Initial Assessment of FDA Hiring and Retention –
A Path Forward

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FDA U.S. FOOD & DRUG ADMINISTRATION
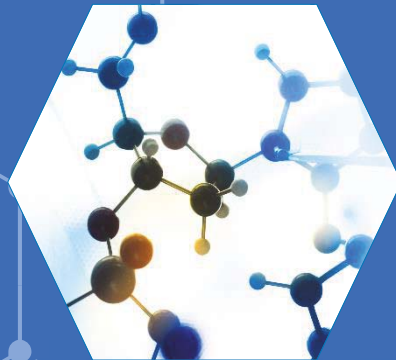
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Section 1. Context

The U.S. Food & Drug Administration (FDA, or Agency) evaluates and approves innovative medical products that bring tremendous benefit to the public every year. FDA relies on a world-class scientific staff, who work together in a complex operational structure. As does any complex organization, FDA faces significant human resource-related challenges. This is especially the case today when many of the specific skills and competencies FDA is seeking are scarce, and competition with other employers is fierce. Building and maintaining the right human capital foundation is critical to FDA's ability to continue to meet its public health mission.

Central to the project of building a solid human capital foundation is a consistent, well-functioning hiring process that attracts talent from the right pools, efficiently acquires and evaluates the most promising applications, and actively welcomes the applicants FDA has decided to hire. Since regaining human resource-related responsibilities from the Department of Health and Human Services (HHS, or Department) in 2012, FDA has struggled to implement an efficient hiring process. Timelines for the end-to-end hiring process are lengthy; candidates and hiring managers report real frustration; and continuing vacancies pose persistent challenges to strategic activities in FDA centers. Although FDA's Office of Human Resources (OHR) has made important improvements around hiring, demands on the Agency's workforce and associated hiring needs continue to grow. There is broad agreement that significant modifications to the hiring process are needed.

This recognition was enshrined in the recent FDA Reauthorization Act of 2017 (FDARA), which enabled the reauthorized Prescription Drug User Fee Act (PDUFA VI), the Biosimilar User Fee Act (BsUFA II), the Generic Drug User Fee Amendments (GDUFA II), and the Medical Device User Fee Amendments (MDUFA IV). As part of the PDUFA and BsUFA reauthorizations, FDA committed to (1) completing the modernization of the hiring system infrastructure; (2) augmenting the hiring staff capacity and capabilities; (3) establishing a dedicated scientific staffing function for the human drug review program; (4) striving to meet the annual, targeted hiring goals by center; and (5) conducting a comprehensive and continuous assessment of the hiring and retention process. [1]

This report describes the findings of an initial diagnosis of the hiring process. The goal was to establish a baseline for assessing FDA's current hiring state and suggest a possible path forward. Given the concentration of PDUFA positions in FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), the diagnosis and resulting report focus primarily on these two centers. The current state is an accumulation of incremental changes that have been made over time to a highly regimented process, a process that was intended to meet the ever evolving needs of the Agency and its stakeholders.

Given that a fundamental redesign of the hiring process would be needed to truly improve recruitment and hiring at FDA, the diagnosis aimed to identify the root causes of current challenges. This report describes the diagnostic process, presents findings, and makes initial recommendations as to a possible roadmap for building a *fit-for-FDA* hiring process for the future. The report also signals the beginning of a long-term modernization process that is aligned with the *Reimagine HHS* initiative. As such, this report does not explicitly cover subsequent changes related to employee retention, value proposition and more, which are forthcoming.

Section 2. Executive Summary

As the Office of Personnel Management's (OPM) "Hiring Excellence" initiative launched in 2016 suggests, FDA is not alone among Federal agencies in its struggle with timeliness, consistency, and quality across its hiring process. Nonetheless, FDA is independently committed to reimagining and modernizing its hiring process. As a first step, FDA has undertaken a diagnosis of the current hiring state, looking to isolate a comprehensive set of root causes for the challenges it faces. Insights from the diagnosis emerged from a broad range of sources, including the following:

> Of 657 FY16
> New Hire survey respondents,
> **only 34%** were satisfied with the
> hiring process overall

- Six quantitative and qualitative surveys; bi-weekly focus groups with >10 attendees; and in-depth 1 on 1 interviews with >35 staff, covering perspectives from across the Agency

- In-depth review of the policies, procedures, and guidance that pertain to the Federal recruitment and selection process

- A series of *customer* focus groups – specifically with FDA hiring managers and new hires – to isolate what creates and destroys value from a customer perspective

- Best practices and learnings sourced from within FDA and external organizations (including the private sector)

- External interviews with a wide range of experts in human capital excellence, lean process optimization, automation, and design thinking

The full set of findings were mapped to a comprehensive root cause *taxonomy*, which captures the universe of potential hiring-related challenges at FDA (see Section 5, Exhibit 5-1). To inform the modernization roadmap, root causes were assessed against two primary dimensions: (1) the degree to which the root cause represents a gap in FDA's hiring process today; and (2) the impact of that gap.

Section 6 presents a summary of the findings, and the Appendix outlines the full set of findings along with detailed supporting evidence. Briefly, the findings suggest the following:

- Process and policy documentation is incomplete – where documentation exists, outputs are not clearly laid out, resulting in substantial variation of process instructions, policy interpretation, and execution

- The end-to-end hiring process itself suffers from substantial complexity, including multiple hand-offs and duplication of work, all of which draw out timelines and frustrates customers

- Unclear positions and responsibilities for the numerous parties involved across the process amplify the complexity of the underlying process, generate executional confusion, and dilute accountability

- The technology and systems underpinning the process do not support process transparency, end user experience, or efficient process execution

- There is a lack of meaningful, collaborative, open, and strategic dialogue between OHR and CDER and CBER, further exacerbating the issues identified above

Taken together, these root causes drive adverse outcomes, a select few of which include the following:

- *Quality of the process:* Of 657 FY16 New Hire Survey respondents, only 34% were satisfied with the hiring process overall[2]

- *Consistency:* Only 11% of CDER and 6% of CBER hiring managers felt that recruiting and hiring processes are standardized and consistent[3]
- *Satisfaction with outcomes:* Only 31% of CDER and CBER hiring managers were "very satisfied" with the quality of their hires[4]

The findings captured in this report confirm the ongoing sense that FDA's hiring process would benefit from a comprehensive redesign and modernization effort. FDA should outline a focused portfolio of easy-to-implement and high-value initiatives that address pain points in the current system. In the meantime, the Agency should continue with current modernization efforts, including development and launch of a controlled pilot to test a completely new and redesigned hiring process. The pilot should test a number of important elements, including the following:

- An optimized, *clean sheet* process design focused on **minimizing handoffs, eliminating unnecessary process steps,** and **reducing total time to hire**

- 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
- Identification and use of **new talent sources**
- **Targeted investments to build HR capabilities** in communication, timeliness, and personal initiative – three core HR competencies with the greatest observed deficiencies
- 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
- 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**

Once the pilot is launched, it should undergo an iterative evaluation process, based on the pilot findings and the five hallmarks of success (i.e., timeliness, accuracy, customer service, employee satisfaction, and quality).

