that is well communicated and integrated with performance management and development processes and resources. CDER and CBER have organization-wide competencies, with separate competency models for their HR workforce. Competency models for OTS and OHCM staff were not available. Given the absence of a unified competency model for FDA's HR workforce, Booz Allen conducted an analysis of CDER and CBER competency models, competencies for the 0201 occupational series recommended by OPM, and information provided in the initial assessment. Based on that information, HR leadership identified six Core Competencies applicable to the HR workforce, four technical competencies applicable to OTS/OHCM and Center OM staff, and three technical competencies applicable to Center PMs/AOs for use in the competency assessment included in the HR Manager Survey (see Exhibit 21).

Exhibit 21: FDA Capability Data—HR Workforce Competencies Identified for Capability Assessment



These competencies closely align to the KSAs identified as important by HR leaders. HR leaders interviewed said the HR workforce needs expertise in HR technical areas and the ability to use a consultative approach to help recruit and retain human drug and biologics review program staff within existing authorities and

[70] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[71] Note: "HR Specialist" is a subset of HR staff within the Agency's HR Organization (i.e., OTS and OHCM, formerly OHR) responsible for FDA recruiting, hiring, and retention.

flexibilities. They also said the HR workforce needs attention to detail, listening, communication, and customer service skills. Additional KSAs identified less frequently include planning and organizational skills, interpersonal skills, negotiation, computer skills, and the ability to make a business case to justify HR's needs (see Supplement Exhibit S-25).

CONCLUSION

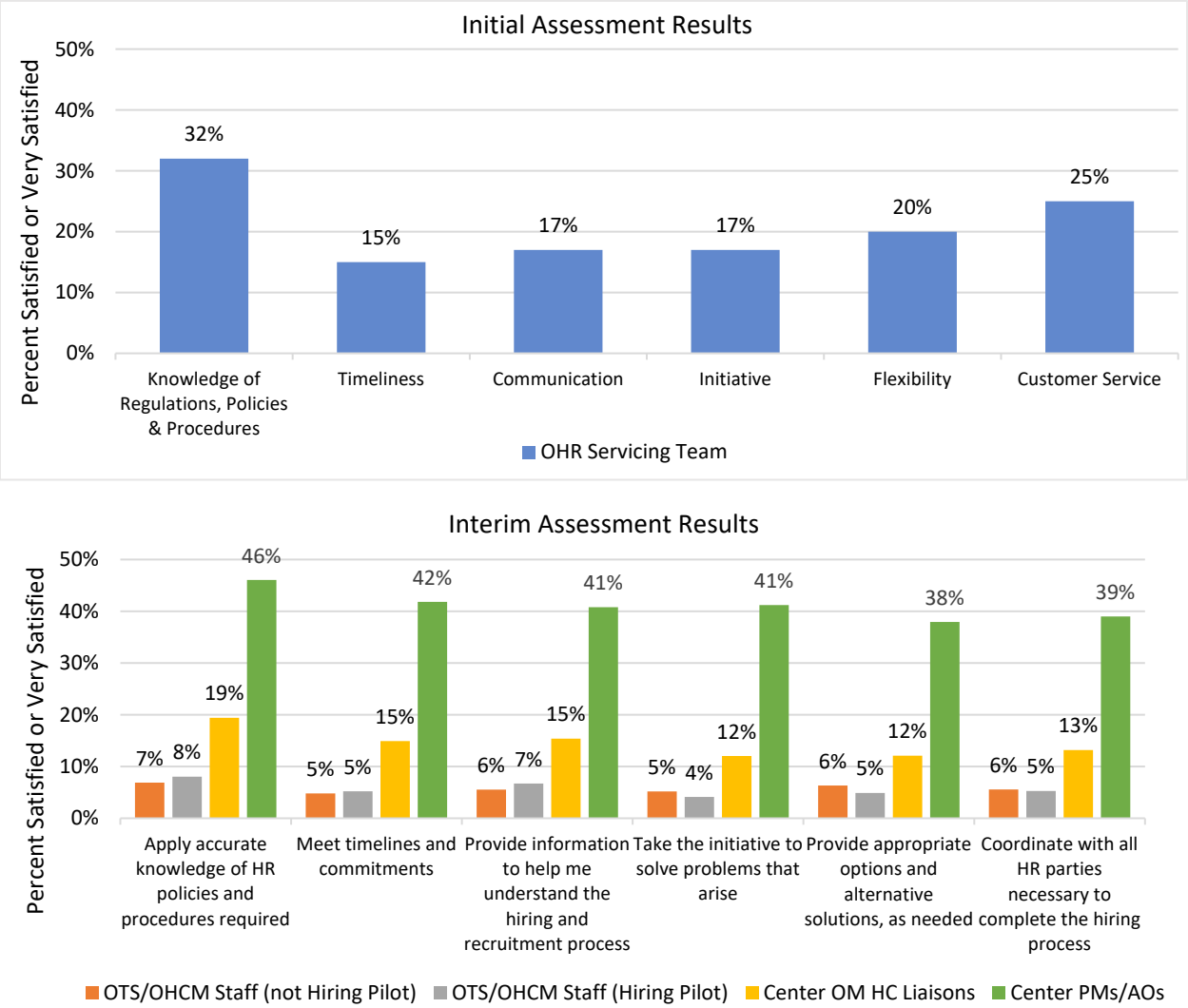
C3-2. FDA faces issues with both HR staff capability and capacity; moreover, FDA does not sufficiently track HR workload, distribution of work, nor HR staff competencies and performance to enable a complete understanding of the challenges and root causes of these issues.

F3.3 Hiring managers are unsatisfied with the abilities of HR staff, especially those in the Agency's HR Organization and Center OMs; however, managers of HR staff reported that HR staff generally meet or exceed competency proficiency requirements.

Hiring managers' survey responses further underscore the extent of hiring effectiveness challenges, especially related to a striking variation in opinions about staff in different HR roles. The Initial Survey (conducted during the 2017 Initial Assessment) asked hiring managers about their satisfaction with the abilities of the OHR Servicing team. Similarly, the recent CDER/CBER Staff Survey conducted for the Interim Assessment asked hiring managers about their satisfaction with the abilities of HR staff in several roles—Center PMs and AOs, Center OM staff, and the Agency's HR Organization (i.e., OTS and OHCM) (both pilot and non-pilot staff)—when they are hiring a new employee. Both Initial and Interim Assessment surveys used a 5-point Satisfaction Scale for these items, and results show the combined percentage of Satisfied and Very Satisfied responses. For purposes of comparison, the items used to rate HR staff in the Initial Survey question are aligned to similar items in the Interim Survey. The Interim HR roles most comparable with the OHR Servicing team (rated in the Initial Assessment) are OTS and OHCM staff.

Interim Assessment results of hiring managers' satisfaction with HR staff are generally lower than the Initial Assessment results (see Exhibit 22). The Interim Assessment results also show a striking and consistent pattern with variation not by the different abilities but by the different HR roles. OTS and OHCM staff received the lowest ratings of all HR roles rated for the Interim Assessment. Across all items, the abilities of Center OM staff received more favorable ratings than OTS and OHCM staff, and the noticeably highest ratings were for the Center PMs and AOs—those who are organizationally closest to the hiring managers. This pattern of results suggests a need for additional review in this area, although the results should be interpreted with caution as the wording of these items in the Initial Assessment and Interim Assessment are not directly comparable.

Exhibit 22: Initial and Interim Surveys (Hiring Managers)—Satisfaction with Abilities of HR Staff in Various Roles[72]



Initial Assessment. Respondents: CDER and CBER hiring managers (n=132). Survey item: "Based on your experience working with your OHR Servicing Team, what is your level of satisfaction with their work in each of the following areas?"
Interim Assessment. Respondents: CDER and CBER hiring managers (responses vary by item; n=265 to 291). Survey item: "When you are working on hiring a new employee, how satisfied are you with the abilities of HR Staff in various roles within FDA?"
A "Not Applicable" response option was also provided; those responses are not included in the Initial or Interim analysis.

Survey results from managers of HR staff provided insights into HR staff proficiency in both Core Competencies and Technical Competencies. Results indicated that 90 percent or more of HR staff meet or exceed proficiency requirements for all of the Core Competencies, which are required for HR staff (see Supplement Exhibit S-26). Managers did identify gaps in a few of the Technical Competencies. The largest gap is in classification, for which 42 percent of all HR staff do not meet proficiency requirements. Otherwise, managers identified much smaller gaps—specifically, 11–16 percent of HR staff do not meet proficiency requirements for other Technical Competencies. It is important to note that not every Technical Competency

[72] Sources: Initial Assessment of FDA Hiring and Retention 11.2017, OTS; CDER/CBER Staff Survey.

is required for each HR position, which accounts for the overall smaller numbers of HR staff reported to meet or exceed proficiency requirements for Classification and other Technical Competencies.

In interviews and focus groups, HR Leadership, OO/OC Leadership, hiring managers, and managers of HR staff expressed views that contrast somewhat with these survey results. They reported that some members of the HR workforce have stronger skills than others; however, many HR staff have gaps in one or more competency. For example, they identified gaps in HR technical skills, communications, and customer service, and the ability to understand hiring managers' needs (see Supplement Exhibit S-27). Respondents also noted that gaps in HR staff capabilities can be addressed through targeted learning and development, more robust onboarding of new HR staff, and better management of poor performance. In addition, they noted that improved retention efforts targeting high performing HR staff can help retain institutional knowledge.

Survey results also show that some managers of HR staff see a need for HR staff training and development, and the priorities varied by Center (see Exhibit 23). Despite the survey results presented above, in which managers of HR staff state that the majority of their HR staff meet or exceed competency proficiency requirements, managers identified training and development needs in ten or more competencies for their HR staff in each Center. Most managers of HR staff (across FDA) identified development needs for Core Competencies, with Communications, Collaboration/Partnering, and Customer Service consistently identified most frequently. Managers of Center AOs/PMs and managers of OTS' HR staff reported that the top development needs were in the Technical Competencies of Personnel and HR Knowledge and Process Management, respectively. While some managers of HR staff identified development needs in other Technical Competencies, they tended to be lower in frequency in comparison to the Core Competencies.

Exhibit 23: HR Manager Survey—Competency Priorities for Learning and Development

In which of the following competencies do your Federal Government HR staff most need additional learning and development? Please indicate your top priorities for potential learning and development opportunities.			
CENTER PMs/AOs	**CENTER OM**	**OTS**	**OHCM**
• Personnel and HR Knowledge (71%) • Problem Solving (62%) • Organizational Awareness (52%) • Communication (48%) • Customer Service (43%) • Collaboration and Partnering (38%) • Management Analysis (38%) • Process Management (38%) • Results Driven (33%) • Additional Areas (14%)	• Communication (73%) • Collaboration and Partnering (55%) • Results Driven (45%) • Organizational Awareness (45%) • Federal HR Technical Knowledge (45%) • Classification (45%) • Process Management (45%) • Problem Solving (36%) • Recruitment (36%) • Customer Service (27%)	• Process Management (56%) • Communication (44%) • Organizational Awareness (44%) • Federal HR Technical Knowledge (44%) • Recruitment (44%) • Collaboration and Partnering (33%) • Customer Service (33%) • Problem Solving (22%) • Results Driven (22%) • Classification (22%) • Additional Areas (11%)	• Collaboration and Partnering (80%) • Customer Service (60%) • Problem Solving (40%) • Communication (40%) • Results Driven (40%) • Federal HR Technical Knowledge (40%) • Additional Areas (40%) • Organizational Awareness (20%) • Classification (20%) • Process Management (20%)

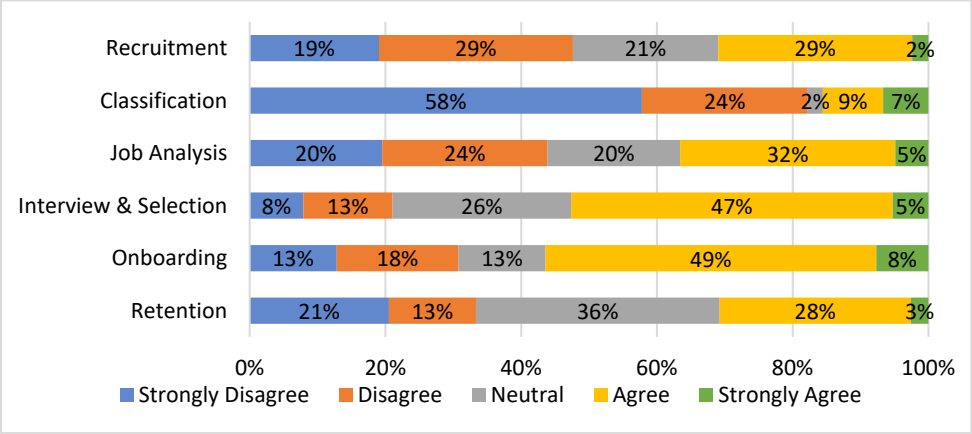
Interview and focus group participants discussed the variance in development needs across their teams and suggested that individualized, tailored training and development plans would be more effective than general training programs required for all staff. In addition, participants noted that capability gaps are exacerbated by the loss of experienced HR staff, and there are large numbers of new HR staff unfamiliar with FDA processes and business needs. Suggestions to address this challenge include more targeted recruiting efforts to hire HR staff with relevant skills and using motivational tools to improve accountability and performance (see Supplement Exhibit S-27).

F3.4 HR Staff and managers of HR Staff say they are unable to manage the current workload and see a need for additional resources to effectively do so, especially in support of classification work.

According to survey data, only five percent of managers of HR staff reported that HR staff are able to manage the workload for recruiting, hiring, and retention of human drug and biologics review program staff. These

responses also suggest additional resources and clear process guidance are needed to help HR staff with workload management (see Supplement Exhibit S-28). Other survey results from HR staff and managers of HR staff also note that they need additional resources, such as process guidance, job aids, centralized information on conducting the hiring process, access to policy experts, and training on FDA's hiring processes and related regulations (see Supplement Exhibit S-20). As presented in Exhibit 24, when asked whether there are sufficient staff for the process stages, managers of HR staff indicated that the greatest deficiency is in staff for classification (82 percent disagree or strongly disagree) and, to a lesser extent, recruiting and job analysis (48 percent and 44 percent disagree or strongly disagree, respectively).

Exhibit 24: HR Manager Survey—Sufficient Staff for HR Functions[73]



Respondents: HR Managers (number of responses varies by item; n=47-49). Survey item: "There are sufficient staff for each of the HR process stages and/or retention initiatives." A "Don't Know" response option was also provided; those responses are not included in this analysis.

HR and Center leadership interviews and focus groups brought attention to the classification backlog when discussing areas impacted by insufficient staffing. Participants also mentioned the change in hiring actions, not necessarily the number of hiring actions to be completed itself, has impacted the workload. For example, the increased use of Hiring Authorities has changed the way HR processes hiring actions, which in some cases has created additional workload, such as the recent DHA process changes required by OPM[74] (see Finding F5.6 for more detail).

Indeed, workload is impacted by a lack of integrated technology and insufficient or antiquated systems. For example, interview and focus group participants reported that there are inefficiencies due to manual data entry in multiple systems that are not integrated, the need to create home-grown spreadsheets to track the status of hiring actions, and lost time due to system time-outs (see Supplement Exhibit S-21). Interview and focus group participants also noted that the current lack of streamlined processes and adequate system integration and functionality intensifies the need for additional HR staff (see Supplement Exhibit S-29). In addition, data on Center gains and losses (see earlier Exhibit 11) highlight how FDA is continually hiring while simultaneously losing talent. This workforce churn contributes to a continuous workload for HR staff.

The ability to fully assess whether FDA has sufficient capacity and effective workload distribution was limited by the lack of quantitative data on workload volume, processing time, and distribution practices. In interviews and focus groups, HR staff and their managers shared that HR workload tracking methods reduce insight into the distribution of work among HR staff and further hinder the ability to effectively manage work, achieve an equitable distribution of work among the team, manage surges, maintain continuity during staff absences, and proactively plan for expected variations in future workload (see Supplement Exhibit S-29).

[73] Source: HR Manager Survey.
[74] Source: OPM Memorandum Direct Hire Authority October 2018, OTS.

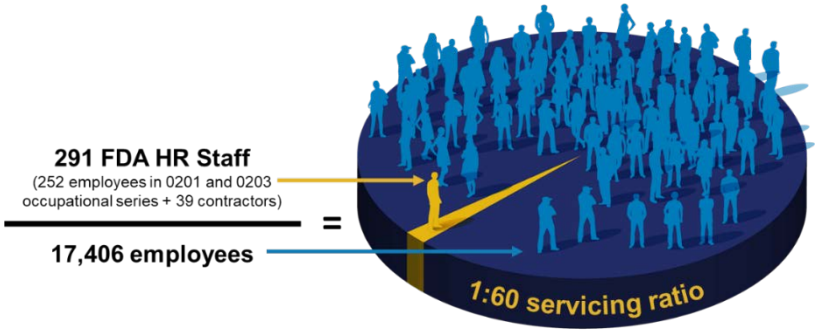
OTS received approval through its Working Capital Fund Council and User Fee Council to hire an additional 27 HR staff, including nine additional staff to support the classification function; they have currently filled a number of those positions. Once all of these positions are filled and staff onboarded, FDA will have increased HR capacity to handle classification and other aspects of the HR workload.

F3.5 FDA's HR Servicing Ratio aligns with government benchmarks; however, high vacancy rates of HR staff positions likely impacts their capacity.

To assess FDA capacity, the assessment team looked at FDA HR staffing levels with government-wide benchmarks. A HR Servicing Ratio of 1:63 was established by OPM for FY2012 and reflects data from 13 federal agencies; however, it has not been updated since. The assessment team then compared FDA HR staffing levels with other known government-wide benchmarks. For example, according to a 2016 study conducted by the General Services Administration (GSA),[75] the HHS HR Servicing Ratio was 1:49, and the average HR Servicing Ratio for all government Agencies was 1:53.

Government benchmarked servicing ratios focus exclusively on Federal Government FTE in the 0201 and 0203 occupational series (e.g., HR Specialists and HR Assistants) and contractors dedicated to the same HR work, and compares that support to the number of employees receiving HR services. The FDA HR Servicing Ratio calculated for this assessment followed that same methodology, with 252 Federal Government FTE in the 0201 and 0203 occupational series (e.g., HR Specialists and HR Assistants), plus 39 contractors dedicated to the same HR work, and compared it to the 17,406 employees receiving HR services[76] (see Exhibit 25).

Exhibit 25: FDA Staff Data—FDA HR Servicing Ratio[77,78]



These calculations resulted in an overall FDA HR Servicing Ratio of 1:60, which is largely in line with the government benchmarks from 2012, but slightly higher than the more recent benchmarks in 2016. While FDA's HR Servicing Ratio appears to be comparable to GSA and HHS HR Servicing Ratios, it is difficult to determine with certainty if the ratio is effective. Specifically, this assessment found that numerous HR staff positions supporting the 1:60 ratio were vacant, and having an understaffed HR function likely plays a large role in resource capacity challenges (i.e., the ability of HR staff to get the work done). While OHCM is currently fully staffed to support the Centers (including CDER and CBER), OTS, CDER OM, and CBER OM are operating with staffing deficits of 21 percent, 15 percent, and 27 percent, respectively. Such large gaps in recruiting and hiring resources result in an increased workload on existing staff, often trailed by burnout and undesired attrition. Exhibit 26 displays the estimated number of HR staff specifically supporting the recruiting, hiring, and retention of human drug and biologics review program staff in CDER and CBER. More importantly, the exhibit highlights the percentage of HR staff vacancies in each organization.

[75] Source: OTS HR Rightsizing Benchmark Report to WCFWG 04.2019, OTS.
[76] Source: OPM Multi-Agency Executive Strategy Committee Report 07.2013, OPM.gov.
[77] Source: FDA Personnel Data FY2016 to FY2019, BIIS.
[78] Note: to make a direct comparison to the OPM benchmark, this analysis excludes individuals performing HR functions at the FDA that do not fall within the 0201 and 0203 occupational series (e.g., HC Liaisons within the Centers).

Exhibit 26: FDA Hiring Data—Estimated Vacancies of HR Staff Who Support to CDER and CBER[79]

ESTIMATED HR STAFF SUPPORTING CDER/CBER	OTS[80]		OHCM[81]	CDER OM	CDER AOs[82]	CBER OM	CBER PMs	Total[83]
	Fully Support	Partially Support[84]						
Federal HR Staff FTE	30	70	22	39	230	6	8	335-405
Contractors	3	0	0	7	unknown	2	unknown	unknown
Sub-Total	33	70	22	46	230	8	8	347-417
Vacancies[85]	9	unknown	0	8	unknown	3	unknown	unknown
Total	42	70	22	54	230	11	8	367-437
Vacancy Rate	**21%**	**unknown**	**0%**	**15%**	**unknown**	**27%**	**unknown**	**unknown**

In addition, the following challenges add to the complexity of determining the effectiveness of HR capacity:

- FDA's decentralized web of HR staff that support the recruiting, hiring, and retention of human drug and biologics review program staff in CDER and CBER is composed of staff in the OTS, OHCM, CDER OM and Program Offices, and CBER OM and Program Offices—making it difficult to determine an accurate count of HR staff and, as a result, to effectively manage and distribute the hiring workload.
- While HR staff within CDER OM and CBER OM provide dedicated support to their respective Centers, both OTS and OHCM provide services across the entire FDA organization, often based on an HR role or service area (e.g., DEU, Title 38 Team, classification).
- In addition to the HR staff within the Centers' OM, each Center also has additional staff who have a collateral duty to support the hiring managers and their teams with administrative HR functions on the Program side.[86]
- HR staff in the Centers' OM and the staff supporting HR in the Center Program Offices are in other occupational series (e.g., 0301); therefore, they are not accounted for in system data nor are they accounted for in the government-wide benchmarks. For this reason, although these staff do perform HR work, they are not represented in the HR Servicing Ratio.
- Organizations may choose to have a lower HR Servicing Ratio for strategic reasons, such as to address backlogs or to invest in providing additional services or service levels.

3.4 Culture, Collaboration, and Communication

Based on interview and focus group feedback, there are underlying issues in regard to how the various groups (i.e., OTS, Center OM HR, HR in Center offices, hiring managers) interact with one another when working on recruiting, hiring, and/or retention efforts. These parties cite factors such as collaboration and communication challenges as major hindrances to performing their roles in executing HR processes in an

[79] Source: HR Staff Headcount 01.15.2020, EHCM, IBAPS, Manual Reporting (Microsoft Excel).
[80] Note: OTS has an overall headcount of 274 HR staff (including FTE, contractors, and vacancies).
[81] Note: OHCM has an overall headcount of 114 HR staff (including FTE, contractors, and vacancies).
[82] Note: As AOs within CDER perform many roles, which may or may not include that of HR functional work, it is nearly impossible to quantify this population of HR support, as their occupational series in not aligned to that of human resources. However, their level of support should be considered when assessing the HR workforce.
[83] Note: Total ranges show fully supporting only (low number) and fully and partially supporting (high number).
[84] Note: "Partially Support" refers to HR staff in OTS that provide support to CDER and CBER as well as other Centers across the Agency based on their role or service area (e.g., DEU, Direct Hire team, Title 38 Team, Classification), and does not equate to 70 full-time equivalent staff.
[85] Includes both FTE and contractor vacancies.
[86] Note: As AOs within CDER perform many roles, which may or may not include that of HR functional work, it is nearly impossible to quantify this population of HR support, as their occupational series in not aligned to that of human resources. However, their level of support should be considered when assessing the HR workforce.

effective and efficient manner. Despite the fact that they are all responsible for the success of the HR functions related to recruiting, hiring, and retaining human drug and biologics review program staff, they do not have a shared perspective on the processes, which ultimately impacts progress. While it was not possible to discern with certainty whether the existing, sub-optimal culture is a cause or an effect of the current challenges with recruiting, hiring, and retention (i.e., whether a sub-optimal culture contributed to the challenges or whether the challenges led to the emergence of a sub-optimal culture), it is evident that the culture is impacting how people work together and must be addressed.

Efficient and effective hiring, recruiting, and retention of high-quality staff requires a unified team effort, with multiple facets of the organization working together to surmount talent challenges. Addressing inefficiencies will require improvements on multiple fronts, including adopting a common vision for a customer-centric culture, more constructive interactions among groups, a shared vision and common goals for the process, clear performance expectations and accountability, clear and useful process guidance, and resources to enable greater transparency, communication, and problem-solving throughout the process. These issues will continue to stand in the way of true success unless explicitly confronted and actively addressed.

Comparison to Initial Assessment: Since the Initial Assessment, challenges related to the lack of a constructive, team-oriented culture and inadequate collaboration and communication continue to hinder the successful execution of recruiting, hiring, and retention functions for FDA. Relevant results from the Initial Assessment Report[87] include:

- Key Finding: *Process documentation is incomplete – where documentation exists, outputs are not clearly laid out, resulting in substantial variation in interpretation of process instructions and therefore execution.*
- Key Finding: *Lack of a customer-focused, intrinsically motivated mindset constrains collaborative and efficient execution.*
- Root Cause (Culture and Mindset): *Inconsistent performance goals, SLAs, or enforcement of expectations undermines accountability throughout process.*
- Root Cause (Culture and Mindset): *Mindsets/behaviors don't support effective and collaborative execution of process.*

CONCLUSION

C4-1. Stakeholders overwhelmingly consider the hiring process to be inefficient and ineffective; improved communication and collaboration—in conjunction with process documentation, and guidance—is widely viewed as key to making improvements.

In interviews and focus groups, some participants expressed a lack of confidence in the abilities and knowledge of others involved in these HR processes. For example, some Center staff raised concerns that HR staff do not have a sufficient understanding of the technical needs of the Centers while some HR staff raised concerns that Center staff do not recognize that compliance with process regulations is essential, even though it can cause process delays. (see Supplement Exhibit S-24) This is further illustrated in Finding F3.3, in which survey responses show that hiring managers gave substantially lower ratings of satisfaction with the abilities of OTS and OHCM staff compared to other Center counterparts in HR roles. While these views are grounded in actual experiences, a sense of longstanding frustration has become a generalized assumption that the process challenges will continue despite improvement efforts. Perceptions such as these inhibit effective communication, collaboration, and accountability. The divergence of opinions across groups is evident throughout this report, in both qualitative themes and different patterns of qualitative responses (e.g., survey results).

