June 5, 2020

U.S. Food and Drug Administration (FDA)

Management's Response to the FDA Interim Hiring and Retention Assessment conducted by Booz Allen Hamilton.

The FDA Reauthorization Act of 2017 (FDARA) enabled the reauthorization of the 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. As a testament to FDA's commitment to continuous improvement this report serves as a snapshot of the work that has been done from the beginning of FY17 (October 1, 2016) through the end of FY2019 (September 30, 2019) in response to the Initial Assessment of FDA Hiring and Retention – A Path Forward that was published in November 2017. Highlights of FDA's response to the assessment as well as the actions we are taking to address the recommendations outlined in the Crosswalk of Conclusions and Recommendations section of the Interim Hiring and Retention Assessment are summarized below.

Conclusion 1 - Strategy

Findings	**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.

Response and Action Plans	FDA agrees with the finding that the Agency lacks an enterprise-wide systems approach to integrate and optimize recruiting, hiring, and retention functions. FDA believes there is opportunity to better integrate the human capital functions through strategic human capital planning in partnership with the Centers and improve its systems approach. The main areas of the employee lifecycle will be talent acquisition (recruitment) and succession planning (retention).
	CDER and CBER created Talent Strategy Plans and the Office of Talent Solutions (OTS) conducted initial talent strategy planning sessions with CDER and CBER management in September 2019. Refreshed plans will be developed on an annual basis to analyze current hiring needs. OTS will expand talent strategy planning sessions with CDER and CBER management to include a focus on leveraging relevant time reporting data, introducing retention strategies, and forecasting needs in targeted areas.
	Talent strategy work has resulted in early positive changes. Since October 1, 2019 – April 30, 2020 FDA has achieved 1,067 gains and 700 losses for an overall net gain of +367. FDA has far outpaced its goal of a10% increase in net gains over FY19. For FY19, FDA's overall net gain was +135. As of April 2020, FDA's overall net gain was +367, which represents a +171% increase over FY19.
	OTS also has worked to strengthen its classification program and for the first time achieved its metric of "75% of classifications were completed within in the 22-day Key Performance Indicator (KPI)". In Q2FY20 FDA achieved 76% for this metric, signaling a breakthrough in classification services.
	FDA Centers have increased Cures hiring in FY20 by 200% over the same time period in FY19. More than 50% of FY20 Cures hires are external recruitments.
	FDA's succession management strategy is maturing, and we are moving toward succession management practices that prepare internal successors through leadership development and knowledge transfer to offer alternatives to external recruitment. In addition, using an enterprise, systems approach, the Office of Human Capital Management (OHCM) and the Enterprise Risk Management Team are conducting a retention study to further understand retention needs at FDA and identify gaps and areas for improvement.
	OHCM is renewing the FDA Succession Plan for 2021-23 and will offer a strategic needs assessment as part of its maturity for mentoring and developing internal successors to create internal talent pipeline and efficiently fill senior level mission critical occupations that become vacant.
	OHCM is developing a Strategic Human Capital Plan to better integrate human capital functions within the new HR infrastructure and to fully implement and optimize the OPM human capital framework within FDA.

Conclusion 2 - Data Management and Systems

Findings	**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.

Response and Action Plans	FDA concurs with the assessment of both data measurement and data integration.
	FDA is implementing an Applicant Tracking System (ATLAS) along with an employee self-service and management self-service application, and FDA Employee Portal (e-Portal), to address the data short-comings, provide data governance and real time integrated data and report building capability that addresses all functions within the OPM 80-day hiring model, strengthen efficiencies, and enhances existing metrics.
	FDA's current Human Resource Information Technology (HRIT) infrastructure is not integrated. The current systems contain manual entry leading to the lack of data integrity. The current structure results in longer hire times, increased man hours spent on tedious manual data entry, and overall delayed responses to human capital needs.
	OHCM developed an HRIT framework and roadmap that provides a high-tech, low-touch HR refresh that creates an innovative HRIT framework to empower and connect FDA employees, fostering an environment of collaboration and transparency. FDA allocated funding to address needed improvement in existing systems to ensure continued enhancement and operations of eClass, ePMAP, eTelework, FDA's Medical Credentialing Database, ePortal and Robotics Process Automation (RPA). The investment will allow FDA to refine its data governance model, consolidate data sources into a single data repository, and ensure proper remediation of data quality issues both now and into the future. Additionally, the application tracking system (ATLAS) being deployed in FY 21 will automate the hiring process by providing transparent tracking throughout the hiring lifecycle and include integration of external applications like EHCM (managed by HHS) and USA Staffing (managed by OPM).