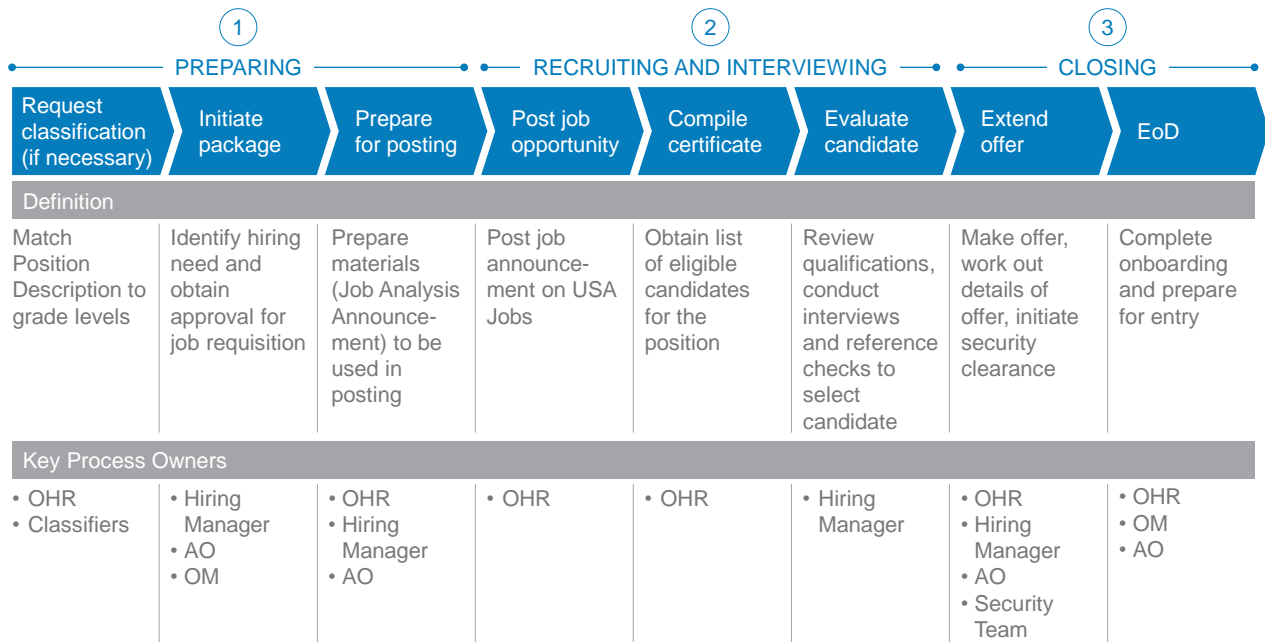In summary, the path forward will rely on piloting, measuring, and scaling up a completely redesigned hiring process. FDA has already begun the design of the pilot, which is slated to launch in 2018. The pilot will be used as a vehicle to hire several mission critical occupations in support of PDUFA VI and BsUFA II. A report on the pilot and on broader issues related to hiring and retention is scheduled for 2020.

Section 3. Basic Facts and Figures on Recruiting and Hiring at FDA

This section presents a high-level overview of the standard process for hiring candidates at FDA and a selection of data points to orient readers to the current performance state. Although there are differences among the numerous *onramps* into FDA (e.g., Corporate Recruitment,[5] Title 42,[6] Commissioned Corps), the *hiring process* referred to in this report essentially reflects the Title 5 hiring process. The end-to-end hiring process is defined as beginning with the opening or allocation of a new vacancy and ending with the entry on duty (EoD) date. The specific steps and primary stakeholders involved are outlined in Exhibit 3-1.

Exhibit 3-1: Schematic of the Title 5 end-to-end process
The Title 5 hiring process (as of FY17) with milestones and primary process owners highlighted.

	PREPARING ①		RECRUITING AND INTERVIEWING ②			CLOSING ③	
Request classification (if necessary)	Initiate package	Prepare for posting	Post job opportunity	Compile certificate	Evaluate candidate	Extend offer	EoD
Definition							
Match Position Description to grade levels	Identify hiring need and obtain approval for job requisition	Prepare materials (Job Analysis Announcement) to be used in posting	Post job announcement on USA Jobs	Obtain list of eligible candidates for the position	Review qualifications, conduct interviews and reference checks to select candidate	Make offer, work out details of offer, initiate security clearance	Complete onboarding and prepare for entry
Key Process Owners							
• OHR • Classifiers	• Hiring Manager • AO • OM	• OHR • Hiring Manager • AO	• OHR	• OHR	• Hiring Manager	• OHR • Hiring Manager • AO • Security Team	• OHR • OM • AO

An overview of who the primary process owners are and the organizational department they report through is outlined in Exhibit 3-2 below.

Exhibit 3-2: Summary of primary stakeholders involved in the hiring process at FDA

	Stakeholder	Role in the hiring process
REPORTS THROUGH CENTER	HM (Hiring Manager)	Identify and justify hiring need, evaluate and select new hire
	AO (Administrative Officer)	Assist Hiring Manager with administrative affairs pertaining to preparing paperwork for package contents, scheduling candidate interviews
	OM (Office Of Management)	Review and approve job requisitions, requests for extensions
REPORTS THROUGH OHR	HR Specialist	Lead job posting, candidate qualification, and offer processes
	Classifier	Classify job requisitions against Position Descriptions, identify Centers' hiring needs
	Call-in center	Answer questions from candidates

Sections 3.1, 3.2, and 3.3 contain a summary of relevant basic performance statistics on the current state of hiring at FDA.

3.1 Time to Hire

Currently, the end-to-end hiring process takes from 150-550 days and an additional 22-300 days if classification is required. Exhibit 3-3 breaks down the observed time-to-hire by process step.

Exhibit 3-3: Schematic of observed range of completion times for hiring process steps

| Time to hire observed for positions filled in FY 16–17 | ~150-550 days |

Request classification (if necessary)	Initiate package	Prepare for posting	Post job opportunity	Compile certificate	Evaluate candidate	Extend offer	EoD
22-300 days	5-30 days	30-90 days	5-30 days	14-60 days	30-90 days	30-45 days	30-200 days

3.2 Vacancy Rate

Over the last several years, the size of the FDA workforce has evolved significantly. The allocated FTE count in CDER alone has increased 50% since 2012. However, many of these allocated positions are not being filled because of the backlog that has grown over time. The current vacancy rates in CDER and CBER are both 14%. Compared to benchmark numbers at other government agencies, which have vacancy rates between 5 and 7%, these vacancy rates are considered high.[7] Absent targeted initiatives to conduct large-scale hiring (e.g., the Generic Drug User Fee Amendments (GDUFA) hiring), these vacancy rates have persisted over time. Exhibit 3-5 compares the number of vacant positions with the number filled for CDER and CBER during the 2017 fiscal year.

Exhibit 3-4: Snapshot of CDER and CBER vacancy rates
The vacancy rates in CDER and CBER as a percentage of total positions allocated as of August 2017.[8]

Total positions allocated

CDER FY17

Vacant
826
14%

Filled
4894
86%

CBER FY17

Vacant
174
14%

Filled
1057
86%
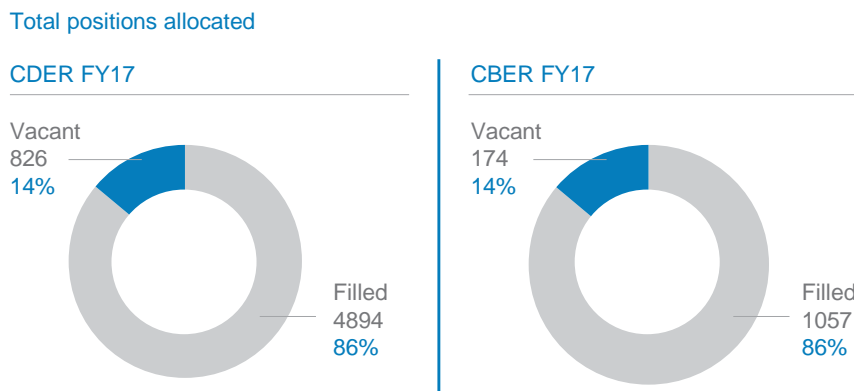
3.3 Satisfaction with Quality

Exhibit 3-5: Snapshot of hiring manager satisfaction rates with quality of new hires.
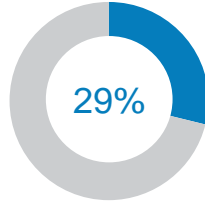*The percentage of hiring manager respondents who self-reported as "very satisfied" with the quality of new hires in CDER and CBER.[9]*

Hiring manager satisfaction rates with quality of new hires

CDER		
Total Hiring Manager Respondents	133	
Total 'Very Satisfied' Responses	39	29%

CBER		
Total Hiring Manager Respondents	34	
Total 'Very Satisfied' Responses	13	38%
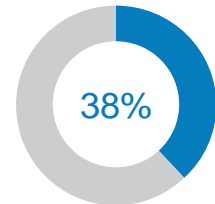
The current hiring process does not yield the desired outcomes. The percentage of CDER and CBER hiring managers, combined, who self-reported being "very satisfied" with the quality of new hires is only 31%. Exhibit 3-5 shows the breakdown by center; 29% of CDER hiring managers and 38% of CBER hiring managers are "very satisfied" with the quality of their new hires, according to a 2016 survey asking them to rate their level of satisfaction. For example, a common sentiment among hiring managers was that, in many cases, HR staff do "not have the technical background" to assess a candidate's qualifications, which can result in qualified candidates being screened out inappropriately and/or unqualified candidates being passed on to the next step in the process. Additionally, as a result of the length of time it can take to process an application, candidates with specialized backgrounds in high demand may be snapped up by competitors before FDA can make an offer.