[87] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.

FDA could make significant strides forward with its recruiting, hiring, and retention challenges by first investing in strategies that will delve into the root causes of these issues and then seek to build creative solutions. Building a more collaborative culture will enable FDA's HR staff to operate with greater teamwork, rooted in strong trust and respect, among the multiple HR service providers as well as the service recipients (hiring managers), all for the benefit of the ultimate customers (candidates, new hires, staff).

F4.1 Overall, the hiring process is seen as ineffective and inefficient, driven largely by complex and unclear process guidance, as well as inadequate collaboration and handoffs among the parties involved in the process.

Similar to findings in the Initial Assessment, the parties who play a role in the hiring process hold a strong conviction that the process is ineffective. Interview and focus group participants noted that challenges with communication and collaboration, as well as process guidance, accountability, and transparency exacerbate process inefficiency and ineffectiveness (see Supplement Exhibit S-31). Participants also pointed out that in the less common situations where parties from different groups collaborated well, the hiring process was much more effective (see Supplement Exhibit S-30 and Supplement Exhibit S-24).

FDA has made little progress in addressing the mindset and behaviors that contribute to hiring process ineffectiveness (see Exhibit 27). In some cases, participants attributed the challenges to shortcomings of other groups involved in the process. For example, CDER and CBER staff cited delays caused by errors and disagreements with OTS staff in how to interpret regulations, and OTS staff pointed to differences of opinion with hiring managers during PD development (e.g., appropriate grade or occupational series).

Exhibit 27: Initial and Interim Comparison—Progress in Culture and Mindset

INITIAL ASSESSMENT RESULTS[88]	INTERIM ASSESSMENT RESULTS	PROGRESS
Mindset and behavior do not support effective and collaborative execution of process: • There is strong mutual distrust between OHR and the Programs. • Often-cited issue is that OHR and HR staff[89] in OM do not do their jobs properly. There is consensus that HR staff fail to find solutions to hiring-related problems.	• Similar to Initial results, themes were expressed about HR staff (OTS/OHCM Staff) capability and errors and need for better collaboration (see Supplement Exhibit S-30). • 5-6% of CDER/CBER hiring managers are satisfied with OTS/OHCM staff's ability to provide options and alternate solutions (see Exhibit 22).	Little to no progress
• HR specialists[90] experience frustration with poor support from senior leadership. • 51% of HR specialists are satisfied with the current level of recognition and rewards they receive for quality work. • 55% of CDER/CBER hiring managers are dissatisfied with OHR servicing team's initiative to solve problems (17% satisfied).	• HR staff – including OTS Staff, OHCM Staff, CBER PMs, CDER AOs, CDER and CBER OM – report needing more direct engagement with OTS/OHCM and with the Center OMs (40% and 33%, respectively) (see Supplement Exhibit S-20). • 4-5% of CDER/CBER hiring managers are satisfied with OTS/OHCM staff's initiative to solve problems (see Exhibit 22).	Progress unclear - Indirect comparison

[88] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[89] Note: There is no definition in the Initial Assessment report to specify which HR roles are included in the term "HR staff."
[90] Note: "HR Specialist" is a subset of HR staff within the Agency's HR Organization (i.e., OTS and OHCM, formerly OHR) responsible for FDA recruiting, hiring, and retention.

INITIAL ASSESSMENT RESULTS[88]	INTERIM ASSESSMENT RESULTS	PROGRESS
• Hiring managers report that HR staff are not service oriented (due to low response times), and that HR staff are not competent (due to numerous inaccuracies and errors). • 37% of CDER/CBER hiring managers are satisfied with OHR servicing team's initiative to solve problems; 15% are satisfied that OHR servicing team meets timelines and commitments.	• HR process accuracy and error data not tracked. • 7-8% of CDER/CBER hiring managers are satisfied with OTS/OHCM accurate knowledge of HR policies and procedures; 5% are satisfied that OTS/OHCM meet timelines and commitments (see Exhibit 22). • Similar to Initial results, themes were expressed about HR competency gaps in communications and customer service (see Supplement Exhibit S-27).	Little to no progress
• Hiring managers focused on timely recruiting and retention of talent to do quality work; HR staff focused on avoiding inappropriate hires and following procedures. • HR staff perceive the hiring managers create bottlenecks and are not accountable for the same timeframes.	• Similar to Initial results, themes were expressed about role clarity, handoffs, and accountability (see Supplement Exhibit S-24). • 86% of CDER/CBER hiring managers report that OHR reorganization made little or no improvement in their overall satisfaction with recruiting, hiring, and retention processes (see Exhibit 19).	Little to no progress

In addition to their importance as a foundation for HR staff performance management (see Finding F3.2), clear and updated hiring processes and procedures are also critical to process efficiency and effectiveness. These resources enable all parties to perform their roles consistently, establish a shared understanding and accountability for the responsibilities of all parties, and carry out effective coordination and handoffs. The Initial Assessment noted that hiring process steps were not clearly documented and existing policies constrained process consistency and efficiency. Interim Assessment results show that FDA has made uneven progress in this area (see Exhibit 28).

Exhibit 28: Initial and Interim Comparison—Progress in Documenting Hiring Processes and Policies

INITIAL ASSESSMENT RESULTS[91]	INTERIM ASSESSMENT RESULTS	PROGRESS
Missing or incomplete documentation for 6 out of 8 process steps	Developed Hiring Pilot process documentation (see Section 2.2.1) Other Title 5 process documentation not updated	Some progress
24% of CDER AOs reported "no" or "unsure" about the existence of SOPs related to hiring process	21-53% of HR staff reported "disagree" or "strongly disagree" that processes and procedures are well documented (see Supplement Exhibit S-32)	Little to no progress
75% of CDER and CBER hiring managers would use a web page or centralized area with information on hiring processes and documented process guidance	CDER and CBER hiring managers reporting a need for more resources (see Supplement Exhibit S-20): • 57%: Web page or centralized area with information on conducting hiring process work • 73%: Documented process guidance	Little to no progress
A lack of clear interpretation guidelines exists for 6 out of 9 hiring-related processes and procedures	Interpretation guidelines for three of the six policies identified as having gaps were updated (see Supplement Exhibit S-33)	Some progress

3.5 Recruiting and Hiring Processes

This section focuses specifically on recruiting and hiring processes, including areas of strength and areas for improvement for each. In this assessment, recruiting and hiring processes were defined as follows:

[91] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.

- Recruiting processes: FDA's process of finding potential candidates who may be qualified to fill positions at the Agency and attracting qualified candidates to apply. The term outreach is also sometimes used to describe this process.
- Hiring processes: FDA's process of reviewing applications, selecting candidates to interview, interviewing candidates, making hiring decisions, and extending initial (or tentative) job offers. (This assessment focuses less on the steps that occur after the initial job offer (e.g., security review, final offer, enter on duty) because the timing of those activities is driven more by FDA's Office of Security Operations and the candidates themselves, rather than the HR workforce).

CONCLUSION

C5-1. FDA has been able to attract human drug and biologics review program staff; however, certain challenges (e.g., lack of a more targeted approach to recruiting, questions about the sufficiency of the HR recruiting staff's capabilities) impact the speed and quality of the process.

FDA is able to attract a large talent pool for the human drug and biologics review program and create a reasonably positive experience for most (albeit not all) of their new hires. However, CDER and CBER hiring managers and others involved in the process raise concerns with the lack of a recruiting strategy, the incomparability of benefits to attract top candidates, and other process-related challenges (e.g., poor communication and collaboration between OTS and the Centers; process delays, including extraneous process regulations; backlog of work) that lead to negative experiences with the overall recruiting process. Moreover, concerns with the HR staff's recruiting capabilities impact the recruiting process, particularly the roles, responsibilities, and handoffs among OTS, the Center's OMs, Program Staff, and hiring managers. Collectively, these experiences lead to generalized misgivings about the recruiting process that can hamper stakeholders' willingness to accept and participate in changes intended to improve recruiting effectiveness. Because FDA does not regularly track the productivity of recruiting efforts (e.g., numbers of applicants and hires generated) the Interim Assessment was unable to objectively determine recruiting outcomes.

F5.1 CDER and CBER attract large numbers of applicants determined to be qualified by OTS.

FDA makes use of flexibilities and incentives, as well as more traditional methods, to help recruit candidates to CDER and CBER. Examples of these recruiting tactics include flexible work arrangements, student loan repayment, and the authorities under the 21st Century Cures Act (see Finding F1.3 for more detail). FDA's certificate logs of vacancy announcements (VAs) in FY2018 and FY2019, combined, show that OTS referred a total of 31,537 qualified applicants to CDER for 1,555 VAs (average 27 referrals per VA) and 19,304 qualified applicants to CBER for 621 VAs (average 31 referrals per VA). The appointment authorities for these VAs are delegated examining (including DHA) and merit promotion. Out of these referrals, CDER made a total of 1,159 selections and CBER made a total of 258 selections. CDER made no selection for 221 VAs (12 percent), and CBER made no selection for 73 VAs (14 percent). Exhibit 29 presents CDER and CBER referrals, VAs, and selections for FY2018 and FY2019.

Exhibit 29: FDA Certificate Log—Number of Qualified and Selected Applications[92]

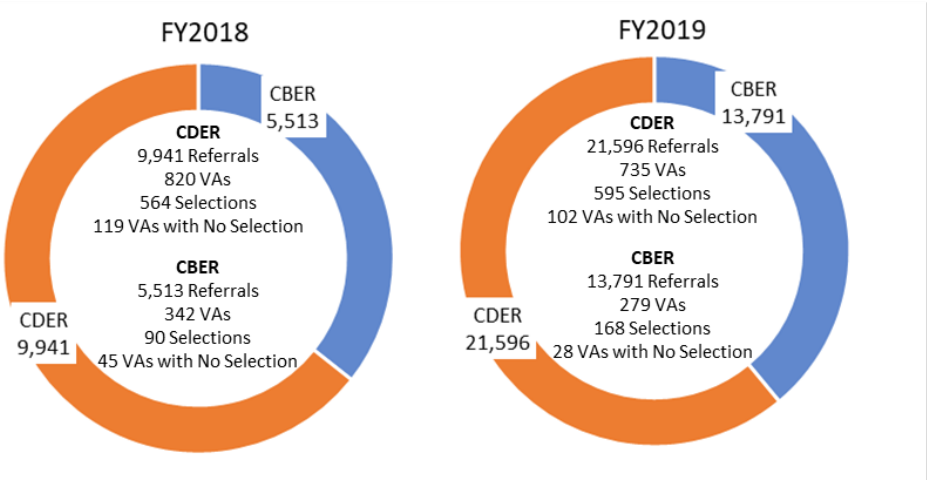


Exhibit 30 shows the occupational series from CDER and CBER vacancy announcements that generated the highest number of referrals in FY2018 and FY2019. Four out of the eight occupational series averaged at least 20 referrals per vacancy announcement. For most of these series, CDER and CBER made selections that were close to or exceeded the number of vacancy announcements (note that some vacancy announcements can be used for more than one selection, which can lead to situations where selection numbers exceed the number of vacancy announcements). However, for five series— Biologist, Health Scientist, Consumer Safety Officer, Operations Research Analyst, and Physician—there were fewer selections than the number of vacancy announcements. Note that, in addition to the selections reflected in this section, which represent delegated examining (including DHA) and merit promotion, FDA also uses other hiring authorities (e.g., Title 38 and Schedule A). For example, in FY2018 and FY2019, an additional 82 Physicians were hired using Title 38 and Schedule A.

Exhibit 30: FDA Certificate Logs—Scientific and Technical Series with the Most Referrals

OCCUPATIONAL SERIES	REFERRALS	VACANCY ANNOUNCEMENTS	AVERAGE REFERRALS PER VACANCY ANNOUNCEMENT	SELECTIONS
GS-1320 – Chemist	15,189	158	96	219
GS-0401 – Biologist	8,924	215	42	192
GS-0601 – Health Scientist	2,243	217	10	209
GS-0660 – Pharmacist	1,730	40	43	87
GS-0696 – Consumer Safety Officer	1,203	164	7	81
GS-1529 – Mathematical Statistician	853	43	20	62
GS-1515 – Operations Research Analyst	682	84	8	33
GP-0602 – Physician	317	33	10	11

F5.2 Despite the high numbers of applications, internal stakeholders view recruiting as ineffective, particularly noting the challenges of targeting the most suitable applicants based on candidate self-assessment on the application questionnaire and the minimum qualification standards.

Interview and focus group themes described several challenges with the recruiting process, such as the apparent lack of a strategic or targeted approach to recruiting, the amount of time and energy CDER and CBER hiring managers must invest to identify candidates, and difficulties finding suitable candidates using

[92] Source: FDA Certificate Log FY2017 to FY2019, USAStaffing.

non-specific qualification standards and the USAJOBS candidate self-assessment questionnaire (see Supplement Exhibit S-34). Specifically, hiring managers and HR staff in CDER and CBER stated that they must spend time on recruiting and outreach, especially for scientific and technical positions, because recruiting exclusively through the FDA's HR Organization does not yield many viable candidates with the appropriate specialized skills. For example, under the current process, candidates are required to complete a self-assessment related to their ability to perform the qualification requirements on the application questionnaire. Based on the self-assessment ratings (which often screen out all but the highest self-rated applicants), an HR Specialist conducts a qualifications review. Next, HR Specialists generate certificates of eligible candidates and provide the certificates to hiring managers. These certificates may include minimally qualified applicants who are perceived by hiring managers as unqualified for the job compared to others with specialized experience known to have applied but who have not been included on the certificate. The reasons for an otherwise-qualified applicant not being referred can vary based on many factors, such as Veterans' preference, application completeness, failure to submit required documentation, or providing modest, but realistic (i.e. non-inflated), answers to the self-assessment. In addition, a candidate's interpretation of standard position descriptions or self-assessment of their own qualifications may not align with the true technical requirements of CDER and CBER jobs (which should be determined by a legally defensible job analysis). These experiences, collectively, erode hiring manager confidence in recruiting process effectiveness and lead to longer process time and more effort required to identify more potentially qualified candidates eligible for selection.

In addition, focus groups with hiring managers, HR staff, and managers of HR staff show that there is no consensus on which positions are most challenging to recruit and warrant targeted recruitment approaches. Among the wide variety of hard-to-fill positions identified, participants mentioned medical and scientific positions including pharmacologists/toxicologists, pharmacists, chemists, and nurses most often (see Supplement Exhibit S-35). This also suggests that recruiting strategies are generally decentralized to the Office-level or even to individual hiring managers rather than addressed as a coordinated effort among OTS, OHCM, and the Centers.

New hires and hiring managers offer valuable perspectives from "both sides" of the recruiting experience. CDER/CBER Staff Survey responses show that both hiring managers and new hires consider employee referrals to be the most productive recruiting source (see Supplement Exhibit S-36). Out of the recruiting channels favored by SST, hiring managers consider professional events (e.g., conferences, career fairs, speaking engagements) to be the most productive. Interestingly, new hires do not consider professional events to be very productive for recruiting. Neither hiring managers nor new hires consider other SST activities (e.g., advertisements, social media, campus visits) to be very productive. However, perception of effectiveness may be impacted by familiarity or prior experience (positive or negative) in using certain recruiting channels.

Interview and focus group participants also expressed an opposing, but less common, observation that recruiting is generally effective, mainly because people want to work at FDA and there are useful recruiting channels already in place. On the other hand, CDER and CBER staff's open-ended survey feedback expressed that compensation, work flexibilities, and benefits at FDA are comparatively less attractive than competitors (e.g., private sector and academia), which is a challenge for recruiting (see Supplement Exhibit S-37).

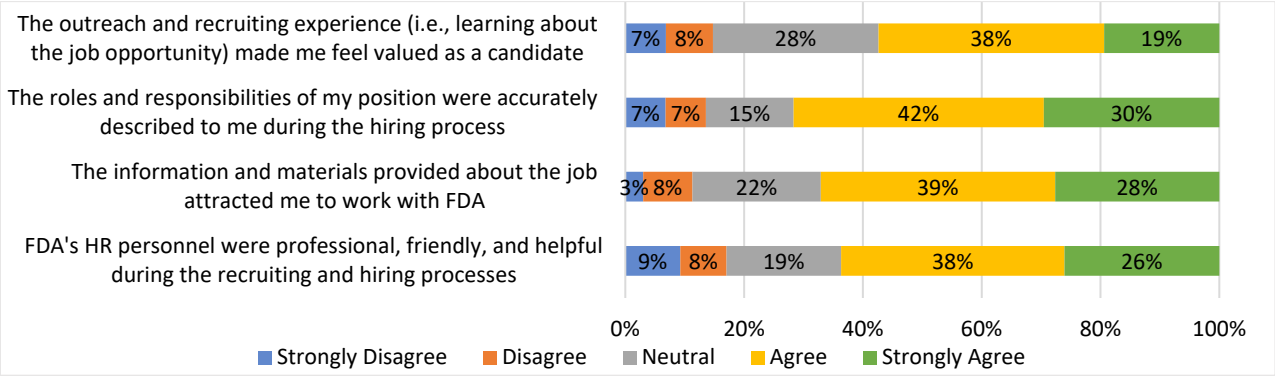
F5.3 According to new hires, candidates who accepted job offers and onboarded generally had a positive experience with FDA's recruiting process.

The majority of CDER and CBER new hires who responded to the CDER/CBER Staff Survey have a favorable view of the recruiting process as well as the HR workforce's recruiting capabilities. Throughout recruiting, new hires may interact with hiring managers and staff in different HR roles (e.g., Center PM and Administrative Officers [AO], Center OM staff, OTS, and OHCM); therefore, their survey feedback cannot be attributed to any specific group. It is also worth noting that these data represent the viewpoints of candidates who successfully completed the hiring process and were selected for the job. However, these

results may not be representative of all candidates' perspectives, including candidates who withdrew from the process due to dissatisfaction or other concerns.

Sixty-three percent of new hire survey respondents say that FDA's HR personnel were professional, friendly, and helpful during the recruiting and hiring process (see Exhibit 31). In addition, the majority of new hires agreed or strongly agreed that FDA's recruiting process provides key factors that contribute to a positive candidate experience, such as clarity of the position's roles and responsibilities (72 percent), information and materials about the job (67 percent), professionalism of HR staff (64 percent), and feeling valued as a candidate (57 percent). On the other hand, the fact that nearly one-fifth of new hires do not agree that the HR staff were professional, friendly, and helpful during the hiring process (17 percent disagree or strongly disagree) indicates that there is a core of dissatisfaction, even among more-positive new hires.

Exhibit 31: CDER/CBER Staff Survey: New Hires—New Hire Experience with Recruiting



Respondents: CDER and CBER new hires. Number of responses varies by question (n=404-420). A "Not Applicable" response option was also provided; those responses are not included in this analysis.

FDA's New Employee Onboarding Survey, completed by CDER and CBER new hires between FY2017 and FY2019, corroborated these findings.[93] Nearly 90 percent of survey participants responded positively about the clarity of the job announcement (Strongly Agree or Agree). Over 80 percent of respondents also had a positive impression (Strongly Agree or Agree) of the HR personnel, the information sent before their first day, and their point-of-contact before reporting to work (see Supplement Exhibit S-38).

CONCLUSION

C5-2. As one indicator of hiring effectiveness, FDA new hires are qualified and able to perform well in their positions; however, stakeholders consider process documentation to be a persistent challenge hindering the efficiency and effectiveness of hiring, especially classification.

Although hiring managers are satisfied with the quality of new hires, they consider the hiring process in general—beset by continuous process variation and limited guidance—to be stressful, time consuming, and ineffective. They want to receive high-quality hiring process support from HR teams, but do not have confidence that HR is able to provide that level of service. HR staff and managers of HR staff are similarly frustrated with process difficulties that impede effectiveness.

F5.4 In general, CDER and CBER new hires are qualified and able to perform well in their positions.

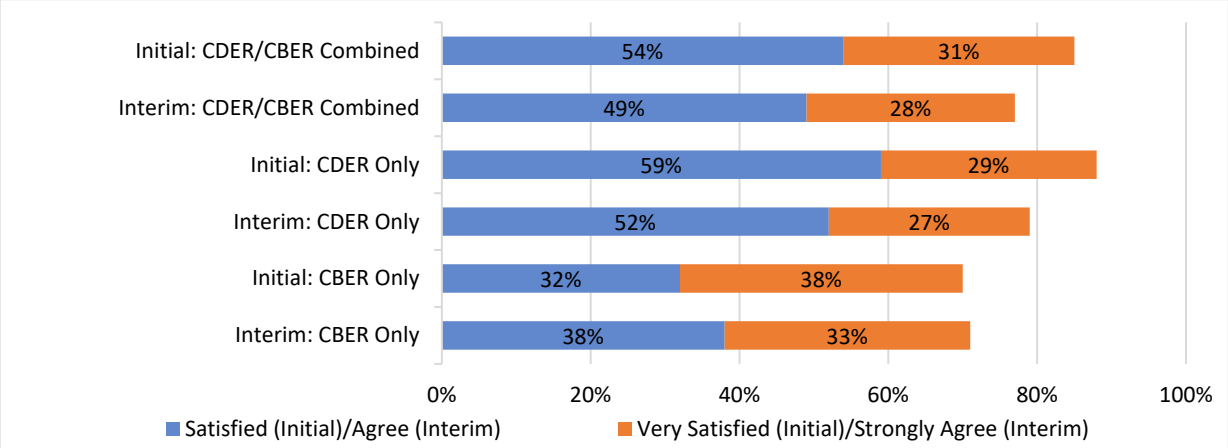
Despite challenges with identifying suitable applicants during the recruiting process (as discussed in Finding F5.2), hiring managers have a positive perception of the new hires that they ultimately select. CDER and CBER hiring managers responded to a similar question about new hires on the Initial Survey conducted as part of the 2017 Initial Assessment and the CDER/CBER Staff Survey conducted for the Interim Assessment.

[93] Source: FDA New Employee Onboarding (NEO) Survey 08.2017 to 11.2019 (responses vary by item; n=514-517).

This Interim analysis shows the percent positive responses (Agree and Strongly Agree) to compare with the Initial analysis (Satisfied and Very Satisfied). Results indicate that, overall, hiring manager perceptions of new hires remained consistently positive, but decreased slightly since the Initial Assessment. Also, CDER results were more positive than CBER results for both the Initial and Interim Assessments.

Exhibit 32 shows that in the Initial Assessment, 85 percent of CDER and CBER hiring managers combined reported a positive perception of new hire quality while, in the Interim Assessment, 77 percent of CDER and CBER hiring managers reported a positive perception of new hire skills. Responses from CDER hiring managers shows a similar pattern, with 88 percent reporting positive perceptions of new hires at the Initial Assessment, then dropping slightly to a total of 78 percent positive perceptions at the Interim Assessment. In contrast, fewer CBER hiring managers reported positive perceptions about new hires, and there was little change between Initial results (60 percent positive) and Interim results (61 percent positive).

Exhibit 32: Initial and Interim Surveys (CDER and CBER Hiring Managers)—Positive Perceptions of New Hires



- ***Initial***. *Respondents: Center hiring managers (total n=167; CDER n=133; CBER n=34). Survey item: "Of the vacancies you filled in FY2015 or FY2016, what is your level of satisfaction with the quality of hire?" Five-point response scale: Very Dissatisfied, Dissatisfied, Neutral, Satisfied, Very Satisfied.*
- ***Interim.*** *Respondents: Center hiring managers (n=292 total; n=244 CDER; n=48 CBER). Survey item: "Of the vacancies I have filled in the past 2 years, I feel the new hires have the skills needed to be effective on the job." Five-point response scale: Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree.*

Interview feedback also further supports this result and provides additional insight. Specifically, participants expressed that FDA consistently hires qualified candidates, despite challenges with the process. FDA's ability to hire quality candidates is due in part to hiring flexibilities such as Cures and DHA (see Supplement Exhibit S-4).

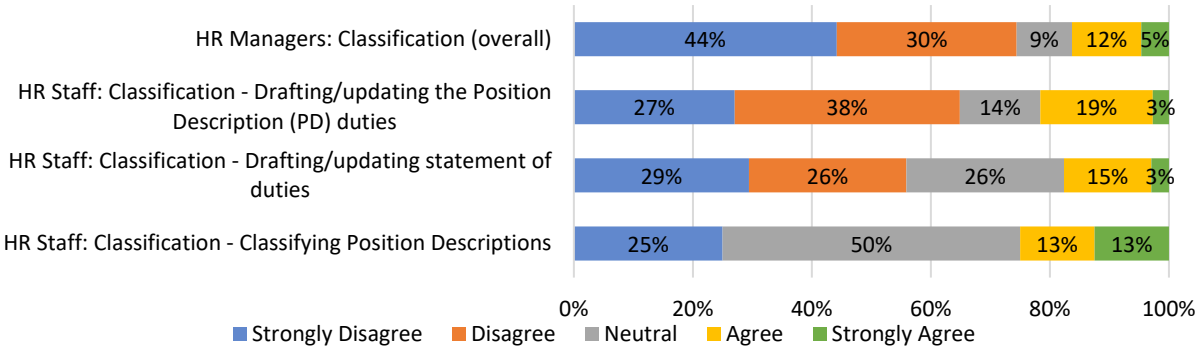
F5.5 The hiring process—particularly classification—is widely seen as ineffective and inefficient; suggestions for improving these challenges include greater transparency, common understanding of process requirements, and more collaborative problem-solving.

As discussed in Section 4.1, CDER and CBER Staff and HR stakeholders across all organizations almost universally acknowledge that the hiring process is inefficient and ineffective and that these challenges have existed for a long time. Survey results from HR staff and managers of HR staff shed more light on efficiency broken down into specific process steps. Over half of managers of HR staff reported that every major step of the hiring process takes too long, particularly classification (87 percent). The majority of HR staff reported that drafting and updating elements of the PD for classification takes too long (66 to 77 percent) (see Supplement Exhibits S-39 and S-40).