Conclusion 3 - HR Staff Capability and Capacity

Findings	**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.
Response and Action Plans	FDA reorganized its Office of Human Resources' functions into two separate offices in 2018 in order to improve service delivery and provide enhanced dedicated leadership. The impacts of that reorganization have begun to show positive results. A resource study was conducted by McKinsey & Co. in 2018 and found that OTS lacked the necessary resources to perform hiring work and as of FY20 an additional 53 FTEs were allocated to provide hiring support across the Agency. Dedicated HR resources were also provided to the CDER and CBER hiring pilot to enhance hiring support for those Centers from FY18 - present. FDA HR leadership continues to address staff capability, capacity, and competencies using various human resource tools. FDA needs to continue to invest in HR capacity and capabilities.
	FDA has newly implemented Service Level Agreements for HR services between HR service providers (OTS and OHCM) and the Centers that will provide greater transparency and improved accountability for the delivery of services.
	FDA will continue to collaborate and enhance the quality, quantity and transparency of its services through the building of the enterprise solutions reflected in the HRIT Roadmap pending investment. The implementation of ATLAS will enable FDA to track HR workload, manage distribution of work, and proactively manage talent plans and results. FDA has implemented a new Talent Academy that outlines HR technical training for HR staff and HR leadership requires completion of Talent Academy coursework as a performance metric.

Conclusion 4 – Culture, Collaboration, and Communication

Findings	**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.

Response and Action Plans	FDA agrees that it needs to continue to enhance its hiring processes through more robust process documentation and guidance. Since October 1, 2019 (which coincides with the end of data collection for the Intern Report on Hiring and Retention), FDA has made steady progress in increasing the number of hires and net gains to the Agency in FY20. FDA plans to communicate more of what is working well and leverage those best practices across the Agency.

OTS and OHCM leadership now directly communicate to FDA hiring managers on a regular basis through e-mail communications, newsletters, and blogs to provide timely information and resources. In addition, HR staff conduct regular recurring meetings with Center staff to review HR activities, remove barriers, and ensure accountability.

Since the data collection period of the report (September 30, 2019), FDA updated 25 policies/procedural guidances and Staff Manual Guides. To ensure FDA HR staff is effectively collaborating and communicating with its internal customers, it implemented the Human Resources Policy Work Group to review and provide comment on draft guidance documents. This collaboration ensures transparency related to policy development and changes and allows for customer feedback to be considered.

Following the final approval of policy/procedural guidance, they are posted on FDA's Intranet site and a communication is released transmitting the guidance as an attachment and a link to its location is provided. In addition, the ongoing briefings and trainings on these policies/procedures are conducted with Center customers.

On March 6, 2020 OTS awarded an Inter-Agency Agreement (IAA) with the Office of Personnel Management (OPM) to improve and optimize its Title 5 Classification Program including developing a plan to remediate issues and instill a long-term standardized operation plan by September 1, 2020. The Agency is also implementing a robust internal communication campaign to orient CDER and CBER on Title 21 (21st Century Cures hiring) efforts including formal and informal training sessions, creation of checklists, job aides, updated guidance, and spot checks. This IAA also provides surge hiring capacity available to CDER and CBER (and any Center) if additional resources are needed.

OTS provides ongoing training and guidance to internal and external stakeholders/customers highlighting the Special Placement Programs (Schedule A hiring authority, 30% or more disabled veterans, preference eligibles, etc.) and how to apply or select candidates using these authorities. OTS will continue to make improvements in these Programs to ensure effective and efficient communication and guidance are communicated.

In order to improve customer experience and collaboration, the FDA Office of Operations (OO) implemented a new culture and communications program called "OO Thrives". OO Thrives is designed to enhance the OO Employee and Center Customer experience in order to improve the culture. Under the Chief Operating Officer's leadership, several trial training and communication initiatives have been developed that will later be expanded to other OO Offices. |

Conclusion 5 – Recruiting and Hiring Processes

Findings	**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.

Response	FDA agrees that it needs to continue improving the efficiency and effectiveness of its processes through better documentation, training, and communications. FDA has completed two Phases of the FDA Hiring Pilot, which has reimagined and successfully tested novel hiring processes (resulting in an average of 40 business-days (70% reduction) in time to hire) and will soon be implementing Phase III. OTS has implemented talent strategy sessions with Centers to maximize the appropriate use of the 9 different authorities available to support hiring and by September 30, 2020 will have conducted a refresh of Center Talent Plans in order to create an FDA Talent Strategy. FDA has awarded a contract to MITRE Corporation to analyze the best practice hiring capacity and capabilities from the hiring pilot and expand them Agency-wide. - Classifier Integration and Position Description Validation - Streamlined Phases of Recruitment and Targeted Timeframes - Defined Interactions with Hiring Partners - Systematic Way to Capture Data and Track Actions The Hiring Pilot will implement and complete Phase III, which will support CDER and CBER Hiring Mangers to rapidly identify and onboard staff with targeted skill sets. FDA will deploy the Applicant Tracking Lifecycle and Analysis Solution (ATLAS) to remove duplicative tracking activities and redundant roles and responsibilities By July 2020, FDA will implement the HHS Hire Now system that will enable FDA to share hiring certificates from other HHS Operating Divisions increasing FDA's access to a broader pool of candidates and gaining efficiencies through shared recruitments.

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June 4, 2020   June 4, 2020