Section 4.   Overview of Recent and Ongoing Improvements

Although the focus of this report is on diagnosing the root causes of suboptimal hiring performance, there are nonetheless recent and in-progress improvements that merit mention. Continued progress on these efforts is imperative – both to ensure compliance with existing PDUFA commitments and to underpin vital continuous improvement in the hiring process. A brief list of recent and in-progress improvements[10] includes the following:

1. Increasing broad-based knowledge of the current hiring process. In the last several months, OHR has detailed a specialized operations analyst to focus on filling gaps in current hiring process documentation. The analyst has already made progress in mapping the end-to-end process flow and building out process-level documentation to support employee awareness and training.

2. Introducing mutually agreed to performance targets in the form of service level agreements (SLAs) with FDA's medical product centers. Over the last several years, FDA's Office of Operations has been building a standard service catalogue for each major office (e.g., HR, IT, Finance). Although true HR service excellence is still currently lacking, coincident with the creation of that catalogue, OHR initiated a process for defining SLAs and finalizing them through the HR Advisory Council, which includes representatives from all FDA centers.

3. Automating position classification-related process steps to speed application progress. OHR has *soft launched* eClass, an automated classification tool that will accelerate one of the more cumbersome aspects of the current process; 500 existing position descriptions (PDs) will be migrated into eClass by the end of FY17, contributing to a growing library of electronic PDs.

4. Gaining process efficiency by expanding and evolving FDA's corporate recruitment capability. Corporate recruiting is an important innovation in the hiring process, enabling FDA to fill multiple vacancies for the same job series across centers through posting a single vacancy notice. Although further refinement and improvements are needed, a wide range of job series are now using the corporate recruiting model to onboard new hires, and more are planned.

5. **Piloting a position-based management system as a bridge to an upgraded HR Information System with customized position management capability**. In response to a PDUFA commitment, OHR worked with FDA's Office of Information Management and Technology (OIMT) to develop a position-based management system. The system, currently being piloted at FDA's National Center for Toxicology Research (NCTR), includes critical linkages to Finance and other HR systems and will be rolled out to the broader FDA community. Importantly, this solution will likely serve as a *bridge* to a forthcoming upgraded Human Resource Information System (HRIS) with a customized position management capability (Oracle 9.2), targeted for a third quarter, 2018 launch.

6. Introducing a critical portfolio of workforce planning support capabilities. Over the last several years, OHR has been gradually introducing strategic workforce planning capabilities, beginning with center-level workforce *snapshots*, and progressing today into offering a portfolio of workforce analytics that can provide more real-time workforce data that hiring managers can use proactively to forecast and plan workforce needs. Building on this initial base, OHR has also begun supporting leadership succession planning, focusing on future, high-potential Agency leaders.

7. **Establishing a dedicated Title 38 team to expedite the hiring process.** To directly address PDUFA hiring needs, a Title 38 team was established to manage a 10-day process from package submission to tentative offer.

Section 5. The Analytical Approach

5.1 Overview of the Analytical Approach

The initial assessment described in this report relied on several streams of input. Together, these streams informed a composite evaluation of the major gaps in the current state of the hiring process, as articulated against the core dimensions of a root cause analytical framework (see Exhibit 5-1). The root cause approach was chosen to ensure that underlying fundamental issues are isolated and evaluated separately from the downstream implications of those root causes. This approach has the added benefit of pointing directly to actionable recommendations. The root cause analytical framework assesses the current state against four principal dimensions:

- **Process and policies**: The underlying mechanics of the process itself in terms of design, documentation, and policy requirements

- **Organization and people**: The organizational structure and individual human factors that affect process execution and customer experience (e.g., hiring managers and candidates)

- **Data and systems**: The enabling systems architecture in place to facilitate process execution and associated data and tools used to monitor process performance

- **Culture and mindsets**: Ways of working among the internal stakeholder groups with primary responsibility for executing the hiring process

Exhibit 5-1: Overview of Root Cause Analytical Framework
Description of Root Cause Analytical Framework elements used to assess the current state of hiring and recruitment at FDA

PROCESSES AND POLICIES
Process is not fully defined or documented in a way that is transparent to all stakeholders

Lack of clear guidelines for interpreting existing policies and legal requirements for recruitment and hiring

Process itself is not well designed

ORGANIZATION AND PEOPLE
Organizational structure limits ability to execute an efficient process

Inadequate resources (FTEs) exist to execute process accurately and efficiently

Unclear and variable roles and responsibilities amongst stakeholders create confusion and redundancy

Skill gaps and inadequate training inhibit successful hiring process

DATA & SYSTEMS
Current data tracking is insufficient to enable effective accountability and end-to-end management of the process

IT systems are not consistently integrated, user friendly, or supportive of an efficient, effective hiring process

CULTURE AND MINDSET
Inconsistent performance goals, SLAs, or enforcement of expectations undermine accountability throughout process

Mindsets/behaviors don't support effective and collaborative execution of process

5.2 Sources of Input

Quantitative data came from both internal surveys and FDA operational metrics, while qualitative insights were gleaned from interviews and focus groups with current FDA employees across the Agency who have been directly involved in the hiring process. Unless otherwise specified, the report uses data gathered from mid-2016 through publication of this report. Where an assessment is made about the degree of progress made along a certain dimension, the report seeks to be as explicit as possible in identifying the source of the determination and the approach taken. Nevertheless, there was some degree of subjectivity, given that some of the analyses included rely on perceptions gathered through live interviews or survey responses. Furthermore, FDA currently lacks meaningful data and core process metrics associated with the hiring process, including accurate time-to-hire statistics across candidate populations or reasons for candidate drop out. Appendix A.3 expands on the findings related to lack of data, which not only inhibits the hiring process but also the richness of this diagnosis. Notwithstanding, this report provides a high-level assessment that seeks to meet the first-order objective of better understanding current state issues and providing a baseline from which recommendations for improvement can be developed.

5.3 Assessment Criteria

Exhibits 5-1 and 5-2 provide directional guidance explaining how specific scores were assigned to the root causes included in the diagnostic.

Exhibit 5-1: Gap assessment and justification
Criteria for the gap assessment against the Root Cause Analytical Framework

Gap assessment criteria

MAJOR	MODERATE	MINOR/NO GAP
Consistent attribution of the root cause as a major impediment to an effective hiring process at FDA, validated by a number of quantitative and qualitative inputs for the assessment	Likely contributing factor to issues observed with the hiring process at FDA, validated by a number of quantitative and qualitative inputs	Root cause not observed at FDA, as deduced from qualitative survey data and working sessions with various stakeholders

Exhibit 5-2: Criticality assessment and justification
Criteria for the criticality assessment against the Root Cause Analytical Framework

Criticality assessment criteria

MAJOR	MODERATE	MINOR/NOT CRITICAL
Without resolving the root cause, hiring and recruitment will fail to improve significantly and meet FDA's goals, synthesized from stakeholder surveys and hypothetical scenario testing	Resolving the root cause is key to having an effective hiring process at FDA, synthesized from stakeholder surveys and hypothetical scenario testing	Resolving the root cause will help improve the state of hiring at the FDA, but is not absolutely necessary, synthesized from stake-holder surveys and hypothetical scenario testing

Section 6. Diagnosis of Current State – Key Findings

The diagnosis revealed a number of root causes that are driving the current state of hiring and recruitment at FDA. They can be grouped broadly into four core categories: (1) processes and policies, (2) organization and people, (3) data and systems, and (4) culture and mindset. Of particular importance are six root causes that must be addressed before improvements in recruitment and hiring can be achieved. The six are as follows:

- 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

- The end-to-end hiring process itself suffers from poor design and substantial complexity, including hand-offs and frequent re-work, leading to drawn out timelines and frustrated customers

- The organizational structure is characterized by a proliferation of shadow HR positions and a geographic division between centralized HR and center-based stakeholders

- A significant skill gap, combined with a lack of training, hinders efficient and accurate execution of the process

- Inconsistent data tracking does not support process transparency and execution accountability

- Lack of a customer-focused, intrinsically motivated mindset constrains collaborative and efficient execution

The collective result of these root causes is a lengthy recruitment and hiring process that produces neither reliable outcomes nor satisfied customers. Error rates are high, and candidate and hiring manager satisfaction rates are low, despite recent improvements in OHR. Taken together, the overarching implication is that FDA will continue to suffer from a suboptimal recruitment and hiring process unless the entire recruiting and hiring process is revamped.