Furthermore, nearly three-fourths of managers of HR staff reported that handoffs are not effective during classification (74 percent disagree or strongly disagree) (see Exhibit 33). Responses from HR staff indicate

that handoffs are not effective during drafting and updating the PDs and the statement of duties (65 and 55 percent disagree or strongly disagree, respectively), but fewer HR staff express concerns about handoffs during the step of classifying PDs (25 percent strongly disagree).

Exhibit 33: HR Managers and HR Staff Survey—Effectiveness of Handoffs for Classification[94]



Respondents: HR Managers (n=49); HR Staff (number of responses for HR Staff varies by item; n=18-26). Survey Item: "There are effective process handoffs between the Office of Talent Solutions (OTS), Center Office of Management (OM, Center Offices, and hiring managers for:" A "Not Applicable" response option was also provided; those responses are not included in this analysis.

Interview and focus group participants expressed that challenges impeding the efficiency of classification are often related to differences of opinion between HR staff and hiring managers about details to be included in the hiring package, which are difficult to resolve because documentation of policies, processes, and procedures is unclear and inconsistent (see Supplement Exhibit S-41). For example, multiple rounds of iterations may occur when parties disagree about specific elements related to classification, such as grade level, required degree, position title, or description of job.

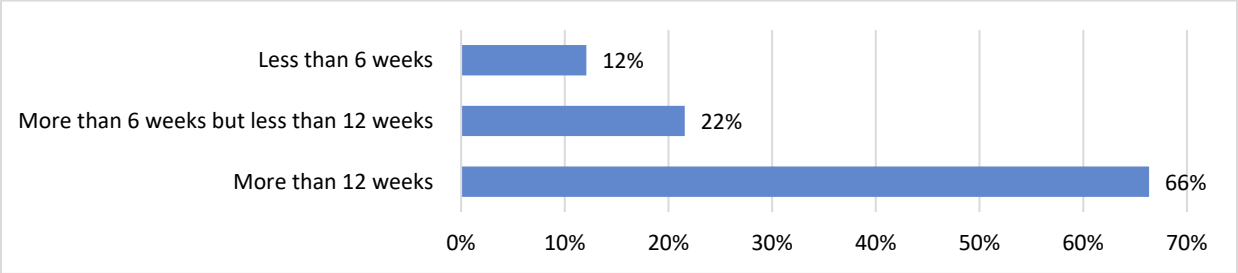
As an added complication, HHS and FDA established requirements for reclassification of PDs, which resulted in a large backlog of classification work. This backlog stresses the capacity of the current HR staff, which further impedes the efficiency of this process step (see Section 3.3 for more detail). Efforts are underway to improve classification, with the recent creation of a centralized and dedicated classification team—enabling FDA to maximize resources and improve the consistency and focused approach to candidate attraction and selection. An additional nine classification positions were approved to address the backlog and current classification actions in queue;[95] however, classification is still considered to be inefficient. This stage of the process notably requires a great deal of interaction, handoffs, and iterations across multiple stakeholders (e.g., hiring managers, CBER PMs, CDER AOs, CDER and CBER OM, and OTS) to share complex information, negotiate to reconcile any areas of disagreement, complete rework as needed to correct errors, and complete procedural actions for accuracy and compliance.

The result of ineffectiveness and inefficiencies is a lengthy process, which in turn has led to FDA missing OPM target timeframes for hiring CDER and CBER staff. OPM process guidelines state that agencies should extend a tentative job offer within 6 weeks after the application process begin.[96] Based on new hire responses to the CDER/CBER Staff Survey, FDA met that target for just 12 percent of CDER and CBER new hires. This is depicted in Exhibit 34, which shows the hiring process time from application through tentative offer for CDER and CBER new hires took more than 12 weeks for two-thirds of new hires in CDER and CBER to receive a tentative job offer. However, the delays did not seem to substantially diminish the experience of candidates going through the process. Based on responses to FDA's New Employee Onboarding Survey, approximately 60 percent of CDER and CBER new hires reported that the hiring timeframes are reasonable, and over 75 percent were satisfied with the hiring process overall. It is worth noting again that these data represent the

[94] Sources: HR Workforce Manager Survey.
[95] Source: STRS Hiring Pilot – SOP (Phase II), OTS; STRS Hiring Pilot Launch Presentation (Phase II), OTS.
[96] Source: Hiring Elements End-to-End Hiring Roadmap, OPM.

perceptual viewpoints of candidates who successfully completed the hiring process; these results are not representative of all candidates' perspectives, including candidates who were not selected for hire or may have withdrawn from the process due to process delays or dissatisfaction (see Supplement Exhibit S-38).

Exhibit 34: CDER/CBER Staff Survey (New Hires)—Results of Hiring Process Times[97]



Respondents: CDER and CBER new hires; n=422. Survey item: "Approximately how many weeks elapsed from when you started the hiring process with FDA (e.g., submitted your application, resume, or curriculum vitae to the time you received an initial [or tentative] job offer from FDA?" A "I Do Not Remember" response option was also provided; those responses are not included in this analysis. Note that all process steps prior to posting the Job Opportunity Announcement are included in these timeframes (e.g., job analysis, classification).

F5.6 Some inefficiencies, due to process changes enacted by OPM or HHS, generate confusion and exacerbate negative views about process efficiency.

In response to challenges with HR staff's performance regarding accuracy and consistency, as well as findings from the OPM audit, HHS and FDA clarified certain policies and procedures, including those related to DE and DHA, to improve quality and mitigate compliance risks. Specifically, as a result of the OPM audit, OPM and HHS enacted changes to policies and procedures for DE—to include establishing a centralized DEU and submitting all DE actions to HHS for review—to enable FDA to retain the hiring authority.

While these additional HHS reviews may increase overall quality and accuracy, Hiring Pilot processing data indicate that the handoffs by OTS, for additional review by HHS, lack visibility and have led to major delays.[98] Since the beginning of the Hiring Pilot, 37 DE positions processed were subject to a separate review by HHS, which effectively halted the progress on these actions. As of September 30, 2019, 42 percent were still being held in the first stage of the process while under review, and more than half of these cases (nine cases, 56 percent) had been delayed since being added to the pilot in 2018. DE review actions conducted by HHS happen outside of FDA's purview, therefore related workflow data were not tracked while in review. As a result, these actions were considered substantial outliers that inflated overall time-to-hire for the pilot based on extreme delays. This contributed to confusion and frustration regarding the efficiency of DE. Feedback from interviews and focus groups reflected stakeholder frustration and confusion related to these additional reviews and safeguards. Common perceptions are that the additional procedures are not clearly defined nor communicated to all parties involved in the process (see Supplement Exhibit S-6). DE actions were evaluated separately since they did not follow the prescribed streamlined process; therefore, Hiring Pilot analysis (shown later in Exhibit 37) was based mainly on merit-promotion actions.

In addition, Direct Hire is a streamlined method to hire under Title 5 that does not involve a competitive rating and ranking process, nor is Veterans' preference applied as is required with DE. For that reason, applicants for Direct Hire positions must be qualified, but they are not subject to the same level of application review as DE. For Direct Hire positions, FDA is required by OPM to post a public notice bulletin via USAJOBS that asserts FDA will be using DHA. OPM further requires FDA to have candidates apply through USAJOBS and answer qualification questions.[99] In the past, hiring managers had the option to informally receive resumes

[97] Source: CDER/CBER Staff Survey.
[98] Source: OPM Audit Remediation Activities 10.30.2019, OTS; STRS Hiring Pilot Data 09.2018 to 11.2019, Manual Reporting (SharePoint/Microsoft Excel).
[99] OPM Memorandum Direct Hire Authority October 2018, OTS.

from potential candidates and pass them to HR for manual screening; thus, staff familiar with the previous process may see the new process as introducing additional, less efficient, and unnecessary requirements. To help clarify the Direct Hire requirements and procedures, FDA established DHA 101 training. The training has been delivered to HR staff in OTS, but it has not yet been offered to CDER and CDER HR staff or hiring managers.[100]

CONCLUSION

C5-3. Based on limited data, some of which are tracked manually, FDA is realizing process efficiencies via the Hiring Pilot, other hiring and compensation flexibilities (e.g., expanded DHA, 21st Century Cures Act, and Title 38), and demonstrated use of shared certificates; however, not all of these approaches are broadly and consistently implemented or measured across CDER and CBER.

As a result of FDA's efforts to implement the Hiring Pilot and make use of available hiring authorities and flexibilities, FDA has achieved initial results and a greater understanding of how to gain efficiencies in the hiring process. To achieve greater impact, FDA needs to maintain and communicate clear and effective guidance (e.g., operating procedures, user training) to enable consistent and expanded usage of the processes to appreciate even more efficiencies in hiring human drug and biologics review program staff. In addition, the processes require reliable data tracking and transparency to pave the way for accurate performance monitoring and additional technology-enabled process efficiencies.

F5.7 The Hiring Pilot demonstrated success in reducing overall time-to-hire with the use of shared certificates and its streamlined process; however, numerous adjustments to the Hiring Pilot, as well as limited outcome data, have made it difficult to measure and assess its true level of effectiveness.

The Initial Assessment evaluated the hiring process against four elements: simplicity, standardization, efficiency, and demand management to establish baseline performance criteria and design a streamlined Hiring Pilot.[101] The Hiring Pilot then designed five new performance criteria based on gaps identified in the Initial Assessment: process timeliness, customer service, employee satisfaction, outcome quality, and process accuracy.[102] While FDA created measures for all five core metrics, data were not available to measure, except for process timeliness. As a result, comparisons between hiring process criteria from the Initial Assessment and Interim Assessment (i.e., Hiring Pilot) cannot be objectively made.

- ***Process Timeliness***: While the number of positions recorded since the start of the pilot (15 months of hiring data) should provide ample data for a comprehensive assessment, some data points are incomplete or inconsistent, limiting the available outcome data to validate the pilot's impact and success. As of end of FY2019, 181 positions completed the hiring process through the Hiring Pilot.[103] Fifty-one of those positions were excluded from analysis due to their being exceptions to the process guidelines (e.g., delegated examining positions that were subject to extraneous HHS process steps). [104] This resulted in a total of 130 hiring actions used in the Hiring Pilot process timeliness analysis. Moreover, within the 130 hiring actions, incomplete data (i.e., timestamps of process stages) resulted in a varying number of data points eligible for analysis of end-to-end timeframes and each process stage.
- ***Customer Service***: A Hiring Pilot Customer Survey in April 2019 resulted in a 4.23 out of 5 average satisfaction score based on 12 responses received out of 28 new hires who were sent the survey (42.8 percent).[105] Hiring Manager interviews were also conducted at the end of Phase 1 (March 2019) via

[100] Source: Meeting Minutes from Discussion with OTS Director 12.16.2019, OTS.
[101] Source: Initial Assessment of FDA Hiring and Retention 11.2017, OTS.
[102] Source: STRS Hiring Pilot Launch Presentation (Phase II), OTS.
[103] Note: An additional 41 positions were in-progress as part of the Hiring Pilot at the end of FY2019.
[104] Source: STRS Hiring Pilot Data 09.2018 to 11.2019, Manual Reporting (SharePoint/Microsoft Excel).
[105] Source: STRS Hiring Pilot Customer Survey Raw Data_4.1.2019, Manual Reporting (Qualtrics).

phone calls, and qualitative information was captured as part of a Phase 1 evaluation, resulting in a new service model for Phase 2 of the Pilot (see Supplement Exhibit S-42).

- ***Employee Satisfaction***: A December 2018 Hiring Pilot Satisfaction Survey sent to 26 STRS Hiring Pilot staff had a 100 percent response rate in which 65 percent indicated they were 'Extremely Satisfied' and 27 percent indicated they were 'Somewhat Satisfied.'[106]
- ***Outcome Quality***: No outcome data are currently available.
- ***Process Accuracy***: No outcome data are currently available.

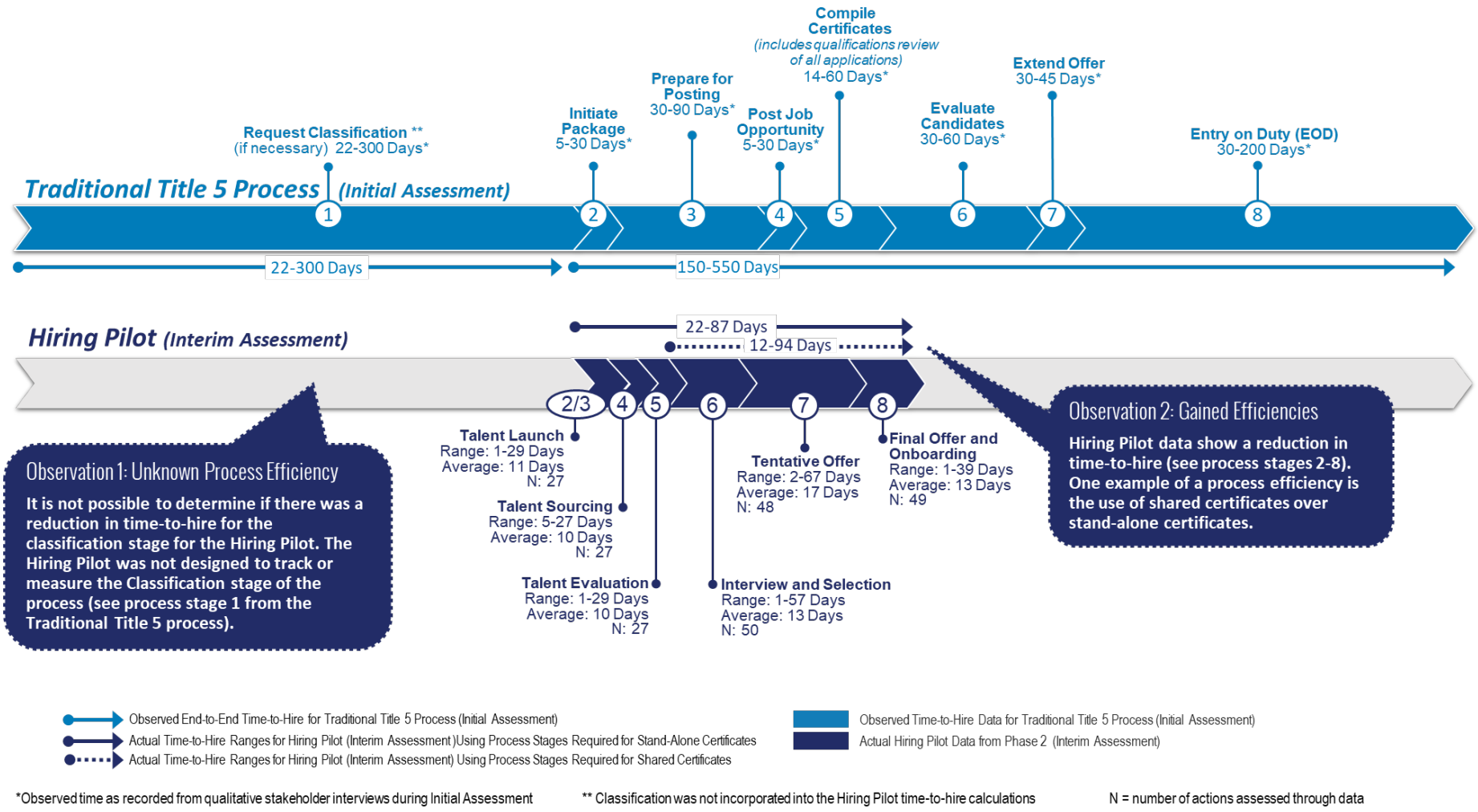
To evaluate process efficiency, the Initial Assessment established timeframe baselines for each Title 5 process step. To reiterate, these timeframes were derived from observed time-to-hire timeframes captured from stakeholder interviews due to limited data availability at the time; no time-to-hire durations were derived from more objective metrics during the Initial Assessment.[107] As a result, only minimum and maximum ranges were provided as initial processing timeframes to use as a basis for comparison. As an additional factor, in the Initial Assessment there is no delineation between MP and DE positions. For the Interim Assessment, the OPM audit resulted in HHS conducting an additional review of all DE hires, which impacted time-to-hire metrics with factors outside of the control of Hiring Pilot HR staff. Therefore, the DE hiring actions were not included in the analysis of Hiring Pilot timeframes. These data issues presented a substantial limitation in comparing time metrics from the Initial Assessment to the Interim Assessment that must be taken into consideration when reviewing results. Accordingly, results are not conclusive about whether expanding the scope of the parameters of the Hiring Pilot would impact process efficiency.

As depicted in Exhibit 35, the Initial Assessment reported that the traditional Title 5 process was associated with a total timeline of 150-550 days, with an additional 22-300 days if classification is required. Following the Initial Assessment, the Hiring Pilot was implemented, which included a redesign of the hiring process and revision of some process steps. To note, classification remains a stage of the streamlined Hiring Pilot process (as applicable); however, it is not possible to determine if there was a reduction in time-to-hire for the classification stage for the Hiring Pilot because the Hiring Pilot was not designed to track or measure the classification stage of the process.

Out of the original 181 Hiring Pilot positions manually tracked by OTS, 130 (72 percent) had start and end-date data to analyze overall time-to-hire. However, once the data were analyzed further against different measures (e.g., Phase 1 versus Phase 2 time-to-hire goals, shared certificates versus stand-alone certificates), many of these positions were missing time stamps by process stage that would provide data points available for analysis. Moreover, incomplete data resulted in a varying number of actions available to assess per process stage. Given these limitations of the analyses, the reader should interpret these findings with caution.

[106] Source: STRS Hiring Pilot Satisfaction Survey Results 12.11.2018, OTS.
[107] Source: Revamping the Hiring Process 09.15.2017, OTS.

Exhibit 35: Time-to-Hire Comparison of Traditional Title 5 Process Versus Hiring Pilot



*Observed time as recorded from qualitative stakeholder interviews during Initial Assessment

** Classification was not incorporated into the Hiring Pilot time-to-hire calculations

N = number of actions assessed through data

In terms of process efficiencies, the use of shared certificates (a method that permits interview selections to be made from a certificate of eligible candidates from another requisition of the same position type) allows the first three Hiring Pilot process stages—Talent Launch, Talent Sourcing, and Talent Evaluation—to be skipped. Hiring Pilot results indicate time savings are achievable through the use of shared certificates as shown in Exhibit 36. The use of shared certificates in the Hiring Pilot saved between 15 and 53 days in end-to-end time-to-hire. On average, overall time-to-hire (from Hiring Package Initiation to Entrance on Duty [EOD]) was over 60 percent faster for positions with shared certificates than with standalone certificates. In addition, average time-to-hire (from Hiring Package Initiation to tentative offer) was reduced by approximately 40 percent using shared certificates over standalone certificates. However, these results are also illustrative of challenges with the Hiring Pilot (e.g., shifting goals leading to changes in the percentage of time the goal is met).

Exhibit 36: FDA Hiring Pilot Data—Average Time-to-Hire[108, 109]

PHASE 1				
Certificate Type	*Start to Tentative Offer (52-82 Days)*		*Start to EOD (80-140 Days)*	
	Average Days	**% Goal Met**	**Average Days**	**% Goal Met**
Stand-Alone Certificates	64	36%	85	41%
Shared Certificates	32	85%	43	86%

PHASE 2				
Certificate Type	*Start to Tentative Offer (69-77 Days)*		*Start to EOD (84-95 Days)*	
	Average Days	**% Goal Met**	**Average Days**	**% Goal Met**
Stand-Alone Certificates	34	100%	56	100%
Shared Certificates	15	100%	41	100%

Note: Phase 1 Start to Tentative Offer (Stand-Alone Certificates n=33, Shared Certificates n=27); Phase 1 Start to EOD (Stand-Alone Certificates n=32, Shared Certificates n=29); Phase 2 Start to Tentative Offer (Stand-Alone Certificates n=25, Shared Certificates n=26); Phase 2 Start to EOD (Stand-Alone Certificates n=23, Shared Certificates n=26). Please note that incomplete data resulted in a varying number of actions available to assess per process stage and therefore do not equate to the 181 total hiring actions completed by the Hiring Pilot.

Although there has been positive feedback regarding the pilot's efficiency, there is still room for improvement. The changes to and limited communication around decisions about which Offices, positions, steps in the process, and HR resources would be included in the Hiring Pilot, as well as changes to procedures and goals, has created confusion among employees. These factors have also contributed to the difficulty in measuring the Hiring Pilot's success. Furthermore, the classification step continues to be detached from the rest of the hiring process and time-to-fill metrics, yet this is a time-consuming task that must still occur and continues to be raised as a point of contention (see Supplement Exhibit S-41).

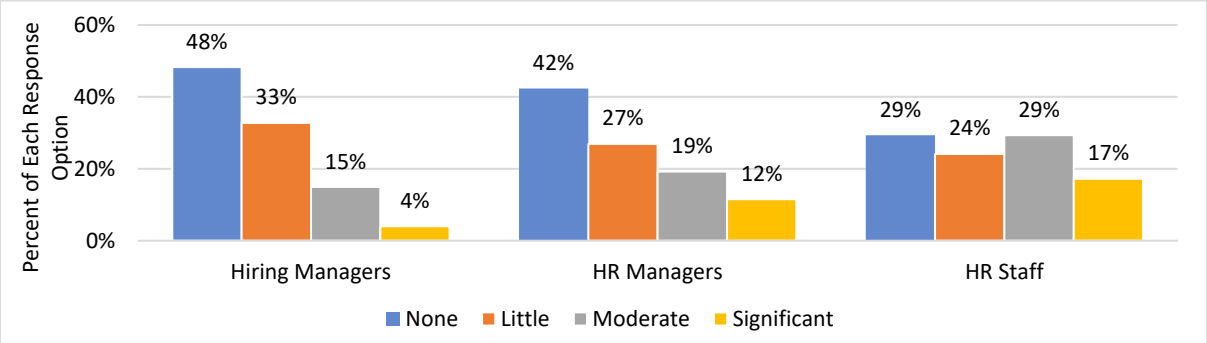
As Exhibit 36 depicts, the Hiring Pilot tracks data from the full end-to-end process (Hiring Package Initiation to EOD—not including classification) to ensure proper data collection, but also separately tracks data from Hiring Package Initiation to Tentative Offer because those are the stages of the process handled by HR and within their control. Additional factors (e.g., a delayed start date requested by the new hire) and stakeholders involved in post-tentative offer activities (e.g., security clearances, onboarding) influence the range of days it may take for the latter stages of the process and impact the total end-to-end hiring timeframe.

Perceptions (from both pilot and non-pilot participants) about the Hiring Pilot are mixed. Feedback captured in interviews and focus groups (from hiring managers, HR staff, and managers of HR staff) show that pilot participants report the pilot as being faster than other hiring processes, which they considered to be inefficient. However, some participants also stated that the Hiring Pilot's effectiveness is unclear due to the limited positions and offices included (see Supplement Exhibit S-43).

[108] Source: STRS Hiring Pilot Data 09.2018 to 11.2019, Manual Reporting (SharePoint/Microsoft Excel).
[109] Note: Calculations based on limited dataset.

Conversely, survey results show opinions about the degree to which the Hiring Pilot and ATLAS impacted overall satisfaction with recruiting, hiring, and retention are largely negative, but opinions vary by group (see Exhibit 37). The majority of Center Hiring Managers, managers of HR staff, and HR staff reported little or no improvement (81, 69, and 53 percent, respectively), with more positive responses among HR staff and managers of HR staff.

Exhibit 37: Interim Surveys (All Respondents)—Improved Overall Satisfaction with Recruiting and Hiring Due to the Hiring Pilot and ATLAS System[110]



Respondents: HR Managers (n=48); HR Staff (n=91); Center (CDER and CBER Hiring Managers only; n=332). Respondents include both Hiring Pilot participants and non-participants. Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to the Hiring Pilot (including ATLAS), in terms of your overall satisfaction?" A "Don't Know" response option was also provided; those responses are not included in this analysis.

F5.8 The Hiring Pilot has reduced the time for some hiring steps through its streamlined process but has not consistently maintained these efficiency gains.

Although the ATLAS system is designed to track dates of the hiring workflow, the timeframe for hiring actions to be included in the Interim Assessment predates ATLAS. Therefore, the data used to assess time-to-hire for the Hiring Pilot (e.g., dates each process step was initiated) were manually entered into a SharePoint system (see Finding F2.2 for more detail about ATLAS). On average, manually-tracked data reported by the Hiring Pilot indicates some efficiencies gained through its streamlined process and through the use of shared certificates (see Supplement Exhibit S-42). However, data also indicate that these efficiencies are not sustained regularly across the full slate of hiring actions (e.g., goals not consistently met). Exhibit 38 shows FDA's progress in each stage of the pilot process against its goal (during both phases of implementation and both with and without shared certificates) and highlights areas of the process that fail to meet the efficiency goal of at least 70 percent of the time.[111] The analysis of each step of the Hiring Pilot is based on varying numbers of actions due to incomplete data. FDA's challenges with data management, in this case, limited the identification of patterns regarding steps across occupations, center offices, and appointment types.

[110] Source: HR Workforce Manager Survey.
[111] Note: Calculations based on limited dataset.

Exhibit 38: FDA Hiring Pilot Data—Phase 1 versus Phase 2 Progress per Stage[112]

Stand Alone Certificates

		Talent Launch	Talent Sourcing	Talent Evaluation	Interview & Selection	Tentative Offer	Final Offer
Phase 1	N	44	**44**	**42**	**31**	**33**	33
	Goal (# of Days)	5-15	**5-10**	**15-20**	**25-30**	**10-15**	20-50
	Average (# of Days)	13	**11**	**24**	**36**	**11**	14
	% Goal Met	84%	**41%**	**69%**	**48%**	**58%**	97%
Phase 2	N	**27**	27	27	**25**	23	**23**
	Goal (# of Days)	**10-11**	10.5	13-15	**25-26**	13-18	**12-14**
	Average (# of Days)	**11**	10	10	**12**	12	**13**
	% Goal Met	**59%**	74%	96%	**68%**	87%	**61%**

Shared Certificates

		Talent Launch	Talent Sourcing	Talent Evaluation	Interview & Selection	Tentative Offer	Final Offer
Phase 1	N	N/A			28	**26**	21
	Goal (# of Days)				25-30	**10-15**	20-50
	Average (# of Days)				13	**25**	25
	% Goal Met				93%	**50%**	90%
Phase 2	N	N/A			25	**25**	24
	Goal (# of Days)				25-26	**13-18**	12-14
	Average (# of Days)				13	**21**	13
	% Goal Met				80%	**52%**	71%

N = number of actions assessed through data

F5.9 DHA is considered one of the more efficient flexibilities for hiring, especially compared to the traditional Title 5 hiring process.