Exhibit 6-1 presents a summary analysis of the key root causes, the severity of the gaps they present and their criticality for success, organized by core categories. For a discussion of the full set of findings along with detailed supporting evidence, see Appendix.

Exhibit 6-1: Framework and assessment of the gap and criticality of the hiring process root causes at FDA

Potential root cause of pain within existing hiring process

● Major ● Moderate ● Minor/No Gap

	Severity of gap	Criticality for success
PROCESSES AND POLICIES		
Process is not fully defined or documented in a way that is transparent to all stakeholders	●	●
Lack of clear guidelines for interpreting existing policies and legal requirements for recruitment and hiring	●	●
Process itself is not well designed	●	●
ORGANIZATION AND PEOPLE		
Organizational structure limits ability to execute an efficient process	●	●
Inadequate resources (FTEs) exist to execute process accurately and efficiently	●	●
Unclear and variable roles and responsibilities amongst stakeholders create confusion and redundancy	●	●
Skill gaps and inadequate training inhibit successful hiring process	●	●
DATA & SYSTEMS		
Current data tracking is insufficient to enable effective accountability and end-to-end management of the process	●	●
IT systems are not consistently integrated, user friendly, or supportive of an efficient, effective hiring process	●	●
CULTURE AND MINDSET		
Inconsistent performance goals, SLAs, or enforcement of expectations undermine accountability throughout process	●	●
Mindsets/behaviors don't support effective and collaborative execution of process	●	●

Section 7. Recommendations for Consideration

FDA has made some progress in recent years to improve its hiring process since regaining direct authority from HHS in 2012. However, much work remains. The results of the diagnosis, however, suggest the need for a fundamental, strategic redesign of the end-to-end hiring process as opposed to a portfolio of point solutions to address targeted challenges (which has largely been the approach of the past).

That redesign process should target five major themes that have been identified and agreed to by FDA leadership as the basis for measures of success going forward – both for the customers of the hiring process, as well as for the Agency at large. These are: (1) *process timeliness,* (2) *process accuracy,* (3) *outcome quality,* (4) *customer satisfaction, and* (5) *employee (HR) satisfaction.* There are three initial recommendations for consideration to set FDA on a path to achieving these measures of success, which are outlined below.

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:

- An optimized, *clean sheet* process design focused on **minimizing handoffs, eliminating unnecessary process steps,** and **reducing total time to hire**

- 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

- Identification and use of **new talent sources**

- **Targeted investments to build HR capabilities** in communication, timeliness, and personal initiative – three core HR competencies with the greatest observed deficiencies

- 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

- 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**

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.

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

In summary, the path forward relies on piloting, measuring, and scaling up a completely redesigned hiring process. FDA has begun the design of a pilot, which is slated to launch in 2018 and will be used as a vehicle to hire several mission critical occupations in support of the PDUFA VI and

BsUFA II commitments. The Agency anticipates providing a readout from the pilot in a FDA Hiring and Retention Interim Assessment report, scheduled to be published in 2020. That report will not only assess progress against these specific recommendations, but will also apply a broader lens to the hiring and retention processes in place at FDA, such as employee retention and value proposition.

Appendix: Detailed Current State Diagnosis Using Root Cause Framework

A.1 Process and policies

Root cause: Process is not fully defined or documented in a way that is transparent to all stakeholders

Substantiating Evidence: Severity of gap (Major)

Severity of gap	Criticality for success
● Major	● Major

6 of the 8 major process steps either *lack documentation* entirely or are documented but in an unclear or inaccessible fashion.

- Six of the eight major process steps either lack documentation entirely or are documented in an unclear or inaccessible fashion. Exhibit A.1-1 summarizes the current state of process documentation, highlighting the major activities under the major process steps that lack clear operating procedures.[11]

- 24% of CDER AOs surveyed about HR processes answered "no" or "unsure" when questioned about the existence of documented SOPs relating to hiring processes.[12]

- 75% of CBER and CDER hiring managers surveyed said that if given the option, they would use a web page or centralized area with information on hiring processes, documented process guidance (e.g., process steps, positions, timelines), and/or checklists and cheat sheets for hiring.[13]

- Although ideal target time frames for each process step exist, the time frames observed are quite different. Exhibit A.1-1 presents the ideal and observed time spent per step throughout the hiring process. The current, end-to-end hiring process takes anywhere from 150-550 days, with an additional 22-300 days if classification is required. This range is skewed by outliers in the upper bound. For reference, the mean time to hire for CBER and CDER FY17 new hires is 152 days, and the median is 128 days.[14] It should be noted that misalignment between the documented and observed time frames for certain process steps, such as EoD date and security and ethics clearance may be due to bottlenecks outside of the hiring team's control (e.g., candidate requests a start date six months from now for a personal reason).

Exhibit A.1-1: Summary of current state of process documentation
Key process steps have a wide range of time to completion and lack clear operating procedures

Aa Indicates outside of hiring team's control
Aa Indicates lack of clear operating procedures

Request classification (if necessary)	Initiate package	Prepare for posting	Post job opportunity	Compile certificate	Evaluate candidate	Extend offer	EoD
Time frame (observed)							
22-300 days	5-30 days	30-90 days	5-30 days	14-60 days	30-90 days	30-45 days	30-200 days
Time frame (SOP)							
22	1-3 days	2-4 days	5-10 days	6-12 days	1-22 days	7-14 days	11-20 days
Key activities							
• Review duties and match Position Description (PD) to grade levels • Determine need based on OPM class standards	• Identify hiring need • Align with HR and OM • Send to OHR • Pre-recruitment outreach	• Conduct quality review • Draft Job Opportunity Announcement (JOA) • Receive approval	• Post job • Outreach for applicants	• Review qualifications • Issue certificate	• Conduct interviews • Select candidates • Request certificate extension (if applicable)	• Extend tentative offer • Security and ethics clearance • Extend final offer	• Onboarding

Substantiating Evidence: Criticality for success (Major)

▪ Without a defined process and readily accessible documentation, stakeholders are unable to inform themselves on how to execute a consistent process, regardless of staff capability. Furthermore, process documentation is a fundamental pre-requisite for implementation of process-enabling technology and systems.

Root cause: Existing set of policies, legal requirements, and/or FDA interpretation of requirements constrain ability to implement process effectively and consistently

Severity of gap	Criticality for success
● Moderate	● Moderate

Substantiating Evidence: Severity of gap (Moderate)

▪ Given the complex, regularly evolving policy landscape, FDA has created policy guidance to help staff execute against hiring-related policies in a standardized manner. HHS and OPM have grouped the hiring-related policies into nine major categories (e.g., benefits, classification and compensation). Exhibit A.1-2 presents these categories in the context of a gap analysis, which tests the presence of documented policy interpretation guidelines for a given policy. Six out of nine hiring-related processes and procedures are missing a comprehensive handbook to guide the interpretation. The criteria for the gap analysis assessment is as follows: "No Gap" was designated if at least 95% of the existing policies under the overarching process had a corresponding SOP; "Moderate Gap" if 50-95% of the policies had a corresponding SOP; and "Major Gap" if less than 50% of the policies had a corresponding SOP. [15] It should be noted that the gap analysis only tests the *presence* of an interpretation document, not its quality or use.

Exhibit A.1-2: Summary of gap analysis of documented policy interpretation guidelines
A majority of hiring-related processes and procedures lack clear interpretation guidelines to advise OHR staff on how to handle existing policies dictated by the Federal government

Hiring Related Processes/Procedures	Assessment of Presence of Documented Interpretation Guidelines at FDA for OPM/HHS Policies	
Employee Relations	⬤	Major Gap
Benefits	⬤	Major Gap
Services to Employees	⬤	Major Gap
Employee Performance, Appraisal and Awards	🔵	Moderate Gap
Classification and Compensation	🔵	Moderate Gap
Employment and Retention	🔵	Moderate Gap
Personnel Information Record Keeping	🔵	No Gap
Employee Training and Development	🔵	No Gap
Attendance and Leave	🔵	No Gap

- The lack of clarity surrounding policies has created the perception among hiring managers that "the specialists are unnecessarily rigid in their application of OPM guidance." Hiring specialists believe "this could be mitigated with up-to-date SOPs that everyone could follow." [16]

- Hiring managers themselves also expressed a desire for greater clarity regarding policies. One such example is the inefficient practice of printing, signing, and scanning a certificate for a selection package instead of e-signing because "they were told they need a wet signature,"[17] although this is not an official rule. Albeit a small task, this lack of clarity is multiplied across multiple steps and dozens of hiring packages, resulting in significant inefficiencies. It should be noted that the slated USA staffing upgrade will include documenting selections in the automated system. Hiring managers in particular expressed a desire to have access to "basic requirements, timelines, policies, and suggestions to help create PDs."[18]

Substantiating Evidence: Criticality for success (Moderate)

- If FDA created a comprehensive interpretation handbook for all relevant policies, efficiency of the current process would be improved. Clearly documented guidelines could also mitigate situations in which staff take an unnecessarily restrictive interpretation of the policy, constraining their ability to fill vacancies with the right people at the right time.

Root cause: Process itself is not well designed

Severity of gap ⬤ Major   Criticality for success ⬤ Major

Substantiating Evidence: Severity of gap (Major)

- The current process design lacks all four elements of hiring process excellence principles: simplicity, standardization, efficiency, and demand management. Exhibit A.1-3 summarizes the assessment of the current state against these four elements. [19]

  - Simplicity

    A majority of steps in the overall hiring process involve multiple handoffs between individuals within teams. Exhibit A.1-4 highlights the number of handoffs and approvals

required at each process milestone.[20] Qualitative commentary captured in focus groups and surveys across various stakeholders revealed the possibility that some of these approvals and handoffs are likely unnecessary and consistently slow down execution. There is agreement among hiring managers that "there are way too many hand-offs, within the center and then at the Agency level."[21]

- Standardization

  There is high variation in both the timing and the general experience of the hiring process from candidate to candidate both for the candidates themselves and the hiring managers.

- Efficiency

  Missed opportunities to parallel process have been highlighted by hiring managers: "the job analysis process (and subsequent announcement on USAjobs) is held hostage to PDs that include tasks that are not relevant to the position"; "with respect to job postings, it feels as if it is one at a time for our division."[22] However, a contributing factor to the "one at a time" processing of positions demonstrates weak strategic workforce planning at the centers.

  There are no mechanisms designed into the process to eliminate candidates who have already applied to that position and have been previously screened out.

  In addition to current data limitations, tracking time spent on rework and non-value-add work, stakeholders have not agreed to what constitutes *value add* vs. *non-value-add*, rendering it difficult to assess whether there has been wasted effort on non-value-add work. However, there is general consensus among hiring specialists that more time is spent than ideal on at least half of the steps in the hiring process.[23]

- Demand management

  There is no mechanism that enables continual performance management. Executive FDA leadership has commented on the absence of a centralized portal, "I have no idea what the performance of my center is from a hiring perspective. There is no simple dashboard that circulates on an ongoing basis. Every time I want to dig into the data, it is a time intensive process that takes people away from their day to day."

  Ongoing efforts to classify PDs for standardized positions currently allow for early preparation for hiring in advance. However, there is still limited utility of parallel processing more broadly.

I have no idea what the performance of my center is from a hiring perspective. There is **no simple dashboard** that circulates on an ongoing basis.

– FDA Leadership

Exhibit A.1-3: Assessment of FDA current state against process excellence design dimensions [24]

	Markers of the process excellence dimension	Current state
●	**SIMPLICITY** • Minimum number of steps • Minimum number of handoffs • Minimal time (from start to finish)	52-58 steps 24-25 handoffs 190-845 days
●	**STANDARDIZATION** • Low variation in how similar cases are handled • Low variation in cycle time	Qualitative capture from hiring manager survey indicates high variability 2 sigma process

●	**EFFICIENCY**
	• Minimizes amount of repeat work required for:
	  — HR
	  — Hiring Managers
	  — Candidate
	• Minimal wasted effort on non-value add work
		Qualitative capture from hiring manager survey and focus groups with HR liaisons indicates low process efficiency

●	**DEMAND MANAGEMENT** • Enables continual performance management • Enables planning hiring timelines in advance	See A.3 for evidence on limited data collection Some continual classification for generic roles

Assessment legend: Weak indicates room for meaningful process excellence improvement | Moderate indicates room for moderate process excellence improvement | Strong indicates process is optimized across dimensions

Exhibit A.1-4: Summary of the number of steps, handoffs, and approvals required at each process milestone

	Request classification (if necessary)	Initiate package	Prepare for posting	Post job opportunity	Compile certificate	Evaluate candidate	Extend offer	EoD
# OF STEPS	4	4	7	4	4	14	11-17	4
# OF PARTIES INVOLVED	5	4	4	5	1-2	4	9	4
# HANDOFFS	3	3	5	3	0-1	5	4	1
% OF STEPS INVOLVING HANDOFF	75%	75%	70%	75%	0-25%	36%	24-36%	25%
# OF APPROVALS REQUIRED	1	1	2	0	0	2	1	0

Substantiating Evidence: Criticality for success (Major)

▪ Without a fundamentally well *designed* process, hiring will remain a challenge. Even if HR and HC staff are upskilled, IT systems are improved, and the culture and mindsets are aligned to support seamless execution, process design-related impediments will continue to drive suboptimal outcomes.

A.2 Organization and people

Root cause: Organizational structure limits ability to execute an efficient process

Severity of gap   Criticality for success
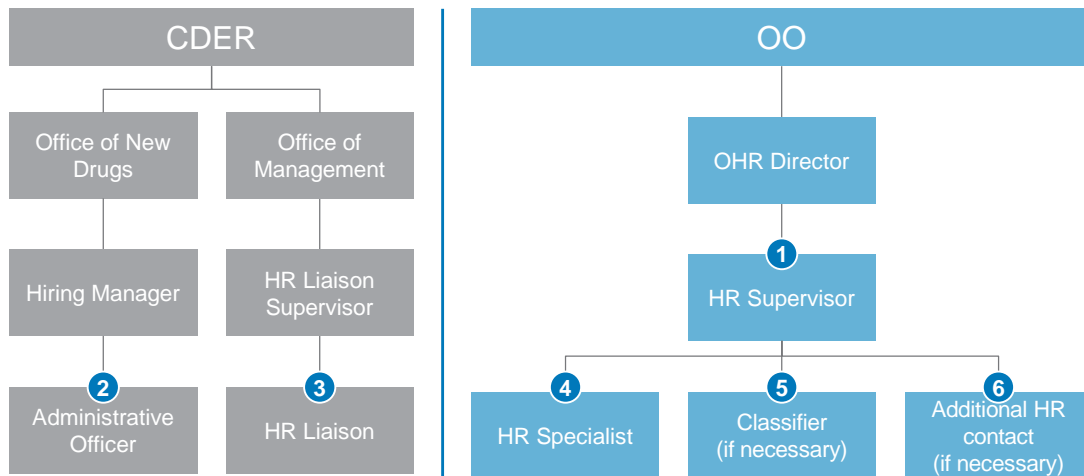● Major   ● Major