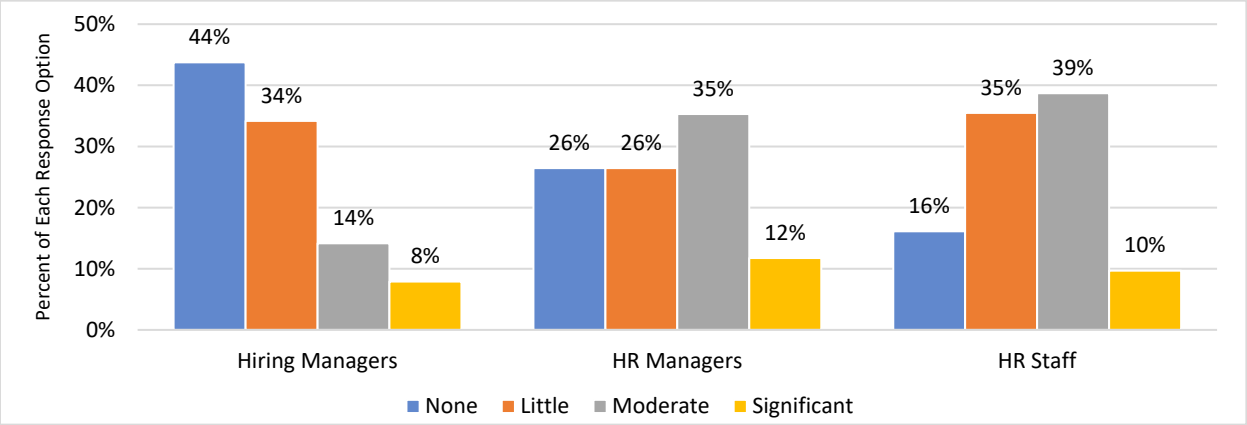
According to survey results, HR staff and managers of HR staff hold generally moderate views about the expanded DHA as a whole. With regards to SOPs, only a small fraction of managers of HR staff say there are sufficient SOPs and whether they are consistently followed (5 percent and 3 percent agree or strongly agree, respectively). On the other hand, HR staff survey results are mixed, generating both positive and negative responses about whether there are sufficient DHA SOPs and whether they are consistently followed (32 and 29 percent agree or strongly agree, and 29 and 27 percent disagree or strongly disagree, respectively). The majority of HR staff say they understand DHA and have used it effectively (59 and 56 percent, respectively). In contrast, only 13 percent of managers of HR staff say they have been able to effectively use DHA (see Supplement Exhibit S-44). [113]

However, despite those challenges, as well as the process confusion and inefficiencies discussed in Finding F5.7, DHA is seen as an efficient option for hiring. For example, interview and focus group participants provided positive feedback regarding the efficiency and effectiveness of DHA and its expansion to include additional occupations (see Supplement Exhibit S-5).

[112] Source: STRS Hiring Pilot Data 09.2018 to 11.2019, Manual Reporting (SharePoint/Microsoft Excel).
[113] Note: Managers of HR Staff (n=50-51); HR Staff Survey (n=116-118) "Please indicate your agreement with the following statements about FDA's DHA." A "Not Applicable" response option was also provided; those responses are not included in this analysis.

Opinions differ among hiring managers and the HR groups (managers of HR staff and HR staff) about the degree to which the expanded DHA positions impacted recruiting, hiring, and retention (see Exhibit 39). Based on the modal (most common) responses, Center hiring managers noted no improvements (44 percent), whereas managers of HR staff and HR staff noted moderate improvement (35 and 39 percent, respectively). These results show that those who provide HR services see more potential for positive impact from using DHA than the service recipients (Hiring Managers).

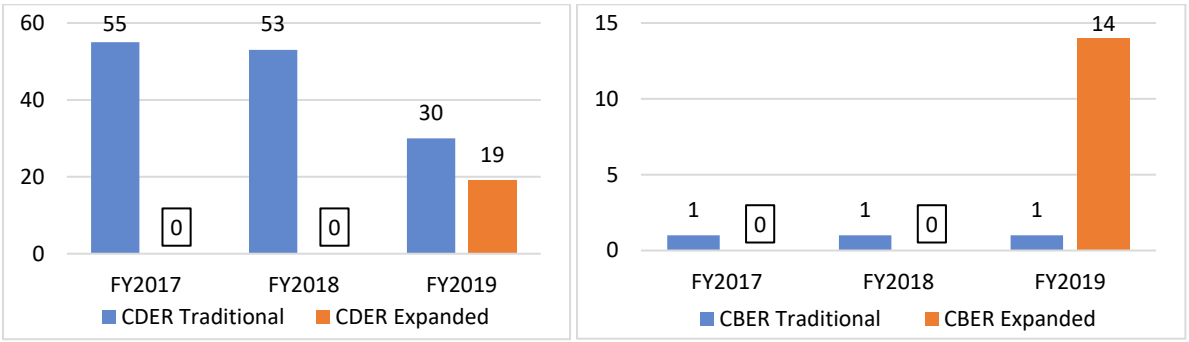
Exhibit 39: Interim Surveys (All Respondents)—Improved Overall Satisfaction with Recruiting and Hiring Due to Expanded DHA[114]



Respondents: HR Managers (n=46); HR Staff (n=91); Center (CDER and CBER Hiring Managers only; n=339). Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to DHA, in terms of your overall satisfaction with the recruiting and hiring processes?" A "Don't Know" response option was also provided; those responses are not included in this analysis.

Both CDER and CBER used DHA for both external hires and internal transfers. CDER's use of DHA decreased by 8 percent from FY2018 to FY2019, with 39 percent of its FY2019 hires falling within the expanded positions (19 out of 49 hires) (see Exhibit 40). CBER's increased use of DHA was directly associated with the expansion of the authority (14 hires under the expanded positions; one hire under the traditional DHA positions). However, because hiring numbers for DHA are low compared to the overall Center gains, DHA remains a low contributor of overall hires for either Center (12 percent of total CDER hires in FY2019 and 12 percent of total CBER hires in FY2019).

Exhibit 40: FDA DHA Data—Count of Hires Using Traditional Versus Expanded DHA[115]



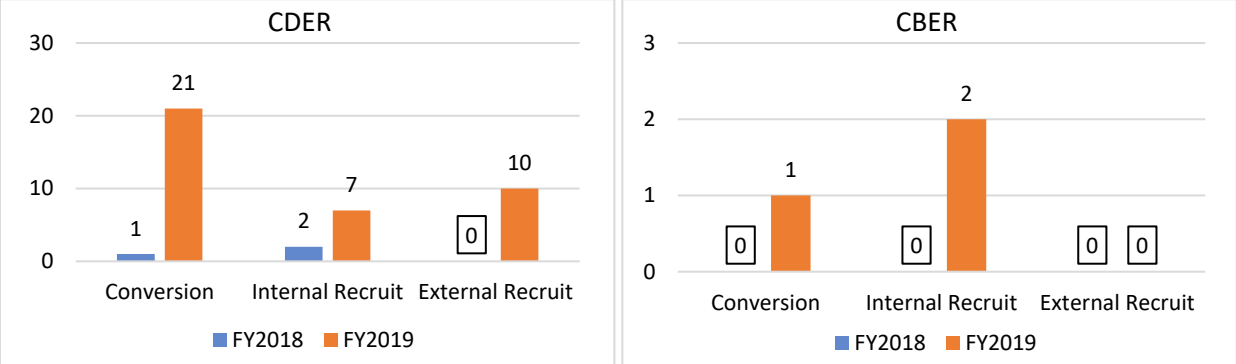
[114] Sources: HR Workforce Manager Survey, HR Workforce Staff Survey, CDER/CBER Staff Survey.
[115] Source: CBER-CDER Direct Hires from 10.01.2016 – 09.30.2019, EHCM.

F5.10 Cures' streamlined hiring process allows FDA to hire external talent more quickly, and stakeholders see a need for enhanced training and guidance to ensure its consistent implementation across the Agency.

The Cures process functions like that of DHA, allowing FDA to bypass elements of the conventional hiring process (e.g., delegated examining). Although the Cures Act was enacted by Congress on December 13, 2016, more than three years later FDA procedures and guidelines are still pending completion.[116]

In FY2019, CDER's use of Cures increased, but CBER has not yet consistently used Cures (see Exhibit 41). CBER's use of Cures has been particularly limited, totaling just six instances, most of which were internal conversions. CDER's total use of Cures (a total of 41 actions in FY2018 and FY2019) has been dominated by internal conversions and internal recruits (methods that are allowed as retention strategies); only a small percentage have been used to hire external recruits. Because hiring numbers for these flexibilities are low compared to the overall Center gains, they have not made a substantial impact on the growth of CDER and CBER's workforce (only 9 percent and 2 percent of overall hires in FY2019, respectively).

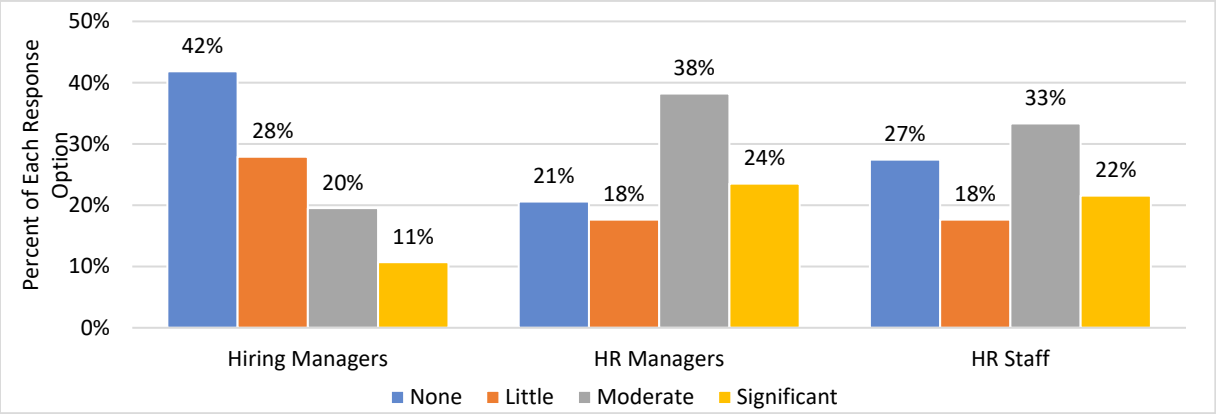
Exhibit 41: FDA Cures Act Data—Number of 21st Century Cures Act Hires[117]



Regarding the extent to which using Cures for hiring can improve overall satisfaction with FDA's recruiting, hiring, and retention functions, hiring managers expressed markedly different views than managers of HR staff and HR staff. The majority of hiring managers (71 percent) report that the use of Cures Act hiring authorities has made little to no improvement with their overall satisfaction with FDA's recruiting and hiring processes (Exhibit 42). Conversely, the majority of HR staff and their managers (55 and 62 percent, respectively) rated Cures Act hiring authority as having made moderate to significant improvements to the recruiting and hiring process. These patterns of responses indicate that HR professionals are more optimistic about Cures than hiring managers. Furthermore, these differences highlight the need to explore further what is behind the hiring managers' negative reactions.

[116] Source: 21st Century Cures Act Legislation, OTS.
[117] Source: Cures Act FDA Hires Report FY2018 and FY2019, Manual Reporting.

Exhibit 42: Interim Surveys (All Respondents)—Improved Overall Satisfaction with Recruiting and Hiring Due to 21st Century Cures Act[118]



Respondents: HR Staff (n=90); HR Managers (n=47); Center (CDER and CBER Hiring Managers only; n=337). Survey item: "How much improvement have you seen in FDA's recruiting and hiring processes due to use of special hiring authorities through the 21st Century Cures Act below, in terms of timeliness, accuracy, quality, and your overall satisfaction?" A "Don't Know" response option was also provided; those responses are not included in this analysis.

Although survey responses from managers of HR staff and HR staff were relatively positive about improvements made due to 21st Century Cures Act, only one-fourth or less of managers of HR staff and HR staff have been able to effectively use this flexibility (16 and 27 percent, respectively). No managers of HR staff agree that there are sufficient SOPs or that the SOPs are consistently followed. On the other hand, HR staff results are more favorable. About one-third of HR staff report that they understand how to use the 21st Century Cures Act and that there are sufficient SOPs (37 percent agree or strongly agree on both items). However, only 13 percent of HR staff agree or strongly agree that the SOPs are consistently followed (see Supplement Exhibit S-45).

Consistent with these survey findings, interview and focus group participants indicated that, while the Cures Act flexibilities have been beneficial, its effectiveness has been limited due to the lack of guidance and inconsistent application. Interview and focus group participants highlighted that inadequate guidance and inconsistent implementation have led to *perceptions* of "staff poaching" between Centers; however, gains and losses data did not show any inter-center movement for Cures appointments.[119] Feedback also indicated an appetite for additional training on FDA policy and procedures for Cures (see Supplement Exhibit S-46).

F5.11 Title 38 is an effective option for CDER and CBER to attract and hire physicians and dentists by offering competitive salary comparable to industry.

Title 38 Physician and Dentist Pay provides special pay and career advancement opportunities for physicians and dentists. During the selection and hiring process, FDA sets pay based on specialty, related experience and training, and supervisory status. CDER and CBER used this authority consistently from FY2017 to FY2019, yielding 70 to 79 CDER new hires per year and 7 to 19 CBER new hires per year (see Exhibit 43).

Exhibit 43: FDA Title 38 Data—Title 38 Hires in CDER and CBER[120]

FISCAL YEAR	CDER HIRES	PERCENT OF TOTAL CDER HIRES	CBER HIRES	PERCENT OF TOTAL CBER HIRES	TOTAL TITLE 38 HIRES
FY2017	77	16%	7	8%	**84**
FY2018	79	17%	19	17%	**98**
FY2019	70	17%	10	8%	**80**

[118] Sources: HR Workforce Staff Survey, HR Workforce Manager Survey, CDER/CBER Staff Survey.
[119] Source: Cures Act FDA Hires Report FY2018 and FY2019, Manual Reporting (OTS).
[120] Source: FDA Title 38 Hiring FY2017 to FY2019, Manual Reporting (OTS).

4. RECOMMENDATIONS

The assessment team provides FDA with recommendations aimed to transform how the Agency recruits, hires, and retains human drug and biologics review program staff. The recommendations are organized into the following sections:

- Strategy
- Data Management and Systems
- HR Staff Capability and Capacity
- Culture, Collaboration, and Communication
- Recruiting and Hiring Processes

These recommendations present data-driven ideas for continuing progress with the five improvement activities that were initiated following the Initial Assessment as well as other ideas that generated based on this Interim Assessment's findings and conclusions. The reader is also urged to consider that, while recommendations are presented singularly, FDA will likely achieve the greatest progress by recognizing the interconnectedness across these recommendations. Finally, in conjunction with addressing these recommendations, FDA should overlay a strong change management strategy to support the workforce through any change processes.

4.1 Strategy

R-1. Assess the strategic alignments among recruiting, hiring, and retention to identify and leverage their linkages with each other and across the talent management life cycle.

FDA should adopt a strategic, systems-thinking approach to talent management—which emphasizes the linkages across HR functions such as (but not limited to) recruiting, hiring, and retention—for the human drug and biologics review program staff. A systems-thinking approach recognizes the interrelatedness among system components and considers how changes to one component can impact other components as well as the overall system. FDA should engage stakeholders from across FDA, including hiring managers and talent management subject matter experts (SME), to determine how to better integrate these functions so that they best meet customer needs, to aid in identification of touchpoints across functions, confirm that decision rights are clearly defined, and to more fully describe expectations for inputs and outputs. FDA should also stand up an advisory group comprised of HR and Center leaders to provide overall direction, enable ongoing coordination and integration across talent management processes, and identify and resolve any cross-cutting issues that impact multiple talent management processes. Finally, FDA should enact a change management plan and awareness campaign to convey this movement toward a more integrated talent management approach, and with the intention that it will provide more customer-focused, more consistent, and higher quality service delivery.

R-2. Develop and implement an integrated human capital strategic plan that focuses on enterprise-wide, time-bound goals and actionable steps for achieving them.

Building on the strategic alignments uncovered in the previous recommendation (R-1), FDA should use a systematic, data-driven approach to build an integrated human capital strategic plan. The integrated plan should document goals and action steps for improving the efficiency and effectiveness of recruiting, hiring, and retention across the human drug and biologics review program staff (and even across FDA overall). FDA should employ a systematic approach (e.g., an analysis of strengths, weaknesses, opportunities, and threats) to capture the information needed to develop the plan. The analysis may surface internal best practices that can be leveraged and/or information on how the priorities of one Center may impact other Centers. FDA should also establish an implementation plan and infrastructure (e.g., tracking and reporting mechanisms) to

drive accountability toward meeting each goal. In addition, FDA should revisit the integrated plan on an annual basis to gauge impact and make revisions, as needed.

R-3. Integrate CDER's and CBER's hiring targets into a unified strategic hiring plan for the human drug and biologics review program staff to prioritize recruiting efforts.

CDER and CBER, supported by OTS, should examine their current approaches for creating hiring plans for the human drug and biologics review program staff. FDA should then create a unified, strategic approach and cadence for regularly analyzing and acting upon hiring data to gauge progress, prioritize, and re-vector its hiring activities, as needed. This review may include a close look at hiring targets and hiring outcomes, predicted and actual attrition, and skill gaps, as just a few examples. It would also be helpful to build the unified strategic hiring plan in conjunction with retention program and succession management program efforts.

4.2 Data Management and Systems

R-4. Put more uniformity and structure into data management and reporting practices for recruiting, hiring, and retention data.

FDA should put in place more uniformity and structure (such as through shared data dictionaries, common nomenclature, and data management protocols) to improve data integrity, access to data, and the confidence others have in data to drive business decisions. FDA should convene a group of individuals who have direct experience with managing recruiting and hiring data. This group should identify existing best practices that could be replicated, identify any significant gaps, and prioritize what data management practices should be addressed first. The group should establish a formal plan for creating, vetting, finalizing, and communicating the data management practices.

In addition, FDA should stand up an HR Data Management Board that meets quarterly to oversee decisions on how data are managed and to adjudicate outstanding issues. Along with establishing and enacting strong data management practices, it will be important to monitor and update these practices so that they continue to be beneficial across the organization. This HR Data Management Board (comprised of OC/OO, Center, OTS, and OHCM leaders with direct involvement in HR data management) should hold formal responsibility for overseeing how recruiting and hiring data are managed. The Board should meet quarterly to address issues, determine needed changes, and celebrate successes. By having a formal forum for these discussions, data management issues can get addressed early on, before they escalate into bigger challenges.

R-5. Compile an inventory and develop a map showing the linkages across major HRIS technologies used for recruiting, hiring, and retention for CDER and CBER.

FDA should create an inventory of the web of disparate HRIS technologies that it currently operates for recruiting, hiring, and retention within CDER and CBER with a specific focus on the linkages among these technologies. This review may include technologies that are OPM-mandated, FDA-wide, and Center-specific. FDA should create a map—derived from pointed conversations with internal IT SMEs or similar stakeholders—that identifies HR system handoffs, workflow bottlenecks, and/or issues that pertain to how the systems are integrated with one another, thereby identifying any potential data management risks due to insufficient system integration issues. Furthermore, FDA should fully integrate any hiring workflow systems (e.g., the Hiring Pilot's ATLAS) with USA Staffing, eClass, and other HRIS to eliminate the need for manual and/or redundant data entry and to improve data integrity.

R-6. In conjunction with the review of existing HRIS technologies, FDA should consider employing additional technological solutions to enhance data management and reporting capabilities.

In addition to inventorying and mapping the linkages among the existing HRIS technologies used for recruiting, hiring, and retention within CDER and CBER, FDA should explore adopting additional advanced

technologies that will promote more efficient and reliable data management. The inventorying and mapping will help to inform the identification of technological solutions beyond the existing HRIS technologies. Based on the results of this assessment, we offer illustrative examples of additional technological solutions that may be worth exploring. One, FDA may wish to consider building an integrated talent dashboard that would serve as a unified view of customer-focused metrics relevant to the entire employee life cycle; this increased transparency can help drive accountability for better data accuracy. Two, FDA may wish to build and use a centralized candidate relationship management tool that will enable FDA to actively mine data that might otherwise be inconsistently captured, inaccessible because it is stored on individual spreadsheets, ignored because it is buried in the applicant tracking system, or outdated due to lack of attention. Three, FDA could identify opportunities to use advanced business process automation technologies (such as Robotic Process Automation [RPA]) to gain efficiencies in the HR staff's workload, such as automating the data entry that occurs with HR processing actions, the onboarding process, time-to-fill metrics, and/or other process steps that tend be routine and/or required for compliance.

4.3 HR Staff Capability and Capacity

R-7. Reframe the roles of OTS' HR staff aligned to CDER and CBER as "HR Business Partners."

As a byproduct of the OHR reorganization, FDA should reframe the roles of OTS' HR staff aligned to CDER and CBER as "HR Business Partners," with a mutual expectation and commitment that these staff will be integrated into Center strategy and business operations. These staff should build a deeper understanding of the Centers' priorities, needs, and operations, enabling them to proactively deliver relevant solutions to the Centers. Recasting the roles will allow these staff to gain a more profound understanding of the Center they support, build stronger connections with Center staff, and gain timely access to information that can help drive more strategic workload planning for the Center to which they are aligned. Furthermore, reframing the roles to include more substantive interactions can help the Centers increase their confidence in the HR staff who support them.

R-8. Establish a workload management process for assessing and distributing work across the HR workforce, leveraging reliable analytic tools.

FDA should establish a reliable and repeatable workload management process to be used for the HR workforce in OTS, OHCM, and the Centers' OMs. This process will facilitate decision making regarding staffing levels and workload allocations for the HR staff who support recruiting, hiring, and retention. The process should be designed to generate the ideal number of HR staff, identify the needed skill sets for HR staff, and capture methods for managing backlogs and bottlenecks to support more efficient service delivery. To support this workload management process, FDA should consider implementing analytic tools—such as workload demand, resource estimation, and/or workflow visualization tools—that allow for monitoring and estimating just-in-time data to align HR staff to the HR workload.

R-9. Hold managers of HR staff—across the Agency's HR Organization, CDER, and CBER—accountable for actively managing staff performance by establishing standardized PMAP goals.

FDA should hold managers of HR staff (i.e., OTS/OHCM staff, Center OM HR staff, and Center AOs and PMs who perform HR work) accountable for actively managing HR staff performance by establishing standardized PMAP goals that address how to regularly monitor staff performance, provide feedback, and recognize contributions. FDA should also develop or leverage existing supporting job aids (e.g., guides, tip sheets, mini-trainings) to help managers of HR staff prepare for and conduct valuable performance feedback conversations. On a semi-annual basis, FDA should verify that managers of HR staff are implementing consistently the goals and job aids.

FDA should actively invest in the career development of its HR workforce—including the HR workforce across OTS, OHCM, the Center OM HR staff, and the Center AOs and PMs who perform HR work—to motivate and

retain a high performing, engaged HR workforce. Providing career development opportunities prepares and encourages these staff to acclimate to the evolving business environment, which benefits the HR staff, their managers and leaders, and the Centers. FDA should develop programs (e.g., an HR competency model, an HR-specific onboarding program, HR career maps, an HR-specific mentoring program) that are specifically tailored to bolster the career experience of HR staff.

4.4 Culture, Collaboration, and Communication

R-10. Shift to a more collaborative, customer-centric culture.

Organizational culture both defines and is defined by people's behaviors and attitudes in the workplace. It is a powerful dynamic that can impact individual and organizational performance, at times even more so that process and technology enhancements. Accordingly, FDA can benefit by establishing a more collaborative, customer-centric culture among the multiple layers of HR service providers and service receivers (e.g., OTS and OHCM staff, Center OM staff, other staff performing HR tasks in the Centers, hiring managers, and Center leadership).

FDA should conduct a series of structured, facilitated sessions (with participants who represent diverse organizations and perspectives, including a mix of OC/OO, Center, OTS, and OHCM leaders) to delve into the root causes of the current culture and, most importantly, generate solutions for shifting the culture. The sessions should also focus on clarifying roles, responsibilities, and relationships, including promoting more constructive interaction among groups based on shared goals. The sessions should also emphasize the need for strong leadership engagement and accountability for driving the cultural shift as these leaders help their groups adopt and embrace new ways of thinking.

Once FDA begins the shift toward a more collaborative, customer-centric culture, FDA should establish feedback mechanisms to assess whether noticeable, positive change is occurring. FDA should establish processes for gathering feedback from varied stakeholders involved as both service providers and service receivers; this could include semi-annual pulse check surveys to gather perceptions from varied sources—such as hiring managers, new hires, and HR staff in the Centers, OTS, and OHCM—on the adoption of a collaborative, customer-centric culture. FDA will want to set reasonable expectations for the speed of change, given that cultural shifts notoriously take a long time to accomplish given the shift of not only behaviors but also underlying attitudes.

R-11. Establish a stakeholder engagement strategy to encourage two-way communications with the goal of increasing awareness and efficient adoption of recruiting and hiring process improvements.

OTS should work collaboratively with the Centers to establish a stakeholder engagement strategy that is attuned to customer needs and that rebuilds their brand as the knowledgeable, communicative source of FDA's HR information. The strategy should document the cadence, channels for communications, and products that will promote better transparency about hiring process improvement efforts. This will increase awareness of progress and acknowledge challenges, such as the reasons behind certain HR practices (e.g., the need to review PDs, the need to practice more proactive position management to improve consistency and compliance). As part of the stakeholder engagement strategy, OTS and the Centers should also recalibrate the expectations held by all parties for customer service delivery. To accomplish this, they should hold sessions to determine the strengths and weaknesses of customer service delivery. During these sessions, stakeholders should mutually define the future state customer service standards and expectations.