Substantiating Evidence: Severity of gap (Major)

▪ Numerous stakeholders have mentioned the organizational separation of OHR from HR liaisons in the centers as a significant barrier to collaboration. This separation is further exacerbated by geographic distance between OHR (offices in Rockville, Atlanta, Chicago, New York, and San Francisco) and CDER and CBER (located in Silver Spring, MD).[25]

▪ A given hiring manager needs to work across multiple offices, with up to six different people to complete a hiring action. In the current state, the hiring manager works with a minimum of two contacts from HR: the HR supervisor and the HR specialist. However, if the position needs to be classified, he or she will also work with a classifier, and if the position is under the authority of Title 38, 42, or Commissioned Corps, for example, he or she will also have to work with another HR contact specific to that authority. In addition to one or more contacts from OHR, a hiring manager also works with an administrative officer within his or her office and an HR liaison within the center's Office of Management. In cases in which escalation (e.g., the package requires higher-level approval to move forward in the process), the hiring manager has two more touchpoints: the HR Liaison Supervisor and the OHR Director, for a total of six touchpoints. Exhibit A.2-1 illustrates the current organizational structure, highlighting the number of touchpoints a hiring manager has to make to complete one hire.

A given hiring manager needs to work across multiple offices, with up to 6 different people, in order to complete a hiring action.

▪

Exhibit A.2-1: Illustration of the organizational design of the proliferated HR positions
The hiring manager must interact with multiple HR points of contact to make one hire. There are multiple other parties involved; this illustration highlights only those from the various HR positions

Substantiating Evidence: Criticality for success (Major)

▪ Simplifying the organizational structure would certainly make the process and flow of information less complex. However, this would have limited impact on improving the overall process if done in isolation.

Root cause: Inadequate resources exist to executive process efficiently and effectively

Severity of gap   Criticality for success
○ Minor/No Gap   ● Moderate

Substantiating Evidence: Severity of gap (Minor/No Gap)

- The current rate at which HR staff make new hires at CDER and CBER is within the benchmark rate expected of them to be able to meet the increase in FTE ceiling driven by the user fee requirements. Between FY15 and 16, the CDER FTE ceiling was increased by 368, requiring that the 28 HR staff dedicated to CDER make 12 to 13 hires each, which aligned with the average number of hires actually made. During the same time period, the 8 HR staff dedicated to CBER were making an average of 8 hires per staff, which exceeded the rate of 2 hires per staff they needed to fill the CBER FTE ceiling increase of 15 positions. Exhibit A.2-2 compares the CDER and CBER HR hire rates (12 new hires per HR staff, 8 new hires per HR staff, respectively) with the benchmark expectations. [26]

Exhibit A.2-2: Assessment of CDER and CBER HR capacity to fill new vacancies
Based on FY16 recruitment rates at CDER and CBER, the number of CDER dedicated HR staff (28) and CBER dedicated HR staff (8) was adequate to fill the number of new hires they needed to make to meet the center increases in FTE ceilings.[27]

Assessment of CDER HR staff capacity to fill new vacancies
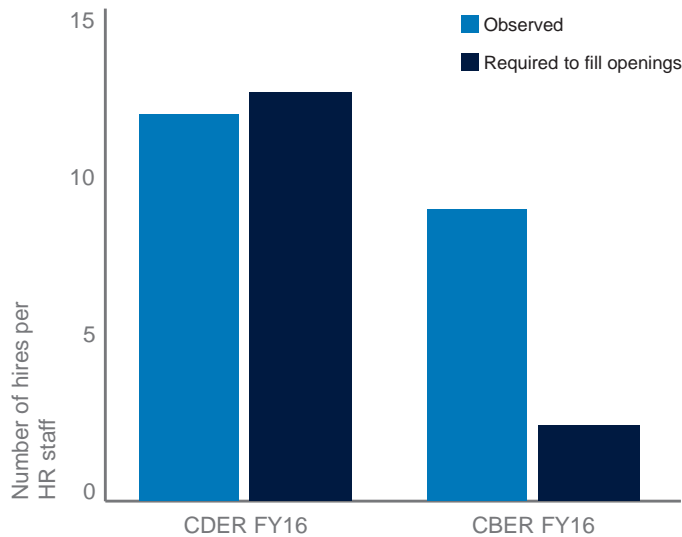
- Qualitative commentary captured by focus groups with hiring managers revealed that a potential bottleneck in the hiring process stems from the classification step due to an insufficient number of classifiers, both at FDA and across Federal agencies.[28]

Substantiating Evidence: Criticality for success (Moderate)

- Although having an adequate number of HR staff is important to be able to bring in new hires, the current high vacancy rates across centers are largely due to a backlog that has accumulated over time. The vacancies can be filled without necessarily increasing resources; one workaround is to increase yield rates.

Root cause: Unclear and variable positions and responsibilities among stakeholders create process confusion and executional redundancy

Severity of gap   Criticality for success
● Moderate   ● Major

Substantiating Evidence: Severity of gap (Moderate)

- Stakeholders in OHR and the centers across the Agency all consistently report some degree of frustration about lack of position clarity**.**
- Qualitative commentary captured in surveys reveals that hiring managers "feel very out of touch with the hiring process because of the number of staff involved" and "do not know who most of them are and what they actually do."[29] They do not have a single point of contact whom they consider their go-to for information and thought partnership for hiring-related duties.

In 7 out of 10 process steps, **only 50%** of the hiring managers surveyed reported being *clear about their responsibilities* in the hiring process

- There is confusion among hiring managers regarding the degree to which they are responsible for preparing a package and getting a candidate through the hiring process. In a survey of ~140 hiring managers, a significant majority reported levels of engagement that deviated from the appropriate level of involvement according to SOPs and agreed upon expectations gathered from focus groups with HR professionals from CDER, CBER, and OHR.[30] In 7 of 10 process steps, only 50% of the hiring managers surveyed reported being clear about their responsibilities in the hiring process and were appropriately involved.
- Exhibit A.2-3 lists the percentage of hiring managers who self-report a level of engagement that aligns with the expected engagement level as dictated by SOPs and HR staff for each sub process.

Exhibit A.2-3: Evaluation of hiring manager involvement in the hiring process

Process step	Sub process step	Appropriate role of hiring manager in sub process step according to HR and SOPs	% of hiring managers who adhere to appropriate engagement level
INITIATE PACKAGE	Updating PD	Always Involved	50%
PREPARE FOR POSTING	Participating in job analysis	Always Involved	50%
	Pre-Consult	Always Involved	50%
	Reviewing JOA	Always Involved	50%
POST JOB OPPORTUNITY	Identifying recruitment sources	Rarely Involved	5%
COMPILE CERTIFICATE	Serving as SME	Sometimes Involved	40%
EVALUATE CANDIDATE	Resume review	Always Involved	50%
	Interviewing	Always Involved	50%
EXTEND OFFER	Assist with incentive package preparation	Always Involved	50%
ONBOARDING	Onboarding	Sometimes Involved	40%

- The misalignment suggests a lack of clarity about the position of a hiring manager. However, it should be noted that hiring managers may deviate from the appropriate level of involvement because they are either (a) not receiving clear communication about their responsibilities in the

hiring process and/or (b) are well aware of their required responsibilities, but do not have the right mindset and motivation to align with the recommended degree of engagement.

- Regardless of the underlying cause, the results comport with survey data, which found that only 25% of HR specialists believe hiring managers are sufficiently involved in the hiring process – in particular, the process steps in which hiring managers should be more involved but a significant majority are not.[31]

Substantiating Evidence: Criticality for success (Major)

- Absence of a clear articulation of positions and responsibilities established for process participants – regardless of how simple or complex that process is – will consistently drive adverse outcomes and dilute accountability.

Root cause: Skill gaps and inadequate training of HR staff inhibit successful hiring process

Severity of gap	Criticality for success
● Major	● Major

Substantiating Evidence: Severity of gap (Major)

- Recent efforts have been made to upskill OHR staff, including making a significant financial investment to bring in instructors to teach customer service, time management, and other competencies to staff. Yet, survey data suggest there remains noteworthy perceived gaps across a range of critical core and technical competencies in OHR. Exhibit A.2-4 summarizes the results of an evaluation by hiring managers of their OHR counterparts' competency levels**.[32]**

Exhibit A.2-4: Summary of assessment of OHR skill gap
Results from CDER hiring manager survey in which they were asked to report their level of satisfaction with their respective OHR Servicing Team [33]

OHR Competencies		% Satisfaction Among Hiring Managers
CORE	Flexibility	20%
	Customer Service	25%
	Communication	17%
	Initiative	17%
	Timeliness	15%
TECHNICAL	Knowledge of Regulations, Policies & Procedures	32%

- Core competencies:
  - Only 20% of hiring managers are satisfied with OHR's current competency with flexibility.[34] Hiring managers have cited that "HR's answer is always 'can't do.'" [35]
  - Only 17% of hiring managers surveyed are very satisfied with OHR's competency level in communication.[36] Many hiring managers have highlighted issues with both proactive and reactive communication. In many cases, OHR does not keep hiring managers informed about where in the hiring process a candidate is and does not respond to queries from both hiring managers and candidates in an accurate, timely, and/or professional manner.

- Only 17% of hiring managers are satisfied with the current level of initiative demonstrated by OHR staff. [37]Based on survey data, hiring managers perceive that OHR staff are not committed to providing "a high quality product." The perception among hiring managers is that for OHR staff, "the recruitment and retention of talent to do high-quality work does not seem to be a purpose or goal. The purpose or goal seems to be the prevention of extra-process practice."[38]

- Only 15% of hiring managers are very satisfied with the timeliness with which OHR staff handle hiring actions and respond to queries. [39] Hiring managers have stated that "HR support seems annoyed when asked to execute HR actions in a timely way."[40]

- Technical competencies:

  - 32% of hiring managers are satisfied with the current knowledge level of OHR staff of regulations, policies, and procedures.[41]A common sentiment among hiring managers is that HR staff do not have the technical background to adequately contextualize a candidate's qualifications, resulting in qualified candidates getting screened out inappropriately and/or unqualified candidates getting passed on to the next step in the process. [42]

  - Both hiring managers and OHR have expressed the desire to have formalized training programs to keep abreast of the constantly evolving policy landscape and the impact on successful execution of HR-related actions in the hiring process. [43] However, currently there are no annual technical mandatory trainings.

Substantiating Evidence: Criticality for success (Major)

- Staff capability is a critical enabler of a seamless process – without well-reinforced competencies in place, HR staff run a real risk of consistently falling short of customer expectations from hiring managers and candidates alike, further limiting positive potential impact on the mission.

A.3 Data and systems

Severity of gap Criticality for success
● Major   ● Major

Root cause: Current data tracking metrics are insufficient to enable effective accountability and end-to-end management of the process

Substantiating Evidence: Severity of gap (Major)

- As Exhibit A.3-1 shows, the current state of metrics tracking at FDA has major gaps across the five dimensions that have been identified as the basis for measures of success: process timeliness, process accuracy, outcome quality, customer satisfaction, and employee (HR) satisfaction. There is a limited amount of data being collected, with a disproportionate focus on process timeliness.[44] These data are housed in the Human Resources Employment Processing System (HREPS), which requires manual entry, calling into question the accuracy of the data. More broadly, the data that are collected are not consistently used for performance management or process improvement efforts.

Exhibit A.3-1: Assessment of current state of data tracking at FDA
State of routine tracking of core metrics required to enable a timely, efficient, quality hiring process

Dimension	Current State of Data Tracking at FDA
PROCESS TIMELINESS	1-2 measurements (e.g., average time to fill by hiring authority, time to fill MCOs)
PROCESS ACCURACY	No measurements collected routinely
OUTCOME QUALITY	No measurements collected routinely
CUSTOMER SATISFACTION	No measurements collected routinely
EMPLOYEE (HR) SATISFACTION	No measurements collected routinely

Substantiating Evidence: Criticality for success (Major)

▪ Without more comprehensive collection of metrics covering process timeliness, accuracy, outcome quality, and customer satisfaction, FDA will face consistent challenges when trying to make data-driven performance management decisions and drive continuous process improvement.

Root cause: IT systems are not consistently integrated, user friendly, or supportive of an efficient, effective hiring process

Severity of gap   Criticality for success
● Major   ● Moderate

Substantiating Evidence: Severity of gap (Major)

▪ There are more than six different IT systems being used for the basic end-to-end hiring process, and they have limited inter-operability and integration, resulting in fragmented visibility into the end-to-end process. Users are required to enter the same data in different systems multiple times, which creates frustration among HR staff.[45] Exhibit A.3-2 illustrates the major IT systems currently in use, broken down by the process steps in which they are being used, along with associated major pain points.

Exhibit A.3-2: IT systems and associated major pain points mapped to hiring process
This diagnosis was conducted in September 2017, before the slated implementation of a new version of USA Staffing in the fourth quarter, 2017 and the CapHR upgrade in December 2017, which may affect the veracity of the present assessment

- The quality of HR systems was rated no higher than a 2 out of 5 consistently throughout interviews, resulting in the consequent development of center-level, *homegrown* systems, specifically within the Center for Tobacco Products (CTP) and the Center for Veterinary Medicine (CVM). [46] Users are more apt to rely on their internal systems, thereby causing the data in the authoritative systems to become outdated.

- There is limited sophistication of IT solutions. No electronic, searchable library exists of PDs, and there is minimal use of automated data mining. More broadly, HREPS, the primary tracking tool being used, still requires manual entry for most data, increasing the likelihood for errors. [47]

Substantiating Evidence: Criticality for success (Moderate)

- Without improving the user experience of the current IT systems, consistent use of enabling IT tools among HR staff will be hard to ensure. However, with the right HR staff competencies and a culture of accountability, the tools may be widely used even if not especially user-friendly.

A.4 Culture and mindsets

Root cause: Inconsistent performance goals, SLAs, or enforcement of expectations undermines accountability throughout process

Severity of gap ● Major
Criticality for success ● Moderate

Substantiating Evidence: Severity of gap (Major)

- The current key performance indicators (KPIs) for OHR professionals do not have meaningful performance targets and, thus, fail to adequately incentivize comprehensive timely execution of the hiring process. The low standards that are officially established for timeliness of the hiring process have created the perception among hiring managers that HR staff are not held

accountable in any way for their actions.[48] HR specialists have noted that a contributing factor to their inability to efficiently execute hiring process steps is the lack of timely responses from hiring managers.

- In addition to timeliness of execution of HR processes related to hiring, accountability measures for timeliness of response to customers, quality, and outcome of their hires are lacking. Since there is no one person with sole accountability for any given hiring action, there is an observed sense that staff pass an action onto the next person and are mostly focused on "their part" of the hiring process.

- It should be noted that financial incentives are limited and the compensation potential for a good performer versus an average or underperformer result in a salary difference of ~1-2%.[49]

Substantiating Evidence: Criticality for success (Moderate)

- Without formal mechanisms to ensure accountability like performance goals, KPIs, and SLAs, the process could still thrive if other elements are in place (e.g., a strong culture of accountability and performance).