R-12. Create and disseminate tactical communication products that will help leaders, hiring managers, and HR staff perform their tasks related to recruiting, hiring, and retention.

FDA should design and develop tactical communication products that will help to drive greater consistency, transparency, and quality in recruiting, hiring, and retention efforts. By producing targeted products, FDA will

equip leaders, hiring managers, and HR staff with tools that can make their jobs more efficient. Illustrative products may include consistently branded candidate-facing recruiting materials; a "Hiring Manager Toolkit" with resources on hiring authorities and processes; retention toolkits with resources on incentives and specific actionable tactics for minimizing undesirable attrition; and an enhanced Employee Value Proposition (EVP) to facilitate more consistent and compelling messaging across the many hiring managers involved in the recruiting process.

R-13. Disseminate communications plans to increase awareness and share critical information about the Cures Act and DHA to support strategic and consistent application of these hiring authorities.

Leveraging the new Cures Governance Committee, OTS should disseminate a formal communications plan for generating greater awareness and sharing critical information about the Cures Act. The communications plan, which should be rooted in a stakeholder analysis, should address what, when, and how information should be communicated to stakeholders in regard to Cures Act related strategy, policy, policy updates, rules, and processes. This plan should also include customer-focused strategies for stakeholder engagement to help clarify any misunderstandings about how OTS and the Centers are using the Cures Act as a recruitment and retention tool. Similarly, OTS should disseminate a formal communications plan for generating greater awareness and understanding regarding OPM requirements for DHA and the perceived impact of such policies on the expediency of DHA hiring at FDA. OTS needs to develop a plan for regularly communicating changes to all parties involved in using this authority so that Center HR staff and hiring managers operate from the most information, thereby reducing lost time spent on outdated rules.

R-14. Reinvigorate standing meetings that occur between OTS and the Centers to improve effectiveness and encourage greater collaboration.

To improve communications and collaboration, OTS and the Centers should broaden the content of their standing meetings that focus on the status of open hiring actions to foster more productive conversation about strategic issues, policy changes, and systemic challenges requiring greater coordination. Senior leadership from OTS and the Center OM HR leaders should partner to mutually agree upon the meeting participants, standard agenda, and cadence based on recurring business decision making needs. They should establish clear ground rules, define accountabilities for meeting preparation, and outline a process for following up on action items.

4.5 Recruiting and Hiring Processes

R-15. Streamline frequently used hiring processes and house the new hiring process maps in a centralized HR knowledge management repository.

FDA should review its frequently used Hiring Pilot and non-Hiring Pilot hiring processes and their associated forms to identify opportunities to streamline and/or consolidate. FDA should update and document HR processes so they are customer-focused, which can improve the customer experience. The review should also include identifying processes where efficiencies have been gained (e.g., the shared certificate process). FDA should also establish and/or update service level agreements (SLA) associated with the frequently used hiring processes.

In addition, to encourage sharing and support access to streamlined hiring processes and forms, FDA should create a centralized HR knowledge management repository. This repository would house Hiring Pilot and non-Hiring Pilot process maps—along with forms, policies, job aids, toolkits, and/or other relevant resources related to recruiting, hiring, and retention—to encourage consistent application of processes. This site could also house the integrated talent dashboard and include links to an integrated set of HR systems that support these processes.

R-16. Resolve the classification backlog and develop SOPs to standardize the classification process.

OTS should analyze the classification backlog to determine which types of positions (e.g., grade level, occupation) and offices are most affected. In close collaboration with Center leaders, OTS should incorporate the Center's hiring targets and priorities into a plan for prioritizing the classification backlog. OTS and Center leaders should collaborate on the backlog plan's details (e.g., timeline, milestones, communications plan for Center Leadership). OTS should also drive standardization in the classification process by developing SOPs. These SOPs would capture, for example, the rules and processes for recertification, audits, required forms, the use of standard PDs, and classification conflict resolution procedures to resolve disagreements between supervisors and their servicing Classifiers. Once the backlog is resolved, FDA should also develop and administer a sound position management program within the classification unit.

R-17. Drive greater accountability for process improvement by documenting and regularly tracking outcome measures, such as customer-centric, key performance indicators (KPI) and success measures.

OTS, CDER, and CBER should instill a greater focus on outcome measurement, which can lead to greater process improvement. FDA should identify, capture, and regularly review customer-centric, key performance indicators (KPI) and success measures for significant recruiting and hiring activities (e.g., SST, DHA, and Cures). With this increased focus, FDA will be better informed and able to identify ways to make processes more efficient and effective. For example, with an emphasis on outcome measurement, it may be possible to discern if there are ways for SST to provide additional support to Center hiring managers with their recruitment efforts while still fulfilling the objectives of the program.

APPENDIX: REPORT SUPPLEMENT

TABLE OF CONTENTS

LIST OF EXHIBITS

This Appendix provides supplemental information for the Food and Drug Administration (FDA) Interim Hiring and Retention Assessment. This supplemental information includes additional results from data analyses that are referenced in the report to provide further insight to the report content. The structure of this supplement mirrors the headings in the main report. The main report references the relevant exhibit as "see Attachment Exhibit S-X." Attachment Exhibits are presented herein in numerical order (Exhibits S-1 to S-46).

Methodology

Exhibit S-1: Overview of Primary Assessment Focus Areas

FOCUS AREA	DESCRIPTION
Human Resources (HR) Process Efficiency	Refers to the consistency and timeliness of existing FDA processes in recruiting, hiring, and retaining sufficient numbers of qualified human drug and biologics review program staff. Includes the extent to which processes support meeting targets as well as potential delays, redundancies, and innovative resources used in the processes related to the Hiring Pilot and other hiring authorities.
HR Process Effectiveness	Pertains to the accuracy, quality, and customer satisfaction of existing FDA processes in recruiting, hiring, and retaining sufficient numbers of qualified human drug and biologics review program staff. Includes the following: quality, diversity and engagement of new hires, results of recruiting initiatives, stakeholder feedback, attrition data (gains and losses), and innovative practices used.
HR Staff Capacity	Describes the overall workload volume and distribution to existing FDA staff performing applicable HR functions. Includes applicable HR workforce size and staffing ratios, access to appropriate technology and supporting resources, applicable HR workforce attrition, and identification of anticipated changes and other issues impacting FDA's ability to manage current and potential future HR workload.
HR Staff Capability	Addresses the knowledge, skills, and abilities (KSA), also referenced as competencies, of existing staff performing applicable HR functions. Includes the identification of requisite KSAs, assessment of current staff proficiency, and completion of training and certification programs.

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Exhibit S-2: Data Collection Methods—Purpose and Details

METHOD	PURPOSE AND DETAILS
Document Review	Provided context and understanding of the mission and functions supporting recruiting, hiring, and retention at FDA (120 documents total). • Reviewed 15 recruiting-related documents, such as recruiting plans and marketing materials • Reviewed 39 hiring-related documents, such as hiring process maps, hiring policies and procedures, workforce analysis profiles, and hiring progress reviews • Reviewed 21 retention-related documents, such as benchmark data on HR Servicing Ratios and policies and procedures related to hiring incentives • Reviewed an additional 42 documents to account for other HR-related information such as policies and procedures, mission requirements (historical/trends), organizational charts, strategic plans, and other background and contextual materials
FDA Data File Review	Offered insights on metrics, workforce and workload trends, and data management practices for Office of the Commissioner (OC)/Office of Operations (OO), Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER). • Reviewed 26 datasets (e.g., process data, workforce data, hiring data, recruiting data, retention data)
Surveys	Captured quantifiable data and a broad range of perspectives from HR staff, managers of HR staff, and CDER/CBER staff, including hiring managers and new hires. Designed three web-based surveys with closed- and open-ended items. • CDER/CBER Staff Survey—Administered to all current, federal human drug and biologics review program staff within CDER and CBER including new hires (defined as staff hired within the past two years) and hiring managers (34 percent response rate) • HR Workforce Staff Survey—Administered to all HR professionals working in Office of Talent Solutions (OTS), Office of Human Capital Management (OHCM), CDER, and CBER (29 percent response rate) • HR Workforce Manager Survey—Administered to all managers of staff performing HR work in OTS, OHCM, CDER, and CBER (78 percent response rate)

METHOD	PURPOSE AND DETAILS
Interviews	Captured insights from OC/OO leadership, CDER and CBER leadership, and HR senior leadership. • Designed structured protocols for each interviewee type • Conducted 29 interviews with 35 participants (occasionally two or more leaders chose to participate in interviews together, due to the nature of their roles and perspective on the assessment topics)
Focus Groups	Captured insights from stakeholders supporting the recruiting, hiring, and retention of human drug and biologics review program staff to understand their unique experiences and perspectives. • Designed structured protocols for each focus group type • Conducted 15 focus group sessions with 117 participants including CDER/CBER hiring managers, managers of HR staff, OTS/OHCM HR staff, and CDER/CBER HR staff

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Improvement Activities

SCIENTIFIC STAFFING TEAM (SST)

Exhibit S-3: FDA's Reported Online Presence (September 2018 Versus September 2019)[121]

	FDA JOBS (PAGE VIEW IN MONTH)	LINKEDIN (TOTAL FOLLOWERS)	TWITTER (TOTAL FOLLOWERS)
September 2018	5,700	210,545	641
September 2019	73,525	289,246	1,428
Percentage Increase	1,190%	37%	123%

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EXPANSION OF THE TITLE 4 DIRECT HIRE AUTHORITY (DHA)

Exhibit S-4: Interview Theme—Recruiting Effectiveness

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What helps the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these helping factors?	FDA is able to hire qualified people despite challenges with the process, in part due to hiring flexibilities (e.g., Cures is good for compensation increase/retention, Direct Hire is good for some positions, Hiring Pilot has potential for success).	Interviews (Int): 2nd out of 4 major themes

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Exhibit S-5: Interview and Focus Group Theme—Feedback on DHA

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has the expansion of DHA improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	DHA helps FDA bring in qualified candidates more quickly and should be expanded to cover additional positions.	Int: 2nd out of 2 major themes Focus Groups (FG): 2nd out of 2 major themes

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[121] Sources: SST Social Media Dashboard 09.2018, OTS; SST Social Media 09.2019, OTS.

Exhibit S-6: Interview and Focus Group Themes—Efficiency of Hiring Flexibilities

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What are the differences in efficiency of processes associated with the STRS Hiring Pilot, Title 5, Title 38, Title 42, and Special Placements and Appointments (e.g., Veterans' preference)?	Schedule A and delegated examining take longer based on verification processes and other appointments (e.g., Cures, Title 38) take longer due to unclear process requirements.	Int: 1st out of 2 major themes FG: 1st out of 2 major themes
To what extent has the expansion of DHA improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Effectiveness of DHA is limited by recent process changes (e.g., requirement to post a job opportunity announcement, reclassify existing position descriptions, directing candidates to apply through USAJOBS), lack of clear communication about process changes, and lack of transparency on status of actions and process inconsistencies.	Int: 1st out of 2 major themes FG: 1st out of 2 major themes

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Strategy

F1.2 The consequences of not having an integrated strategy for recruiting, hiring, and retention include sub-optimal effectiveness of each function and insufficient plans to manage complex cross-functional dynamics, such as workforce gains and losses.

Exhibit S-7 shows the number of CDER and CBER employees in diversity categories who were hired into FDA (gains) and left FDA (losses) during FY2017, FY2018, and FY2019. These figures do not include transfers within FDA because, in those situations, the Agency would still retain the diverse talent. Results show that there were more gains than losses in almost every diversity category and every fiscal year, with the exception of a net loss of five veterans in FY2019. In other words, although there has been considerable diversity among the losses, CDER and CBER has consistently yielded an increase in workforce diversity.

Exhibit S-7: FDA CDER and CBER Hiring Data—Diversity Gains and Losses[122]

DIVERSITY CATEGORY	FISCAL YEAR	GAINS	LOSSES	NET NUMBER OF DIVERSE EMPLOYEES RETAINED OR LOST
Veterans Preference Eligible	**FY2017**	19	12	7 retained
	FY2018	19	19	0
	FY2019	19	24	5 lost
Reported Disability	**FY2017**	32	15	17 retained
	FY2018	17	14	3 retained
	FY2019	21	12	9 retained
Female	**FY2017**	301	127	174 retained
	FY2018	268	155	113 retained
	FY2019	246	154	92 retained
Non-White	**FY2017**	253	107	146 retained
	FY2018	266	133	133 retained
	FY2019	116	87	29 retained

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[122] Source: FDA Personnel Data FY2016 to FY2019, Business Intelligence Information System (BIIS).

F1.3 FDA has established some targeted initiatives, such as OTS' new dedicated SST and FDA's succession management plan, that serve as a preliminary Agency-level strategic framework for establishing a more comprehensive, integrated strategy.

Exhibit S-8: Focus Group and Interview Themes—Impact of SST

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has SST improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Perceived issues with SST's effectiveness include difficulty recognizing the value of the team's services (e.g., lack of strategy, no calculated return on investment, limited usefulness of resumes collected, general lack of awareness of the team), difficulty coordinating job opportunities with viable hiring processes, and the belief that Centers are already effective at recruiting.	Int: 1st out of 3 major themes FG: 1st out of 2 major themes
	It has been helpful to have a coordinated FDA presence (e.g., at events and in branding and advertisements) and it is useful to have a scientist on the recruiting team.	Int: 2nd out of 3 major themes
	The team has helped establish a unified FDA presence and branding materials (e.g., metro ad campaigns), a social media presence (e.g., LinkedIn), and coordinated recruiting at external events (e.g., conferences).	FG: 2nd out of 2 major themes
	Effectiveness could be improved by better metrics and coordination between SST and the Centers.	Int: 3rd out of 3 major themes

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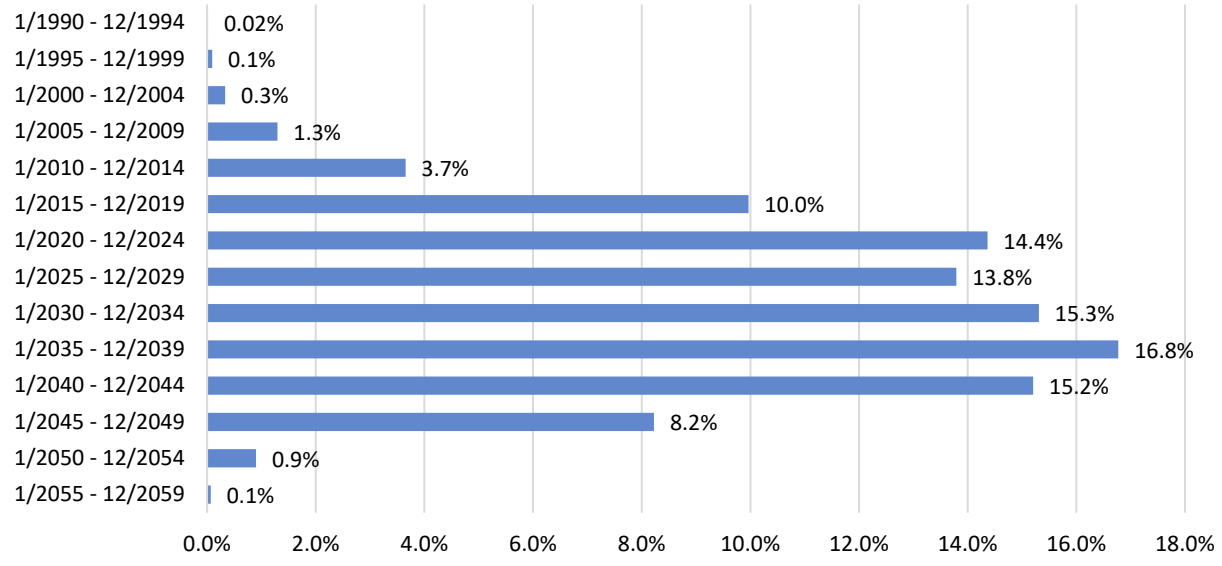
F1.4 Attrition rates for CDER and CBER are low compared to other government agencies; however, it remains a concern due to pockets of high turnover, high rates of retirement eligibility, and the challenges of filling vacancies.

Exhibit S-9: Earliest Retirement Eligibility Date for All Active Permanent and Temporary FDA Employees[123]



BIIS Report Data: n=16,025

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[123] Source: FDA Retirement Eligibility Report 09.28.2019, BIIS.

Exhibit S-10: Interview and Focus Group Theme—Impact of Turnover

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
In what ways do challenges related to retention of human drug and biologics review program staff affect the ability to get work done in [CDER/CBER]?	Staff turnover, especially among those with technical specialties or specific training needed to do the work, creates workload disruptions and increases that overload staff, lead to burnout, and impact work quality.	Int: 1st out of 1 major theme

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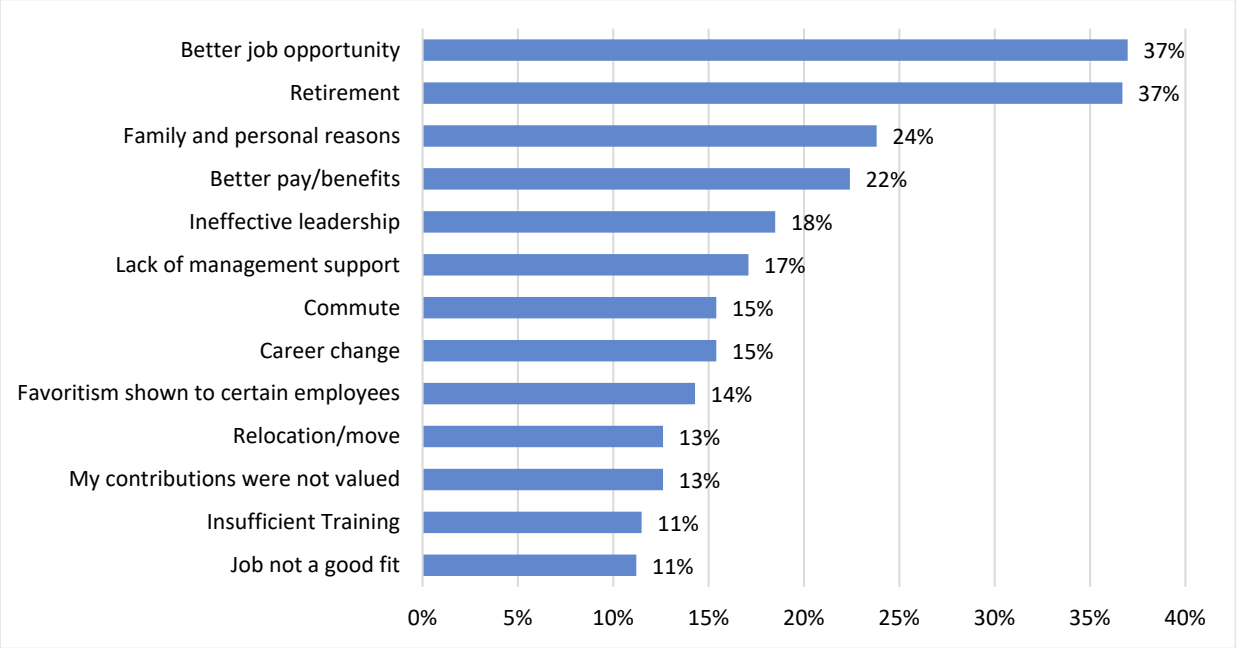
F1.5 The main reasons employees would leave CDER and CBER are retirement, opportunities for higher compensation, and greater potential for career advancement and career growth.

Exhibit S-11: FDA Exit Survey—Reasons CDER and CBER Employees Left FDA[124]



Respondents: CDER and CBER staff (n=1015). This item type is Select All That Apply, so the response numbers count all selections provided by survey participants. While exit surveys are not the most reliable source of turnover information, they can provide insights in combination with other data sources.

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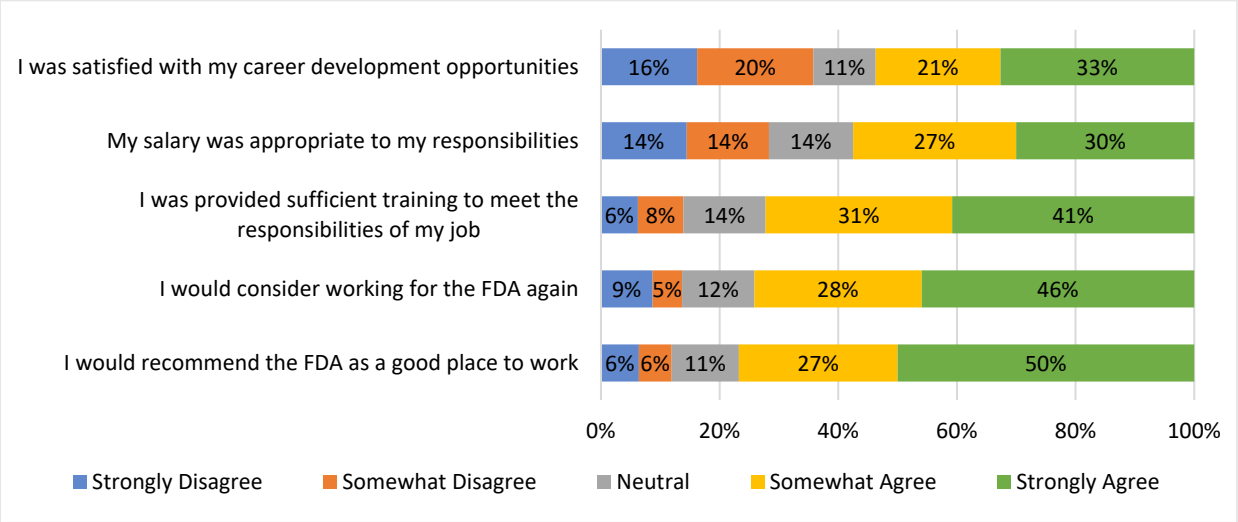
[124] Source: FDA Exit Survey Data 06.1.2016 to 9.30.2019.

Exhibit S-12: FDA Exit Survey—Perspectives on Job Factors and FDA Overall[125]



Respondents: CDER and CBER staff (n=344-353). While exit surveys are not the most reliable source of turnover information, they can provide insights in combination with other data sources.

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Exhibit S-13: Interview and Focus Group Theme—Reasons for Turnover

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What are the top reasons for turnover among the human drug and biologics review program staff? What are the top reasons why they stay?	The main reason for turnover is that staff can easily find a better job situation elsewhere; they are primarily attracted by higher compensation and better opportunities for promotion, but also by more flexible work schedules and remote work.	Int: 2nd out of 3 major themes FG: 1st out of 2 major themes

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Exhibit S-14: Center Staff Survey Theme—Retention

OPEN-ENDED QUESTION	THEME(S) FROM SURVEY COMMENTS	STRENGTH OF THEME
Please provide any additional feedback you may have regarding improvements to recruiting, hiring, and retention of human drug and biologics review program staff at FDA.	It is perceived that inconsistent (e.g., promotion policies varying by Office) and opaque promotion process has impacted staff perception of upward mobility within FDA and further challenges retention efforts.	Center Survey: 4th out of 4 major themes

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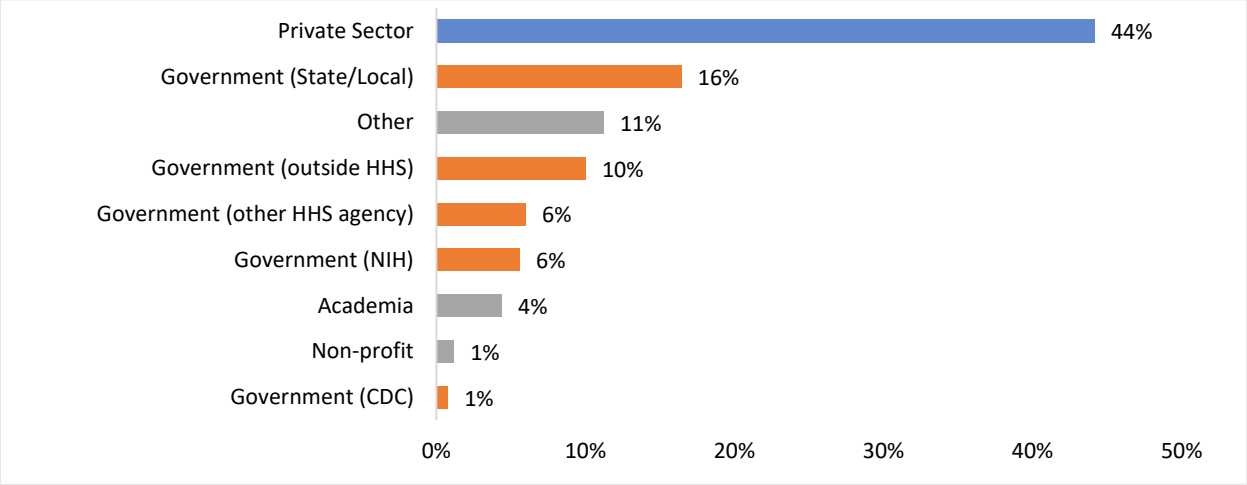
[125] Source: FDA Exit Survey Data 06.1.2016 to 9.30.2019.

F1.6 When considering a job search, CDER and CBER staff are most interested in staying with FDA as an employer; if they do look elsewhere, it is nearly evenly split between the private sector (including pharmaceutical firms) and other government agencies.

Exhibit S-15: Exit Survey—Next Employer After Leaving FDA[126]



Respondents: CDER and CBER staff (n=354). Survey item: "I'm leaving the FDA to go to: [list of options, plus Other, as shown in chart]." While exit surveys are not the most reliable source of turnover information, they can provide insights in combination with other data sources. Orange bars show different options for government jobs (39 percent, combined).
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F1.7 The top reasons people stay at FDA include both intrinsic motivators (e.g., a commitment to the work and mission support from one's manager and team) as well as extrinsic motivators (e.g., salary increases, student loan repayment); to mitigate the risk of attrition, Centers sometimes offer retention incentives, which can be beneficial but can also have unintended consequences, such as pay inequities.

Exhibit S-16: Interview and Focus Group Themes—Retention

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What are the top reasons for turnover among the human drug and biologics review program staff? What are the top reasons why they stay?	The top reasons people stay include commitment to the work and mission; salary increases (e.g., increases due to Cures conversions), promotion, and other financial incentives (e.g., student loan repayment); work-life balance; and amenities at FDA's campus (e.g., day care, farmer's market).	Int: 1st out of 3 major themes
What helps the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these helping factors?	Factors that help with retention include workplace flexibilities, financial incentives (e.g., student loan repayment), employee resource groups, and effective management of employees.	Int: 1st out of 4 major themes
What retention initiatives have been put in place in [CDER/CBER]? How well are they working? What, if any, suggestions for improvement and/or ideas for additional retention initiatives do you have?	Retention initiatives are not used to their fullest strategic potential.	Int: 4th out of 4 major themes

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[126] Source: FDA Exit Survey Data 06.1.2016 to 9.30.2019.

Exhibit S-17: Interview and Focus Group Themes—21st Century Cures Act

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has this activity improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Effectiveness of 21st Century Cures as a retention tool is limited by inadequate training and guidance for HR staff (e.g., procedures are still being drafted) and limitations on eligible occupations (e.g., within medical product centers), along with concerns of creating pay inequities.	Int: 1st out of 2 major themes
	Effectiveness of 21st Century Cures as a retention tool is limited by a lack of guidance (e.g., defined SOPs on pay bands and Statement of Duties) and inconsistent implementation across the Centers, which has led to perceptions of "staff poaching" by other Centers.	FG: 1st out of 2 major themes

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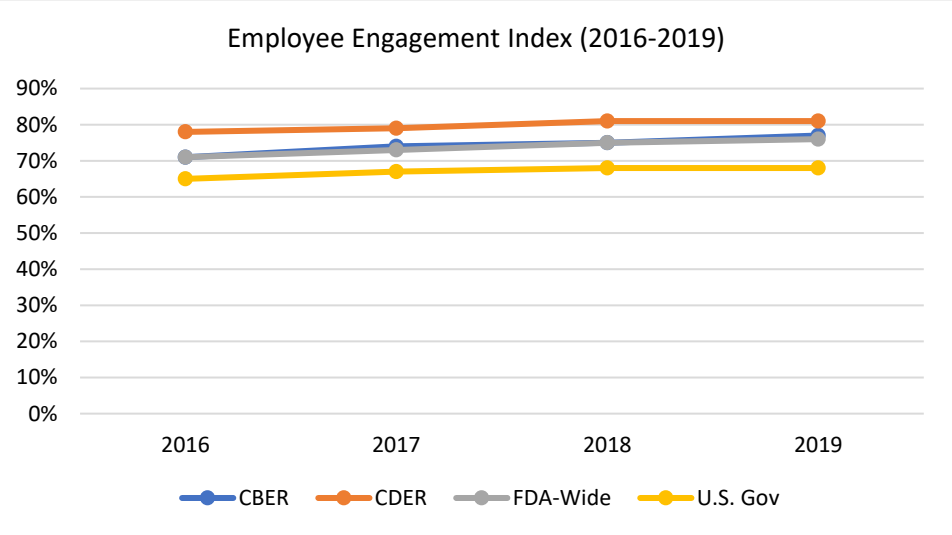
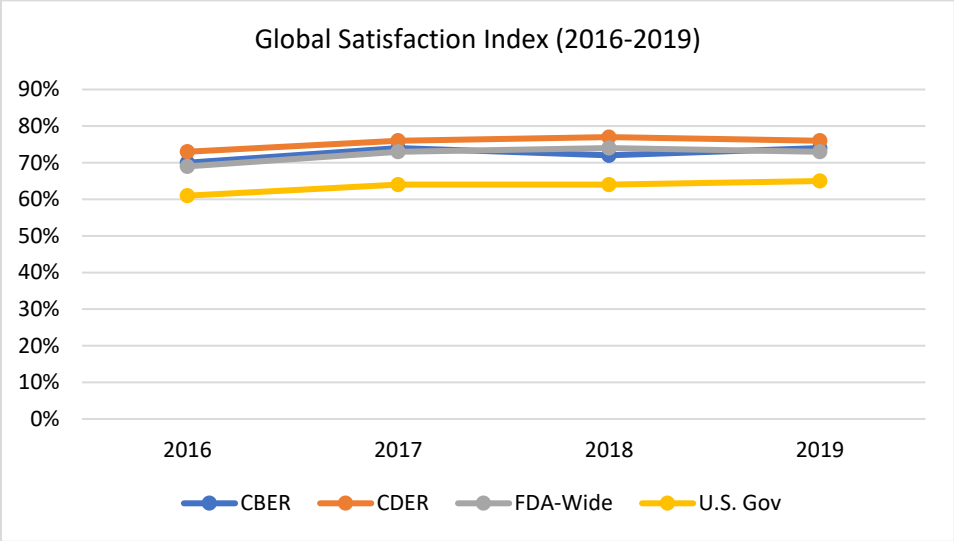
Exhibit S-18: FDA Federal Employee Viewpoint Survey (FEVS) Results—Employee Engagement Index (2016-2019)[127]



Respondents: FY2016 (CBER n=672, CDER n=2,594, FDA n=10,599, US Gov n=407,789); FY2017 (CBER n=696, CDER n=2,600, FDA n=10,209, US Gov n=486,105); FY2018 (CBER n=771, CDER n=2,991, FDA n=10,603, US Gov n=598,003); FY2019 (CBER n=846, CDER n=3,706, FDA n=12,250, US Gov n=615,395).

[127] Source: Federal Employee Viewpoint Survey Results FY2016 to FY2019, OHCM.

Exhibit S-19: FDA FEVS Results—Global Satisfaction Index (2016–2019)[128]



Respondents: FY2016 (CBER n=672, CDER n=2,594, FDA n=10,599, US Gov n=407,789); FY2017 (CBER n=696, CDER n=2,600, FDA n=10,209, US Gov n=486,105); FY2018 (CBER n=771, CDER n=2,991, FDA n=10,603, US Gov n=598,003); FY2019 (CBER n=846, CDER n=3,706, FDA n=12,250, US Gov n=615,395).

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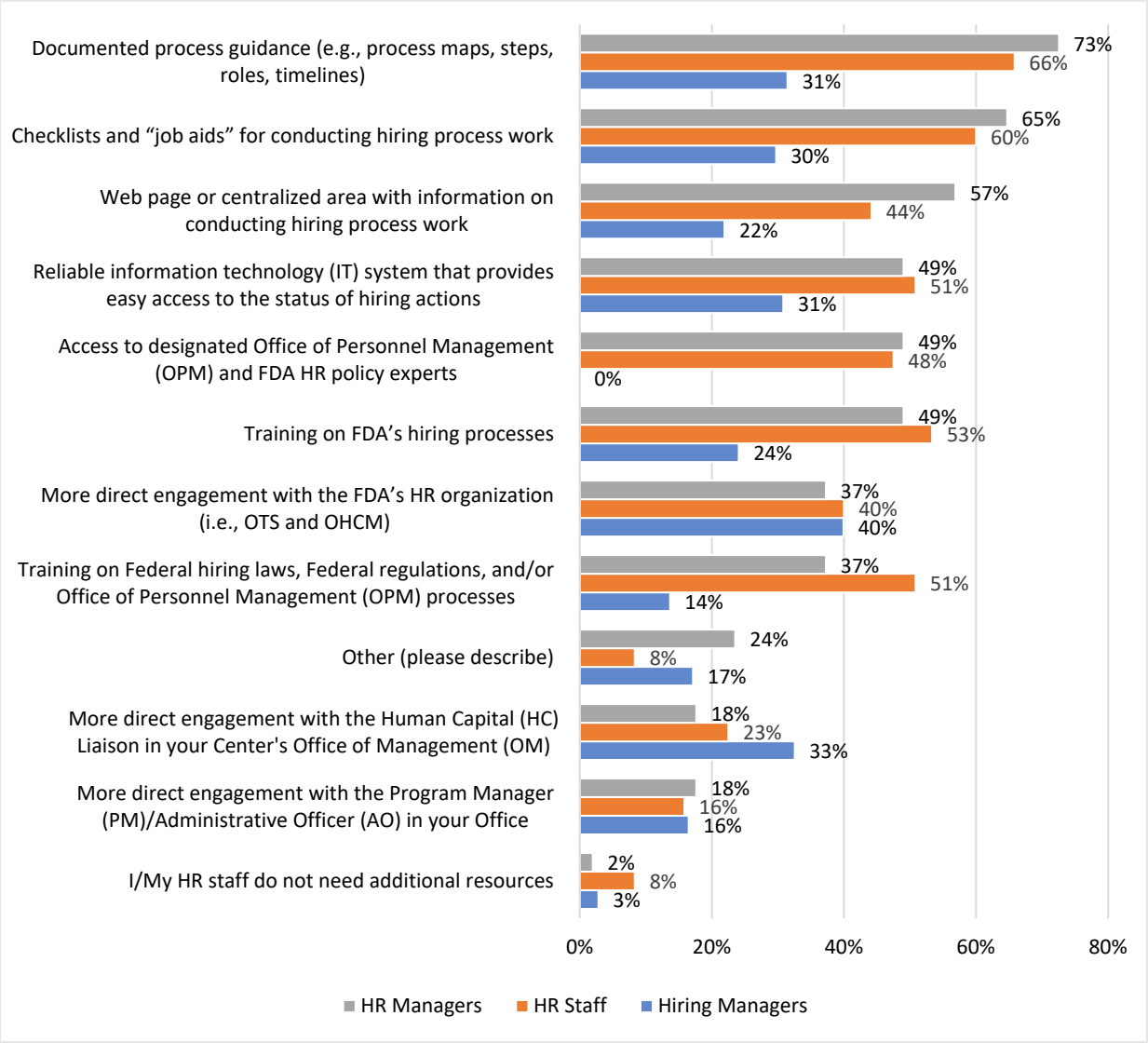
[128] Source: Federal Employee Viewpoint Survey Results FY2016 to FY2019, OHCM.

Data Management and Systems

F2.2 FDA's current ATLAS system has the potential to improve the effectiveness and efficiency of the hiring workflow, but the system alone will not address all the technology requirements.

Exhibit S-20: Interim Surveys (HR Managers, HR Staff, and Hiring Managers)—Need for Additional Resources[129]



Respondents: HR Workforce Manager Survey (HR Managers, n=243); HR Workforce Survey (HR Staff, n=561); CDER/CBER Staff Survey (Hiring Managers, n=1201). Survey item: "What additional resources would help you be more successful when working through/performing work related to the recruiting and hiring processes and/or retention initiatives?" This item type is Select All That Apply, so the response numbers count all selections provided by each group of survey participants.

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Return to Main Report – Exhibit 27
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[129] Sources: HR Workforce Manager Survey; HR Workforce Survey; CDER/CBER Staff Survey.

Exhibit S-21: Interview and Focus Group Themes—Hiring Process Challenges

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What helps or hinders your ability to perform your recruiting, hiring, and retention work?	Challenges include heavy workloads, technology deficits (e.g., different systems needing to be updated with the same information), classification (e.g., PMs advocating for higher position description (PD) grades than may be warranted by regulations), and collaboration (e.g., HR's extended response times to inquiries from hiring managers).	FG: 1st out of 3 major themes
What changes to workload volume, staffing levels, technology, and/or other resources may impact the HR staff's capacity to manage the recruiting, hiring, and retention work? What, if any, additional resources are needed?	The reduced staff levels (e.g., staff attrition due to leadership changes), implementation of ATLAS (e.g., helping with visibility and accountability throughout the hiring process), and the overall increase in FDA's hiring needs have impacted HR's workload.	Int: 1st out of 2 major themes

Return to Main Report – Section F2.2
Return to Main Report – Section F3.4

Exhibit S-22: Interview and Focus Group Themes—ATLAS System Impact

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has the ATLAS system improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Effectiveness of the ATLAS system is limited by quality issues (e.g., inaccurate or incomplete data) and system limitations (e.g., delayed roll-out, lengthy platform navigation, inability of hiring managers to view applicants' files).	Int: 1st out of 3 major themes FG: 1st out of 3 major themes
	Effectiveness could be improved by increased transparency (e.g. complete data on all hiring actions and system access to more users, as appropriate).	Int: 2nd out of 3 major themes
	ATLAS has helped enhance process visibility and improve stakeholder interactions (e.g., facilitated more communication between different groups working on the hiring actions).	Int: 3rd out of 3 major themes
	There is a reputation among non-Pilot participants that the ATLAS platform is not a useful solution.	FG: 2nd out of 3 major themes

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HR Staff Capability and Capacity

F3.1 With the OHR reorganization, OTS centralized expertise in Classification, DE, and Policy and Accountability into their own organizational units; however, success is limited because OTS maintains a large backlog of classification work, is not fully staffed, and has not yet updated all critical HR policies and procedures.

Exhibit S-23: Interview and Focus Group Theme—OHR Reorganization Effectiveness

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has the OHR reorganization improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Effectiveness of the OHR reorganization is limited by a lack of transparency (e.g., undocumented policies, unclear rationale for HR changes), staffing changes (e.g., added leadership, but not enough HR staff), and lack of clarity about the new organizations' structure and services.	Int: 1st out of 2 major themes FG: 1st out of 2 major themes

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F3.2 Although some new training and performance management resources are available for OTS staff; FDA lacks a unified framework to manage the work of all HR staff, including competency models, performance standards, training and development, and workload management.

Exhibit S-24: Interview and Focus Group Themes—HR Process Coordination

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
How well do the various Offices involved in recruiting, hiring, and retention (e.g., FDA's OO, the Centers' OMs, and the Centers' Divisions) coordinate with each other and manage process handoffs?	Handoffs across the various offices are inconsistent, unclear, and lack visibility; issues with lack of responsiveness and transparency between Centers and HR cause redundancies and re-work.	Int: 1st out of 3 major themes FG: 3rd out of 4 major themes
	Coordination and handoffs are hindered by HR staff availability, performance and capability issues and an existing disconnect between the Centers and HR regarding HR's understanding of the Centers' service requirements and the Centers' understanding of HR's regulatory requirements.	Int: 2nd out of 3 major themes FG: 1st out of 4 major themes
	Communication channels vary—the level of direct engagement between the Centers' Divisions and HR varies based on office and hiring process; based on pilot experiences, leaders believe coordinating with OM adds value to the process, but to HR staff, the value is not clear.	Int: 3rd out of 3 major themes FG: 4th out of 4 major themes
	Issues with lack of responsiveness and transparency between Centers and HR impede successful coordination. Center stakeholders believe more consistent and valuable information sharing could improve process handoffs.	FG: 2nd out of 4 major themes
How does efficiency in the recruiting and hiring processes ultimately impact [CDER's/CBER's] ability to accomplish the human drug and biologics review program work?	Due to the inability to backfill vacant positions quickly, Centers shift hiring priorities constantly and re-distribute workload to other staff, which creates workload disruptions and increases that overload staff, lead to burnout, and impact work quality.	Int: 1st out of 1 major theme

Return to Main Report - Section F3.2
Return to Main Report - Section C4-1
Return to Main Report – In Exhibit 27

Exhibit S-25: Interview Themes—Important KSAs for Recruiting, Hiring, and Retention

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What do you think are the 3-4 most important KSAs for recruiting, hiring, and retention?	In order to accurately assess candidate qualifications and process personnel actions, the HR workforce needs expertise in HR technical areas (e.g., knowledge of applicable laws, policies and authorities related to staffing, classification and pay setting) and attention to detail.	Int: 1st out of 4 major themes
	Soft skills (e.g., listening, communication, customer service) are also important, so the HR workforce can guide hiring managers through the process and provide transparency in a professional manner.	Int: 2nd out of 4 major themes
	The HR workforce needs a better understanding of FDA (and what that means for the workforce skills the work requires) and should use a consultative approach to help recruit and retain CDER and CBER staff within existing authorities and flexibilities.	Int: 3rd out of 4 major themes
	Participants identified a handful of other important KSAs, including planning and organizational skills, interpersonal skills, negotiation, computer skills, and the ability to make a business case to justify HR's needs.	Int: 4th out of 4 major themes

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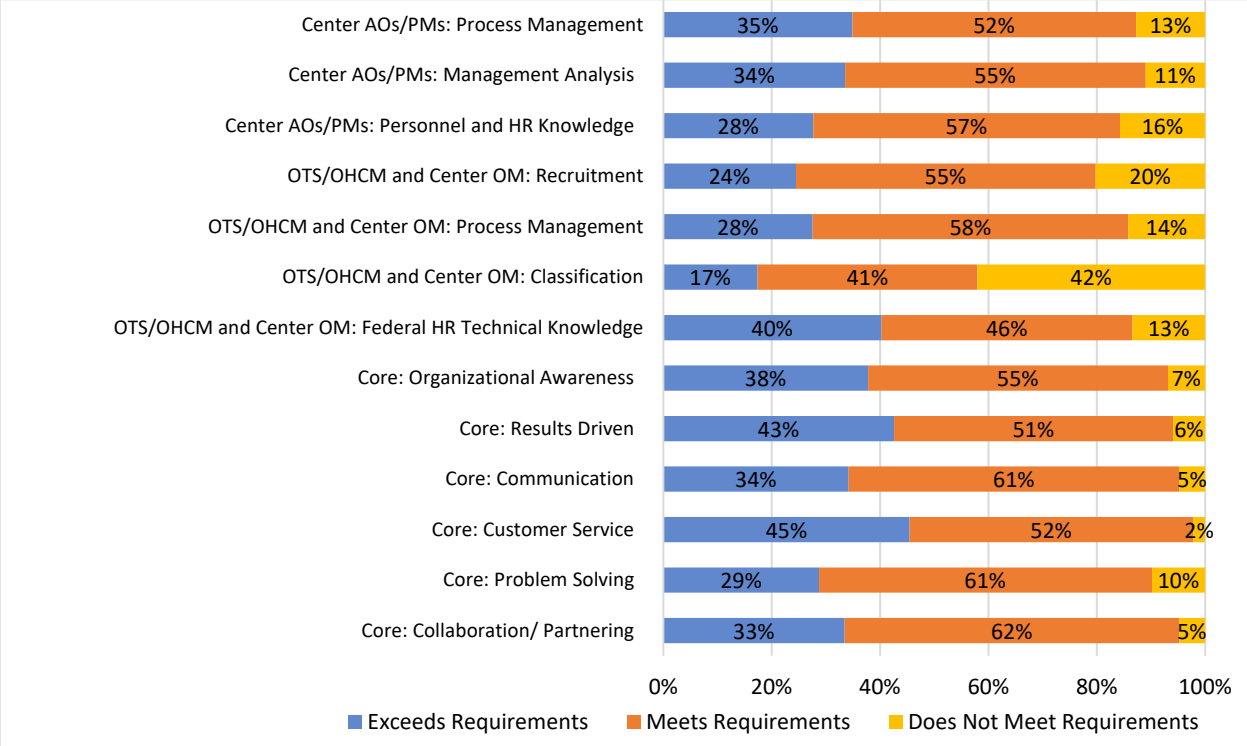
F3.3 Hiring managers are unsatisfied with the abilities of HR staff, especially those in the Agency's HR Organization and Center OMs; however, managers of HR staff reported that HR staff generally meet or exceed competency proficiency requirements.

Exhibit S-26: HR Manager Survey—Competency Proficiency[130]



Respondents: The number of HR staff being rated for each competency varies (n=137-275). Survey item: "In which of the following competencies do your Federal Government staff most need additional learning and development?" A "Does Not Require This Competency" response option was also provided; those responses are not included in this analysis.

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Exhibit S-27: Interview and Focus Group Themes—HR Staff Competency Gaps[131]

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent do HR staff have the KSAs needed to meet or exceed performance targets for recruiting, hiring, and retention?	Many of the HR staff have gaps in one or more of the KSAs identified as key.	Int: 1st out of 4 major themes
	With a few exceptions, many of the HR staff have gaps in one or more of the KSAs identified as key.	FG: 1st out of 1 major theme
	Some members of the HR workforce have stronger skills than others.	Int: 2nd out of 4 major themes
	Capability gaps are exacerbated by losses of skilled HR staff, a large number of new HR staff, and challenges associated with the process of managing poor performers.	Int: 3rd out of 4 major themes
	To address these gaps, some recommend more targeted recruiting efforts, while others recommend a more focused training strategy, use of motivational tools, and reshaping roles to better match the talent that FDA has.	Int: 4th out of 4 major themes

[130] Source: HR Workforce Manager Survey.

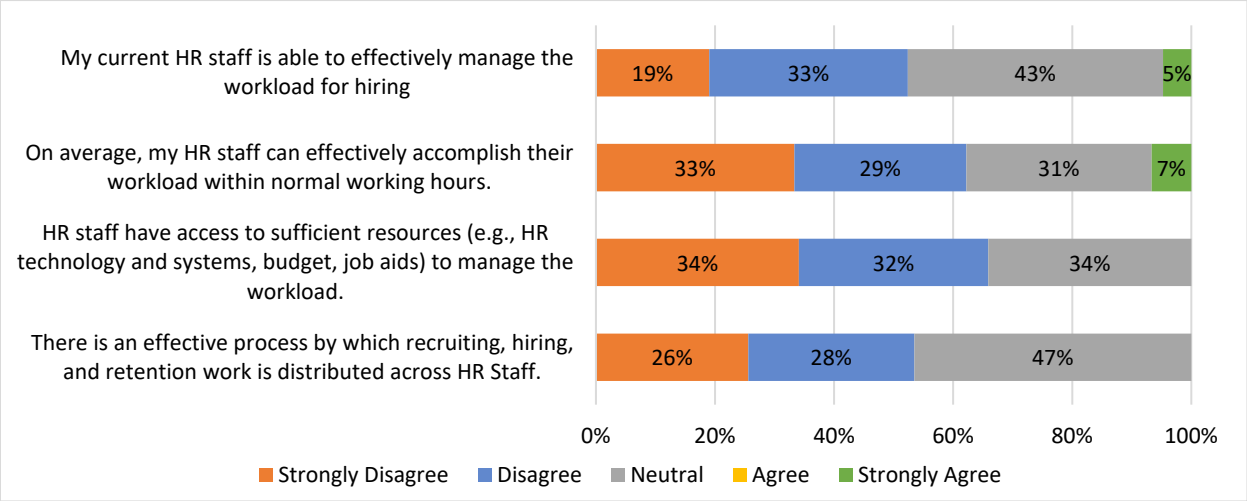
[131] Note: Also includes relevant comments from the interview question: "To what extent do HR staff have the KSAs needed to meet or exceed performance targets for recruiting, hiring, and retention?"

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What, if any, critical skill gaps exist for HR Staff (e.g., OTS, OHCM, CDER: HC Liaisons within the Center, HC Liaisons within OM, CBER: HC Liaisons within OM, PMs within the offices)?	Specific gaps include HR technical skills, followed by communications and customer service, ability to understand hiring managers' needs, and technology.	Int: 1st out of 1 major theme
	Communications and customer service were the biggest skill gaps identified, followed by HR technical skills and the ability to understand hiring managers' needs.	FG: 1st out of 2 major themes
	Other skill gaps identified less frequently include computer skills, time management, process management, organizational skills, and accountability.	FG: 2nd out of 2 major themes

Return to Main Report - Section F3.3
Return to Main Report - Section F3.3, second reference
Return to Main Report - In Exhibit 27

F3.4 HR Staff and managers of HR Staff say they are unable to manage the current workload and see a need for additional resources to effectively do so, especially in support of classification work.

Exhibit S-28: HR Manager Survey—HR Workload Management[132]



Respondents: HR Managers (number of responses varies by item; n=47-49). Survey item: "Please indicate your agreement with the following statements." A "Don't Know" response option was also provided; those responses are not included in this analysis.

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Exhibit S-29: Interview and Focus Group Themes—Resources for Recruiting, Hiring, and Retention

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent are there sufficient HR staff, technology, and/or other resources to [recruit/hire/retain] sufficient numbers of qualified human drug and biologics review program staff?	There are insufficient personnel, technology, and funding resources to track and manage the workload (including classification); this impacts HR's ability to conduct quality reviews and results in backlogs. This is especially a challenge for the Centers, who say they have increased responsibilities, but have not received additional resources.	Int: 1st out of 2 major themes

[132] Source: HR Workload Manager Survey.

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
	With a couple of exceptions, participants believe there are insufficient personnel and other resources to manage the workload; there is a backlog in classification and FDA needs better systems for managing and distributing the work, more streamlined processes with clear standard operating procedures (SOP), better defined roles and accountability (to minimize re-work), and integrated systems that provide sufficient transparency regarding the status of actions.	FG: 1st out of 1 major theme

Return to Main Report – Section F3.4
Return to Main Report – Section F3.4, second reference

Culture, Collaboration, and Communication

F4.1 Overall, the hiring process is seen as ineffective and inefficient, driven largely by complex and unclear process guidance, as well as inadequate collaboration and handoffs among the parties involved in the process.