Root cause: Mindset and behavior do not support effective and collaborative execution of process

Severity of gap	Criticality for success
● Major	● Major

Substantiating Evidence: Severity of gap (Major)

- The current mindset and behavior of HR and HC staff do not align with organizational elements that drive strong performance:
    - There is strong mutual distrust between OHR and the Programs.[50]
    - Operational discipline is an often-cited issue across the board: "The administrative staff in the programs, OM, and OHR do not do their job properly. They lose documents, do not keep track of applicants." [51]
    - There is broad consensus that HR staff often fail to proactively find solutions to hiring-related challenges, focusing instead on communicating challenges. [52]
- Motivation is another core element of a healthy organization, which is weak in OHR due to a lack of personal ownership and rewards and recognition.
    - Survey data has revealed that HR specialists experience frustration with poor support from senior leadership. [53]
    - 51% of HR specialists reported being satisfied with the current level of recognition and rewards they receive for quality work.[54]
- There is a perception of weak personal ownership. 55% of CDER hiring managers are dissatisfied with the extent to which the OHR servicing team takes "initiative to solve problems that arise." [55]

- External focus, namely customer orientation, is lacking.
    - The perception among hiring managers is that "HR is not service-oriented" due to low response times, and the perception among new hires is that HR is not competent due to numerous inaccuracies and errors. [56]
- Low employee involvement and a lack of a shared vision are consistently observed issues among HR staff at FDA.
    - Hiring managers have noted that "there is a profound disconnect of mission. The timely recruitment and retention of talent to do high-quality work do not seem to be a purpose or goals. The purpose seems to be prevention of extra-process practice… I had

someone in HR tell me the purpose of her job was to prevent inappropriate hires and make sure all procedures were followed. She succeeded in her goals, but we remain under ceiling." [57]

- Hiring specialists have also expressed frustration with hiring managers, who "create bottlenecks in the process because they are not held accountable to the same timeframes." [58]

Substantiating Evidence: Criticality for success (Major)

- Without changing the mindset and behavior of the staff at FDA who are involved with hiring and recruitment, the process cannot be executed effectively and efficiently, no matter how well it is designed and enforced. Implementation of the process requires a healthy climate, with strong leadership, motivation, direction, and external orientation.

Glossary

Acronym	Definition
AO	Administrative Officer
BsUFA	Biosimilar User Fee Act II
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
DMS	Division of Management Services
EoD	Entry on Duty
FDA	Food and Drug Administration
FDARA	FDA Reauthorization Act of 2017
FDAU	Food and Drug Administration University
FTE	Full Time Employee
FY	Fiscal Year
GDUFA	Generic Drug User Fee Amendments
HC Liaison	Human Capital Liaison
HHS	Department of Health and Human Services
HM	Hiring Manager
HR Specialist	Human Resources Specialist
HREPS	Human Resources Employment Processing System
HRIS	Human Resource Information System
JOA	Job Opportunity Announcement
KPI	Key Performance Indicator
NCTR	National Center for Toxicology Research
OHR	Office of Human Resources

Acronym	Definition
OHR IO	Office of Human Resources Immediate Office
OIMT	Office of Information Management and Technology
OM	Office of Management
OO	Office of Operations
OPM	Office of Personnel Management
PD	Position Description
PDUFA	Prescription Drug User Fee Act
PMAP	Performance Management Appraisal Program
SLAs	Service Level Agreements
SME	Subject Matter Expert
SOPs	Standard Operating Procedures

Footnotes

1. https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf; https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf

2. New Hire Survey administered to 683 New Hires in FY16; 657 responded to this particular question on satisfaction (2016)

3. Calculated by quantifying the number of "Always" responses from CDER and CBER hiring managers on the extent to which hiring and recruitment processes are standardized and followed, from the 2016 CDER and CBER hiring manager surveys; 163 CDER hiring managers and 32 CBER hiring managers responded to this particular question (2016)

4. Calculated by quantifying "Very Satisfied" responses from CDER and CBER hiring managers to a question asking about their level of satisfaction with the quality of hire of the vacancies filled in FY15 or FY16 from the 2016 CDER and CBER hiring manager surveys; 167 responded to this particular question (2016)

5. The Corporate Recruitment Model allows multiple vacancies to be filled with one vacancy posting

6. OPM Hiring Authorities (https://www.opm.gov/policy-data-oversight/hiring-information/hiring-authorities/)

7. State Department HR Report "Five Year Workforce and Leadership Succession Plan Fiscal Years 2016-2020" (September 2016); USDA Office of Field Operations Employment and Vacancy Data (2013)

8. Data from center maintained databases (September 2017)

[9]   Data from USA Staffing (September 2017)

[10]   Qualitative commentary captured from stakeholder interviews with OHR leadership (October 2017)

[11]   Focus group with HR liaisons with CDER and CBER (September 2017)

[12]   Survey administered to 47 CDER AOs, 46 responded to this specific question (2016)

[13]   Calculated by quantifying the number of CDER and CBER hiring managers who listed one or more of the three particular resources as options they would use if given the option; 140 responded to this question from the 2016 CDER and CBER hiring manager survey (2016)

[14]   The mean and median were calculated from the 94 FY17 CBER and CDER new hires for which time to hire data was available on USA Staffing (2017)

[15]   FDA OHR Policy Documentation Review (2016)

[16]   Qualitative commentary captured in survey administered to 37 hiring specialists (2016)

[17]   Focus group with HR liaisons (from CDER and CBER) and OHR (September 2017)

[18]   Qualitative commentary captured in survey administered to 234 CDER and CBER hiring managers (2016)

[19]   Industry standard best practice design principles

[20]   Information gathered in focus groups with center HR and SOP documentation provided by OHR (2017)

[21]   Qualitative commentary captured in Survey administered to 234 CDER and CBER hiring managers (2016)

[22]   Qualitative commentary captured in Survey administered to 234 CDER and CBER hiring managers (2016)

[23]   Qualitative commentary captured in Survey administered to 37 hiring specialists (2016)

[24]   Sigma calculation was performed on a subset of ~180 positions filled in FY17 with data on total time to hire from CDER and CBER pulled from USA Staffing (September 2017)

[25]   Qualitative commentary captured in survey administered to 234 CDER and CBER hiring managers (2016)

[26]   Data on CDER HR staff count pulled from CapHR by ESSD group, data on FTE ceiling increases obtained from CDER/Office of Management/Division of Budget Execution and Resource Management/Financial Accountability Branch (October 2017)

[27]   CDER HR Staff Hire Rate was calculated by dividing the number of CDER FY16 new hires by the number of CDER HR staff. Benchmark rate was determined by dividing the FTE ceiling increase between FY15-16 by the number of CDER HR staff (2015, 2016)

[28]   Qualitative commentary captured in focus groups with hiring managers (September 2017)

[29]   Qualitative commentary captured in CDER and CBER hiring manager survey (2016)

[30]   CDER and CBER hiring manager survey (2016)

[31]   Calculated by identifying the number of HR specialists surveyed who reported being 'Satisfied' or 'Very Satisfied' with hiring manager level of involvement; 28 HR specialists responded to this particular question (2016)

[32]   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with several core competencies in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

[33]   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with several core competencies in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

[34]   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with the particular competency observed in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

[35]   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

[36]   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with the particular competency observed in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

37   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with the particular competency observed in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

38   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

39   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with the particular competency observed in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

40   Qualitative commentary captured in CDER and CBER hiring manager survey (2016)

41   Calculated by quantifying the number of CDER hiring managers who reported being "Satisfied" or "Very Satisfied" with the particular competency observed in their OHR Servicing Team; 132 responded to this question from CDER hiring manager survey (2016)

42   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

43   Qualitative commentary captured in CDER and CBER hiring manager surveys and HR specialist survey (2016)

44   80 day tracker CDER-CBER FY17 – USA Staffing (2017)

45   Assessment of Hiring and Retention Metrics (June 2017)

46   Focus groups with center HR staff (September 2017)

47   Focus groups with center HR staff (September 2017)

48   OHR Service Level Agreement (SLA) Documentation (2017)

49   Focus group with hiring managers (September 2017)

50   Qualitative commentary captured in CDER and CBER hiring manager surveys, and HR specialist surveys (2016)

51   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

52   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

53   Qualitative commentary captured in HR specialist survey (2016)

54   Calculated by quantifying the number of HR specialists who reported being "Satisfied" or "Very Satisfied" with the level of rewards and recognition they receive for quality work; 29 responded to this question from HR specialist survey (2016)

55   Calculated by quantifying the number of CDER hiring managers who reported being "Dissatisfied" or "Very Dissatisfied" with their OHR servicing team's initiative; 123 responded to this question from CDER hiring manager survey (2016)

56   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

57   Qualitative commentary captured in CDER and CBER hiring manager surveys (2016)

58   Qualitative commentary captured in HR specialist survey (2016)