Exhibit S-30: Interview and Focus Group Themes—HR Process Communication and Collaboration

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What helps the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these helping factors?	The hiring process is more effective in the atypical situations where there are collaborative partnerships between hiring managers and qualified, reliable HR staff, and when clearly defined processes and guidelines are in place to establish transparency and a shared understanding of how to conduct the process consistently and accurately.	Int: 4th out of 4 major themes FG: 1st out of 1 major theme
What could be improved about how recruiting, hiring, and retention work is managed and distributed?	Challenges with collaboration between OTS/OHCM and Center level HR staff (e.g., contentious meetings, lack of transparency and ownership for errors) have affected HR's ability to manage the workload and prioritize work.	Int: 1st out of 1 major theme

Return to Main Report – Section F4.1
Return to Main Report – Section F4.1, Exhibit 27

Exhibit S-31: Interview and Focus Group Themes—Overall Hiring Process Effectiveness

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
Overall, how effective is recruiting, hiring, and retention for human drug and biologics review program staff in [CDER/CBER]?	Because of overwhelming and persistent challenges, hiring, and to a lesser extent, recruiting and retention, are considered ineffective.	Int: 1st out of 2 major themes FG: 1st out of 2 major themes
	Some aspects of recruiting, hiring, and retention are effective, due in part to recent improvements (e.g., use of Cures Act, Hiring Pilot, instances of more effective collaboration).	Int: 2nd out of 2 major themes FG: 2nd out of 2 major themes
What hinders the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these hindering factors?	The hiring process is too long and cumbersome (including issues with Classification and Qualification review), complicated by unclear and changing policies and procedures, highly restrictive HR requirements, backlogs, inconsistencies, and issues getting qualified candidates on certificates.	Int: 1st out of 4 major themes FG: 1st out of 5 major themes

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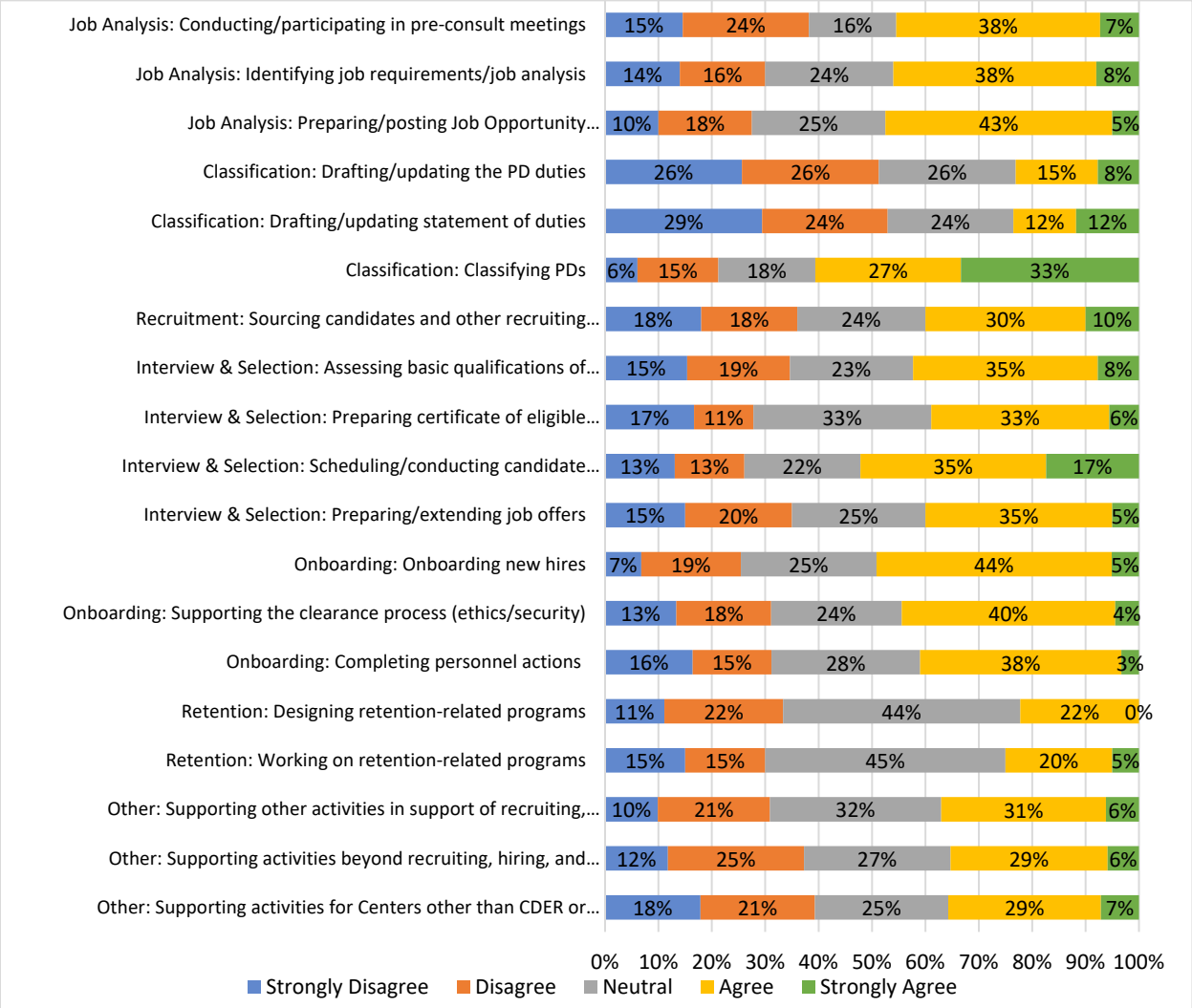
Exhibit S-32: HR Staff Survey—Processes and Procedures are Well Documented[133]



Respondents: HR Staff (n=9-82). Survey item: "In this stage, processes and procedures are well documented". Responses were based on a five-point agreement scale (1-Strongly Disagree; 2=Disagree; 3=Neutral; 4=Agree; 5=Strongly Agree).

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Exhibit S-33: Policy Documents and SOPs Updated Since the Initial Assessment (September 2017)[134]

POLICY AREA	CORRESPONDING POLICY DOCUMENT SOP	LAST UPDATED
Employee Performance, Appraisal, and Awards	FDA Performance Management Appraisal Program	1/1/2020
	FDA Reward and Recognition Program	11/13/2018
Classification and Compensation	HHS Instruction 511-1: Position Classification	5/16/2018
	Market Pay (Title 38)	6/18/2019
Employment and Retention	FDA SOP 300-04: Subject Matter Experts	11/8/2019
	FDA SOP 300-21: Merit Promotion Plan for Non-Bargaining Units	9/18/2019
	FDA SOP 300-13: Direct Hire Authority	6/12/2019
	HHS Instruction 302-1: Employment in the Excepted Service	9/6/2018

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[133] Source: HR Workforce Staff Survey.
[134] Source: InsideFDA.gov; Initial Assessment OHR Policy Documentation Review 2018, OTS.

Recruiting and Hiring Processes

F5.2 Despite the high numbers of applications, internal stakeholders view recruiting as ineffective, particularly noting the challenges of targeting the most suitable applicants based on candidate self-assessment on the application questionnaire and the minimum qualification standards.

Exhibit S-34: Focus Group and Interview Themes—Factors that Help and Hinder Recruiting Effectiveness

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What helps the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these helping factors?	Recruiting is generally effective because people are attracted to working at FDA; existing recruiting channels and corporate recruiting resources have been useful.	Int: 3rd out of 4 major themes
What hinders the effectiveness of recruiting, hiring, and retention of human drug and biologics review program staff in [CDER/CBER]? What is the cause of these hindering factors?	Recruiting challenges include: lack of a strategic or targeted approach to recruiting; the need for Centers to identify their own candidates, especially for technical, scientific, and specialized positions; USAJOBS' rigid questionnaires and non-specific job announcements and qualification standards; limited options for hiring processes; and a hiring backlog that was exacerbated by the government shutdown in 2018-19.	Int: 1st out of 3 major themes FG: 4th out of 5 major themes

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Exhibit S-35: Focus Group Theme—Challenging Positions to Recruit, Hire, and Retain

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What positions and/or career levels in [CDER/CBER] pose the greatest challenges to recruit, hire, and retain? What do you think causes these challenges?	Medical and scientific positions, including pharmacologists and toxicologists, oncologists, pharmacists, chemists, and nurses.	FG: 1st out of 3 major themes

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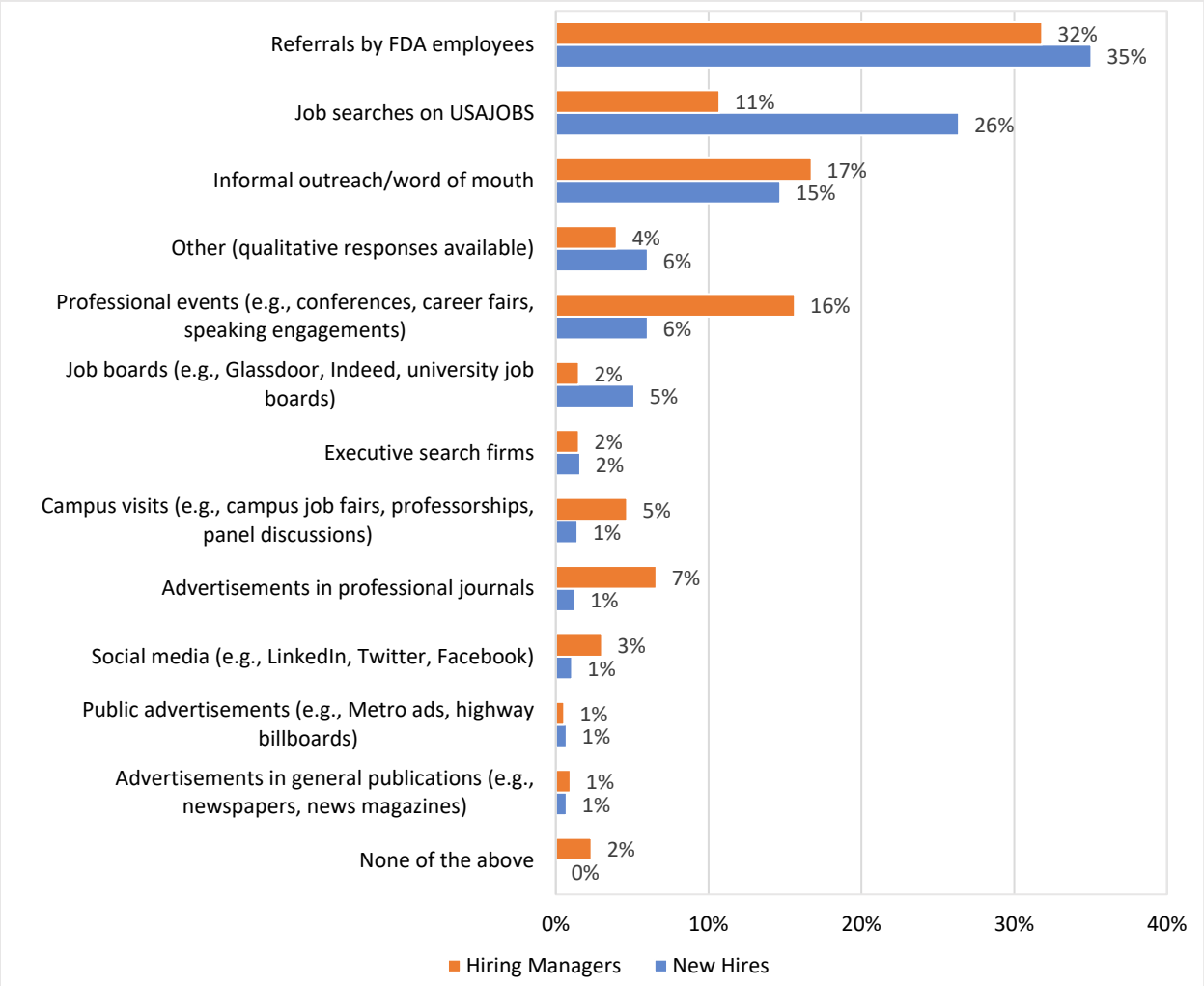
Exhibit S-36: CDER/CBER Staff Survey (Hiring Managers and New Hires)—Most Productive Recruiting Channels[135]



Note: The number of responses for each group exceeds the total number of survey respondents, as participants were permitted to make multiple selections. New hires = 565 responses; hiring managers = 729 responses. Likewise, the total percentages presented in the chart exceeds 100 percent for new hires and hiring managers.

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Exhibit S-37: Center Staff Survey Theme—Recruiting

OPEN-ENDED QUESTION	THEME(S) FROM SURVEY COMMENTS	STRENGTH OF THEME
Please provide any additional feedback you may have regarding improvements to recruiting, hiring, and retention of human drug and biologics review program staff at FDA.	Recruiting qualified human drug and biologics review program staff poses a challenge due to incomparable compensation and work flexibilities (e.g., extensive telework opportunities) offered by the private and academic sector; benefits offered by FDA are no longer an incentive to candidates as similar benefits are now being offered externally.	Center Survey: 2nd out of 4 major themes

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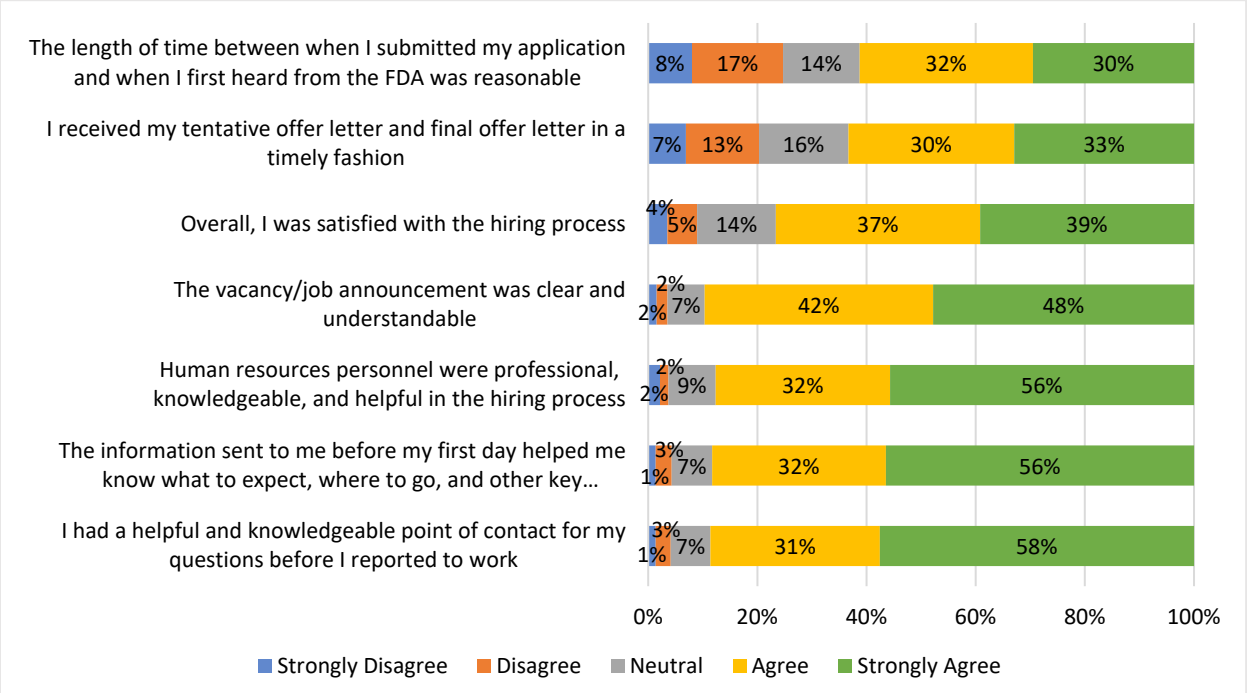
[135] CDER/CBER Staff Survey.

F5.3 According to new hires, candidates who accepted job offers and onboarded generally had a positive experience with FDA's recruiting process.

Exhibit S-38: FDA New Employee Onboarding Survey (CDER and CBER New Hires)—New Hire Experience with Recruiting[136]



Responses: Number of responses varies by question (n=514-517). A "Not Applicable" response option was also provided; those responses are not included in this analysis.

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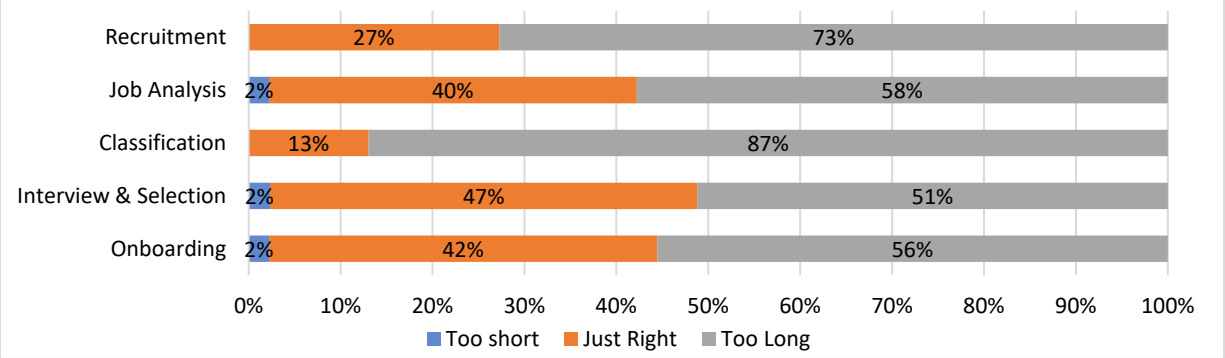
Return to Main Report – Section F5.5

F5.5 The hiring process—particularly classification—is widely seen as ineffective and inefficient; suggestions for improving these challenges include greater transparency, common understanding of process requirements, and more collaborative problem-solving.

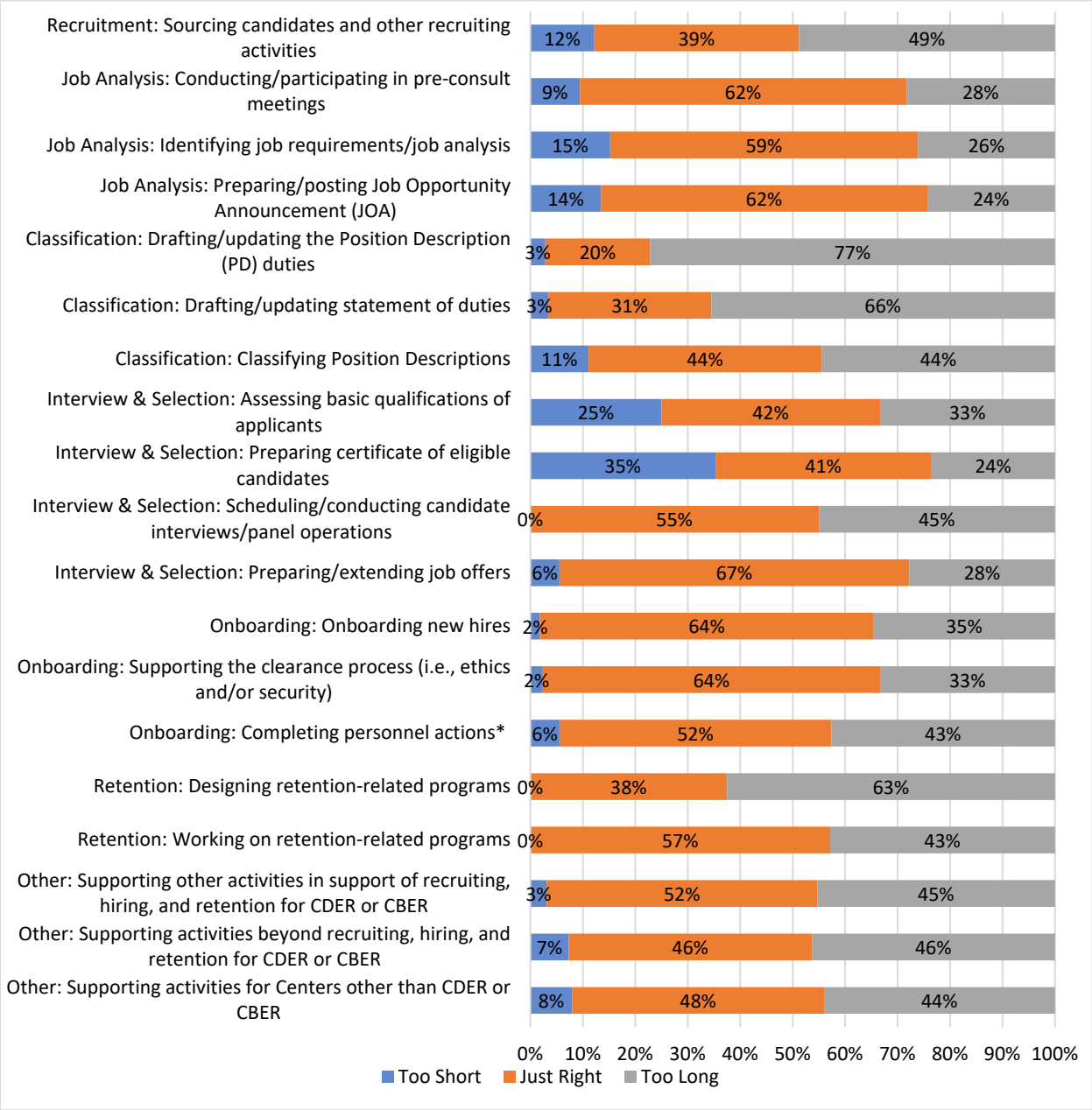
Exhibit S-39: HR Manager Survey—Length of Process Steps (Too Short, Too Long, Just Right)[137]



Respondents: Managers of HR Staff (n=41-46). Survey item: "On average, the time it takes to complete this stage is:".

[136] Source: FDA New Employee Onboarding (NEO) Survey 08.2017 to 11.2019.
[137] Source: HR Workforce Manager Survey.

Exhibit S-40: HR Staff Survey—Length of Process Steps (Too Short, Too Long, Just Right)[138]



Respondents: HR Staff (n=9-79). Survey item: "On average, the time it takes to complete this stage is:". A response option of "Don't Know" was also provided, and those responses are not included in the analysis.

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[138] Source: HR Workforce Staff Survey.

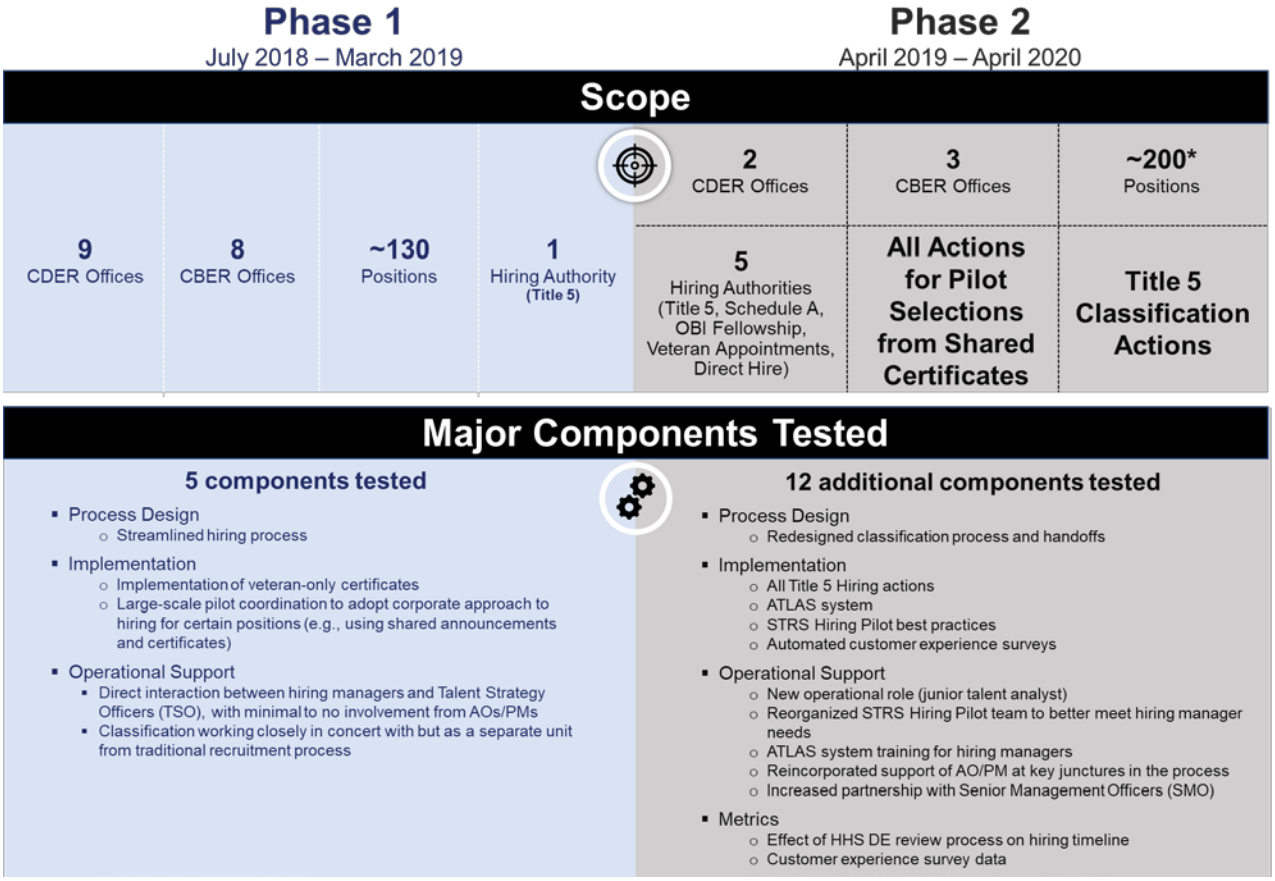
Exhibit S-41: Interview and Focus Group Themes—Process Efficiency

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
What hinders the efficiency of the recruiting and hiring processes? What causes these challenges?	Center staff believe classification experiences significant delays due to back and forth between hiring managers and HR staff based on HR's lack of consistency due to limited documentation of guidance and historical information due to poor system integration and data management.	Int: 7th out of 7 major themes FG: 5th out of 5 major themes
Where do you see the most efficiencies AND inefficiencies in the recruiting and hiring process?	Inefficiencies (e.g., inaccurate offer letters, personnel processing errors, delayed correspondence) are most prevalent during package creation, classification, evaluation, and selection phases.	Int: 1st out of 1 major theme FG: 1st out of 2 major themes

Return to Main Report – Section F5.5
Return to Main Report – Section F5.7

F5.7 The Hiring Pilot demonstrated success in reducing overall time-to-hire with the use of shared certificates and its streamlined process; however, numerous adjustments to the Hiring Pilot, as well as limited outcome data, have made it difficult to measure and assess its true level of effectiveness.

Exhibit S-42: Hiring Pilot Data—Phase 1 versus Phase 2[139]



*Quantity reflects the planned scope but is inconsistent with the actual number of positions reflected in the Pilot data.

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[139] Sources: STRS Hiring Pilot – SOP (Phase II), OTS; STRS Hiring Pilot – Stand-Alone Processes (Phase I and II), OTS; STRS Hiring Pilot Launch Presentation (Phase II), OTS; STRS Hiring Pilot Data 09.2018 to 11.2019, Manual Reporting (SharePoint/Microsoft Excel); STRS Hiring Pilot Scope of Activities (Phase II), OTS.

Exhibit S-43: Interview and Focus Group Themes—Hiring Pilot

QUESTION	MOST RELEVANT THEME(S)	QUESTION
What are the differences in the efficiency of processes associated with the STRS Hiring Pilot, Title 5, Title 38, Title 42 and Special Placements and Appointments (e.g., veterans' preference)?	The Hiring Pilot is perceived as being faster while all other hiring processes are generally considered inefficient.	Int: 2nd out of 2 major themes FG: 2nd out of 2 major themes
What are the differences in the effectiveness of processes associated with the STRS Hiring Pilot, Title 5, Title 38, Title 42 and special placements and appointments (e.g., veterans' preference)?	Hiring options considered to have issues include: Title 5 (e.g., well-understood but also long and arduous), Title 38 (e.g., difficulties with process coordination), special placements (e.g., bottlenecks for validation requirements) and the Hiring Pilot (e.g., effectiveness unclear due to limited positions/Offices included).	Int: 1st out of 2 major themes
To what extent has the STRS Hiring Pilot improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Hiring Pilot effectiveness is limited by communication issues (e.g., last-minute notification of changes, inconsistent messages), changes in participating Offices over time, excluding Center OM staff during Phase I), limited training for HR staff, and a perception of misleading performance metrics (e.g., excluding the time-consuming classification step).	Int: 1st out of 2 major themes FG: 1st out of 2 major themes
	The Hiring Pilot has helped streamline the process (e.g., reduced time-to-hire) and improve accountability (e.g., added well-defined roles and metrics), and it should be expanded beyond Title 5 roles.	Int: 2nd out of 2 major themes
	Those who did not participate in the Hiring Pilot received inconsistent invitations: some Offices were given the option to join (but declined to participate), while others applied and were rejected (e.g., after they were initially told they could join).	FG: 2nd out of 2 major themes

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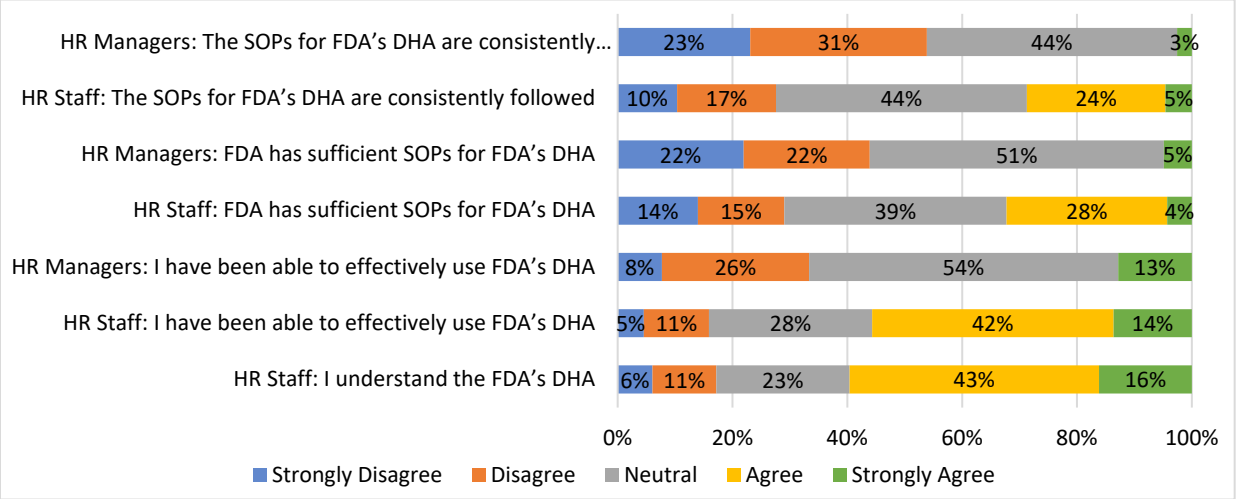
F5.9 DHA is considered one of the more efficient flexibilities for hiring, especially compared to the traditional Title 5 hiring process.

Exhibit S-44: Manager and HR Staff Surveys—DHA[140]



Respondents: The number of responses varies for each question: HR Staff (n=116-118); Managers of HR Staff (n=50-51). Survey item: "Please indicate your agreement with the following statements about FDA's Direct Hire Authority." A "Not Applicable" response option was also provided; those responses are not included in this analysis.

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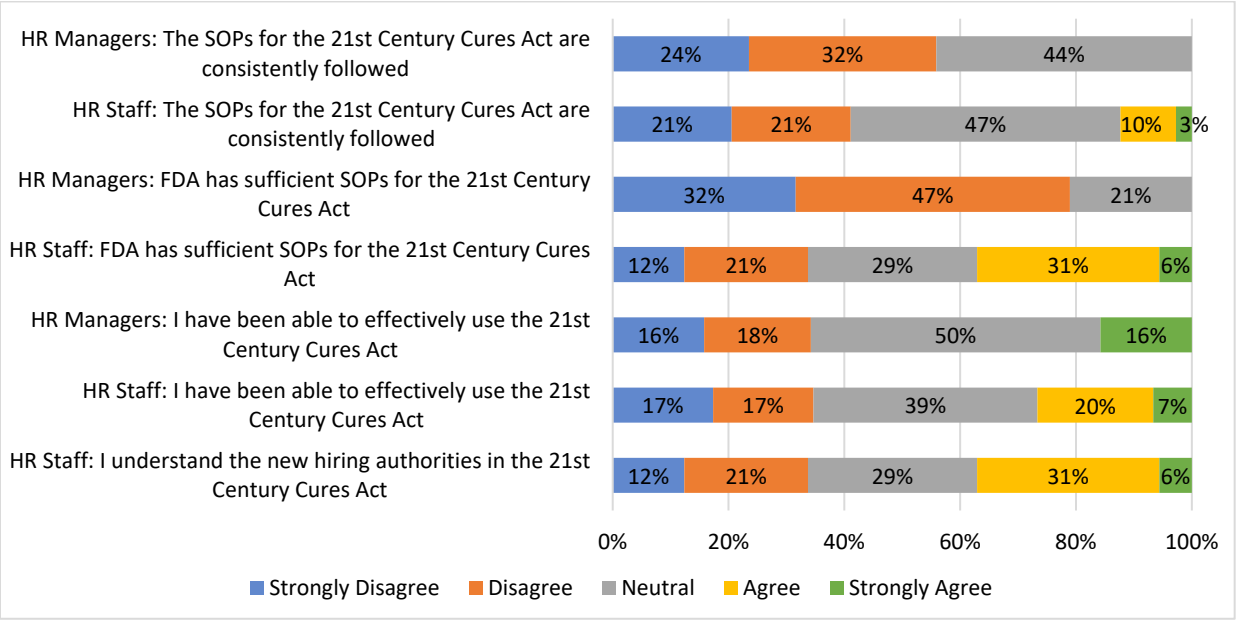
[140] Sources: HR Workload Staff Survey; HR Workload Manager Survey.

F5.10 Cures' streamlined hiring process allows FDA to hire external talent more quickly, and stakeholders see a need for enhanced training and guidance to ensure its consistent implementation across the Agency.

Exhibit S-45: HR Managers and HR Staff Surveys—21st Century Cures Act[141]



Survey item: "Please indicate your agreement with the following statements." Respondents: Number of responses varies for each survey item: HR Staff (n=116-125), Managers of HR Staff (n=50-52). A "Not Applicable" response option was also provided; those responses are not included in this analysis.

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Exhibit S-46: Interview and Focus Group Theme—21st Century Cures Act

QUESTION	MOST RELEVANT THEME(S)	STRENGTH OF THEME
To what extent has the 21st Century Cures Act improved the recruiting, hiring, and retention of human drug and biologics review program staff? What factors are helping or getting in the way of this activity's success?	Effectiveness of the Cures Act hiring flexibility is limited by inadequate training and guidance for HR staff (e.g., implementation started before procedures were finalized), as well as inconsistent implementation across the Centers that led to perceptions of "staff poaching."	Int: 1st out of 2 major themes FG: 1st out of 2 major themes

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[141] Sources: HR Staff Survey; HR Workforce Manager Survey.

ATTACHMENT: EXHIBIT DESCRIPTIONS FOR ASSISTIVE TECHNOLOGY USERS

Exhibit 1: Study Design

This graphic shows the study design, broken into three assessments: Initial (November 2017), Interim (March 2020), and Final (December 2021). A breakout of assessment components is listed for each time period, as well as current improvement activities.

The Initial Assessment in November 2017 assessed Hiring Process. It focused on:

- Key findings
- Root causes
    - Processes and policies
    - Organization and people
    - Data and systems
    - Culture and mindsets
- Recommendations

The Interim Assessment in March 2020 is currently assessing Recruiting, Hiring, and Retention. It is focused on:

- Progress since the Initial Assessment
    - Progress against Initial Assessment recommendations
    - Progress on improvement activities
- Findings and Conclusions
    - Strategy
    - Data Management and Systems
    - HR Capability and Capacity
    - Culture, Collaboration, and Communication
    - Recruiting and Hiring Processes
- Recommendations

The Final Assessment in December 2021 has a design that is to be determined.

Current Improvement Activities include:

- OHR Reorganization into OTS and OHCM
- Hiring Pilot
- CURES Act
- Expansion of Direct Hire Authority
- Scientific Staffing Team

Potential Future Improvement Activities will include those that are new and/or continuing.

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Exhibit 2: Interim Assessment Methodology

Our Interim Assessment methodology includes a four-step approach:

1. Plan Assessment

Action: Develop Data Collection Instruments

- Assessment framework
- Custom data collection instruments
- Tracking tool for FDA system data

2. Capture Data

Action: Collect Quantitative and Qualitative Metrics

- FDA organization documents
- FDA data files
- Leadership Interviews
- HR stakeholder focus groups
- Center and HR Workforce Surveys
- Benchmarking data

3. Analyze Data

Action: Develop Recommendations to Address Gaps In Performance

- HR process efficiency
- HR process effectiveness
- HR staff capacity
- HR staff capability
- Progress and effectiveness of improvement activities
- Recommendations to address identified gaps and priority areas

4. Synthesize Results

Action: Develop Documents

- Assessment report
- Public meeting presentation
- Public comments evaluation
- Implementation plan

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Exhibit 6: Implementation Progress of Improvement Activities

The graphic uses a test tube beaker filled to varying levels to visualize the levels of implementation progress (foundational, integrated, and optimized) for each of the five improvement activities.

- **Full Beaker = Optimized:** Activity is fully implemented, widely known and embraced within CDER and CBER, and measurably transforming recruitment, hiring, and/or retention.
- **2/3 Full Beaker = Integrated:** Activity is partially implemented, gaining awareness within CDER and CBER, and has made some incremental improvements to recruiting, hiring, and/or retention.
- **1/3 Full Beaker = Foundational:** Activity is designed but not yet implemented, is not yet well known among CDER and CBER, and has not yet demonstrated impact to recruiting, hiring, and/or retention.

The test tube levels visually indicate that all five improvement activities fall within the Integrated level of progress. Each improvement activity lists representative accomplishments that resulted in the integrated implementation level and also recommend activities to help obtain optimal implementation (which are aligned to select recommendations in this Interim Assessment, such as R-2, R-8, etc.).

- **STRS Hiring Pilot**
  - Representative accomplishments resulting in integrated implementation:
    - Demonstrated reduced time-to-hire with certain parameters through its streamlined process
    - Demonstrated time-savings through the use of shared certificates
    - Introduced applicant tracking with the ATLAS system
    - Created a new Talent Strategy Officer role to improve communications with hiring managers
  - Suggested activities aligned to report recommendations:
    - Improve data management and reporting capabilities (R-4, R-6) tied to outcome/success measures (R-17)
    - Expand system integrations (R-5)
    - Increase pilot communication products (R-12)
    - Create a centralized knowledge management repository for pilot documentation and communications (R-15)
- **OHR Reorganization**
  - Representative accomplishments resulting in integrated implementation:
    - Instituted new levels of management focused on the Centers
    - Separated pre-employment activities from employee experience services
    - Centralized dedicated teams with functional expertise to enhance quality control and scalability for critical or specialized hiring components
    - Enhanced HR employee accountability with new HR performance management action plans
  - Suggested activities aligned to report recommendations:
    - Design a well-coordinated organizational strategic plan (R-2)
    - Create a stakeholder engagement strategy (R-11) and tactical communication products (R-12)
    - Foster a collaborative, customer-centric culture (R-10) and reframe roles (R-7)
    - Develop workload management processes and tools (R-8)

- **21st Century Cures Act**
  - Representative accomplishments resulting in integrated implementation:
    - Made 47 appointments across CDER and CBER (data through Sept 30, 2019)
    - Delivered mandated FDA Workforce Planning Report, Recruiting and Retention Plan, and Recommendations to Congress
    - Implemented governance structure, including a HR Cures Working Group and Steering Committee
    - Designed and implemented new Alternative Pay Structure (APS)
  - Suggested activities aligned to report recommendations:
    - Create a strategic stakeholder engagement strategy (R-11) along with a detailed communication plan (R-13) and tactical communication products (R-12) regarding FDA's procedures and use of Cures
    - Define outcome/success measures (R-17) tied to specific hiring goals and targets (R-3)
- **Scientific Staffing Team**
  - Representative accomplishments resulting in integrated implementation:
    - Generated a unified FDA recruitment brand and presence at external events
    - Launched new FDA social media presence for recruitment and outreach; increased online traffic
  - Suggested activities aligned to report recommendations:
    - Created 100+ external partnerships with government, professional associations, and academic institutions to develop a pipeline of highly qualified candidates with a focus on STEM talent
    - Hosted 12+ academic visits on the White Oak campus in 2018 and 2019
    - Introduced a recruiting effort for Veterans and persons with disabilities
    - Create a strategic stakeholder engagement strategy (R-11) and tactical communication products (R-12) with a collaborative, customer-centric culture (R-10)
    - Identify outcome/success measures (R-17) tied to specific hiring goals/targets (R-3)
- **Expansion of Direct Hire Authority**
  - Representative accomplishments resulting in integrated implementation:
    - 100% of CBER Direct Hires and 30% of CDER Direct Hires in FY2019 were associated with the authority's expanded positions
  - Suggested activities aligned to report recommendations:
    - Create a detailed communication plan (R-13) and tactical communication products (R-12) regarding OPM requirements for and FDA's procedures and use of DHA
    - Define outcome/success measures (R-17) tied to specific hiring goals and targets (R-3)

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Exhibit 8: OHR Reorganization

In July 2018 the Office of Human Resources was reorganized into the Office of Talent Solutions and the Office of Human Capital Management.

Originally, the Office of Operations, led by the Chief Operating Officer, oversaw the Office of Human Resources. The Office of Human Resources included the following divisions:

- Division of Enterprise Services and Solutions
- Workforce Relations Division
- Division of Training and Development
- Division of Human Capital Solutions
- HR Services Division I
- HR Services Division II

As a result of the reorganization, the Office of Operations now oversees two new offices, the Office of Talent Solutions and the Office of Human Capital Management. The Office of Talent Solutions focuses on Policy, Sourcing, Recruiting, and Hiring. The Office of Human Capital Management focuses on Onboarding, Developing, Supporting, and Retaining. (Note: While OHCM manages work-life retention programs, OTS manages monetary retention programs and incentives.)

The Office of Talent Solutions (OTS) is led by the OTS Director and includes the following divisions:

- Division of Talent Services I
- Division of Talent Services II
- Division of Talent Services III
- Division of Talent Services IV
- Division of Talent Sourcing and Staffing (Title 38, Scientific Staffing and Outreach, Customer Care and Quality)
- Classification Unit
- FDA Commissioned Corps Affairs Staff
- Scientific Talent Recruitment Staff
- Business Operations Staff
- Policy and Accountability Staff
- Executive Resources Staff

The Office of Human Capital Management is led by the OHCM Director and includes the following divisions:

- Division of FDA Training and Development
- Division of Human Resources Systems
- Division of Strategic Talent Management Programs
- Division of Employee and Labor Relations
- Performance Management and Awards Staff
- Management Investigations and Administrative Inquiries Staff
- Business Operations Staff

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Exhibit 22: Initial and Interim Surveys (Hiring Managers)—Satisfaction with Abilities of HR Staff in Various Roles

These bar charts show CBER and CDER hiring managers responses to survey items on satisfaction with HR staff in various roles of CBER and CDER hiring managers captured during initial and interim assessment in two separate charts. HR staff response choice used in the initial assessment chart is OHR Servicing Team. Responses are presented for several abilities: Knowledge of regulations, policies, and procedures, timeliness, communication, initiative, flexibility, and customer service. Specific responses are: Knowledge of regulations, policies, and procedures: 32%, timeliness: 15%, communication: 17%, initiative: 17%, flexibility: 20%, and customer service: 25%.

Response choices for the interim assessment chart are OTS/OHCM Staff (not Hiring Pilot), OTS/OHCM Staff (Hiring Pilot), Center OM HC Liaisons, and Interim: Center PMs/AOs. Responses are presented for several abilities: Apply accurate knowledge of HR policies and procedures required, Meet timelines and commitments, Provide information to help me understand the hiring and recruitment process, Take the initiative to solve problems that arise, Provide appropriate options and alternative solutions, as needed, and Coordinate with all HR parties necessary to complete the hiring process. Specific responses are: “Apply accurate knowledge of HR policies and procedures required”: OTS/OHCM Staff (not Hiring Pilot) 7%, OTS/OHCM Staff (Hiring Pilot) 8%, Center OM HC Liaisons 19%, Center PMs/AOs 46%; “Meet timelines and commitments”: OTS/OHCM Staff (not Hiring Pilot) 5%, OTS/OHCM Staff (Hiring Pilot) 5%, Center OM HC Liaisons 15%, Center PMs/AOs 42%; “Provide information to help me understand the hiring and recruitment process”: OTS/OHCM Staff (not Hiring Pilot) 6%, OTS/OHCM Staff (Hiring Pilot) 7%, Center OM HC Liaisons 15%, Center PMs/AOs 41%; “Take the initiative to solve problems that arise”: OTS/OHCM Staff (not Hiring Pilot) 5%, OTS/OHCM Staff (Hiring Pilot) 4%, Center OM HC Liaisons 12%, Center PMs/AOs 41%; “Provide appropriate options and alternative solutions, as needed”: OTS/OHCM Staff (not Hiring Pilot) 6%, OTS/OHCM Staff (Hiring Pilot) 5%, Center OM HC Liaisons 12%, Center PMs/AOs 38%; “Coordinate with all HR parties necessary to complete the hiring process”: OTS/OHCM Staff (not Hiring Pilot) 6%, OTS/OHCM Staff (Hiring Pilot) 5%, Center OM HC Liaisons 13%, Center PMs/AOs 39%.

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Exhibit 35: Time-to-Hire Comparison of Traditional Title 5 Process Versus Hiring Pilot

The graphic compares the Traditional Title 5 hiring process (from the Initial Assessment) to the Hiring Pilot process (from this Interim Assessment).

The Traditional Title 5 hiring process stages result in a total timeline of 150-550 days, with an additional 22-300 days if classification is required. The process includes eight stages and observed timeframes as recorded from qualitative stakeholder interviews during the Initial assessment:

- Stage 1: Request Classification if necessary (22-300 days);
- Stage 2: Initiate Package (5-30 days);
- Stage 3: Prepare for Posting (30-90 days);
- Stage 4: Post Job Opportunity (5-30 days);
- Stage 5: Compile Certificates which includes a qualifications review of all applications (14-60 days);
- Stage 6: Evaluate Candidates (30-60 days);
- Stage 7: Extend Offer (30-45 days); and
- Stage 8: Entry on Duty (30-200 days).

The Hiring Pilot hiring process stages result in a total timeline of 22-87 days using process stages required for stand-alone certificates, and 12-94 days for process stages required for shared certificates. The Hiring Pilot was not designed to track or measure the classification stage of the process (see process stage 1 from the Traditional Title 5 process), and therefore it is not possible to determine if there was a reduction in time-to-hire for the classification stage for the Hiring Pilot.

For stand-alone certificates, the process include includes six stages (mirroring stages 2-8 from the Traditional Title 5 hiring process but with revised names for the stages) and lists actual time-to-hire ranges and averages of days from recorded Hiring Pilot data, and the number of actions assessed for the particular process stage:

- Combined Stage 2 and 3: Talent Launch (Range: 1-29 Days; Average: 11 Days; N: 27);
- Stage 4: Talent Sourcing (Range: 5-27 Days; Average: 10 Days; N: 27);
- Stage 5: Talent Evaluation (Range: 1-29 Days; Average: 10 Days; N: 27);
- Stage 6: Interview and Selection (Range: 1-57 Days; Average: 13 Days; N: 50);
- Stage 7: Tentative Offer (Range: 2-67 Days, Average: 17 Days, N: 48); and
- Stage 8: Final Offer and Onboarding (Range: 1-39 Days, Average: 13 Days, N: 49).

Regarding gained efficiencies, the Hiring Pilot data show a reduction in time-to-hire (see process stages 2-8). One example of a process efficiency is the use of shared certificates over stand-alone certificates.

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Exhibit 38: FDA Hiring Pilot Data—Phase 1 versus Phase 2 Progress per Stage

The graphic shows data comparing Pilot Phase 1 and Phase 2 for the use of Stand Alone Certificates and Shared Certificates. When stand alone certificates are used, the action progresses through all five hiring process stages (Talent Launch, Talent Sourcing, Talent Evaluation, Interview and Selection, Tentative Offer, and Final Offer). When shared certificates are used, the first three process phases are not applicable, and the action progresses through Interview and Selection, Tentative Offer, and Final Offer. Detailed information-for stand alone certificates in Phase 1 for each process phase includes Talent Launch (N=44, Goal=5 to 15 days, Average=13 days, and Percent Goal Met = 84%), Talent Sourcing (N=44, Goal=5 to 10 days, Average=11 days, and Percent Goal Met = 41%), Talent Evaluation (N=42, Goal=15 to 20 days, Average=24 days, and Percent Goal Met = 69%), Interview and Selection (N=31, Goal=25 to 30 days, Average=36 days, and Percent Goal Met = 48%), Tentative Offer (N=33, Goal=10 to 15 days, Average=11 days, and Percent Goal Met = 58%), and Final Offer (N=33, Goal=20 to 50 days, Average=14 days, and Percent Goal Met = 97%). Detailed information-for stand alone certificates in Phase 2 for each process phase includes Talent Launch (N=27, Goal=10 to 11 days, Average=11 days, and Percent Goal Met = 59%), Talent Sourcing (N=27, Goal= 10.5 days, Average=10 days, and Percent Goal Met = 74%), Talent Evaluation (N=27, Goal=13 to 15 days, Average=10 days, and Percent Goal Met = 96%), Interview and Selection (N=25, Goal=25 to 26 days, Average=12 days, and Percent Goal Met = 68%), Tentative Offer (N=23, Goal=13 to 18 days, Average=12 days, and Percent Goal Met = 87%), and Final Offer (N=23, Goal=12 to 14 days, Average=13 days, and Percent Goal Met = 61%). Detailed information-for shared certificates in Phase 1 for each process phase includes Interview and Selection (N=28, Goal=25 to 30 days, Average=13 days, and Percent Goal Met = 93%), Tentative Offer (N=26, Goal=10 to 15 days, Average=25 days, and Percent Goal Met = 50%), and Final Offer (N=21, Goal=20 to 50 days, Average=25 days, and Percent Goal Met = 90%). Detailed information-for shared certificates in Phase 2 for each process phase includes Interview and Selection (N=25, Goal=25 to 26 days, Average=13 days, and Percent Goal Met = 80%), Tentative Offer (N=25, Goal=13 to 18 days, Average=21 days, and Percent Goal Met = 52%), and Final Offer (N=24, Goal=12 to 14 days, Average=13 days, and Percent Goal Met = 71%).

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Exhibit S-42: Hiring Pilot Data—Phase 1 versus Phase 2

The graphic compares the Traditional Title 5 hiring process (from the Initial Assessment) to the Hiring Pilot process (from this Interim Assessment).

The Traditional Title 5 hiring process stages result in a total timeline of 150-550 days, with an additional 22-300 days if classification is required. The process includes eight stages and observed timeframes as recorded from qualitative stakeholder interviews during the Initial assessment:

- Stage 1: Request Classification if necessary (22-300 days);
- Stage 2: Initiate Package (5-30 days);
- Stage 3: Prepare for Posting (30-90 days);
- Stage 4: Post Job Opportunity (5-30 days);
- Stage 5: Compile Certificates which includes a qualifications review of all applications (14-60 days);
- Stage 6: Evaluate Candidates (30-60 days);
- Stage 7: Extend Offer (30-45 days); and
- Stage 8: Entry on Duty (30-200 days).

The Hiring Pilot hiring process stages result in a total timeline of 22-87 days using process stages required for stand-alone certificates, and 12-94 days for process stages required for shared certificates. The Hiring Pilot was not designed to track or measure the Classification stage of the process (see process stage 1 from the

Traditional Title 5 process), and therefore it is not possible to determine if there was a reduction in time-to-hire for the classification stage for the Hiring Pilot.

For stand-alone certificates, the process include includes six stages (mirroring stages 2-8 from the Traditional Title 5 hiring process but with revised names for the stages) and lists actual time-to-hire ranges and averages of days from recorded hiring pilot data, and the number of actions assessed for the particular process stage:

- Combined Stages 2 and 3: Talent Launch (Range: 1-29 Days; Average: 11 Days; N: 27);
- Stage 4: Talent Sourcing (Range: 5-27 Days; Average: 10 Days; N: 27);
- Stage 5: Talent Evaluation (Range: 1-29 Days; Average: 10 Days; N: 27);
- Stage 6: Interview and Selection (Range: 1-57 Days; Average: 13 Days; N: 50);
- Stage 7: Tentative Offer (Range: 2-67 Days, Average: 17 Days, N: 48); and
- Stage 8: Final Offer and Onboarding (Range: 1-39 Days, Average: 13 Days, N: 49).

Regarding gained efficiencies, the Hiring Pilot data show a reduction in time-to-hire (see process stages 2 8). One example of a process efficiency is the use of shared certificates over stand-alone certificates.

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