

CONFIDENTIAL AND PROPRIETARY

FDA Hiring Initial Assessment Public Meeting

9:00 am – 12:00 pm, November 30, 2017
White Oak Campus, Building 31, Great Room A



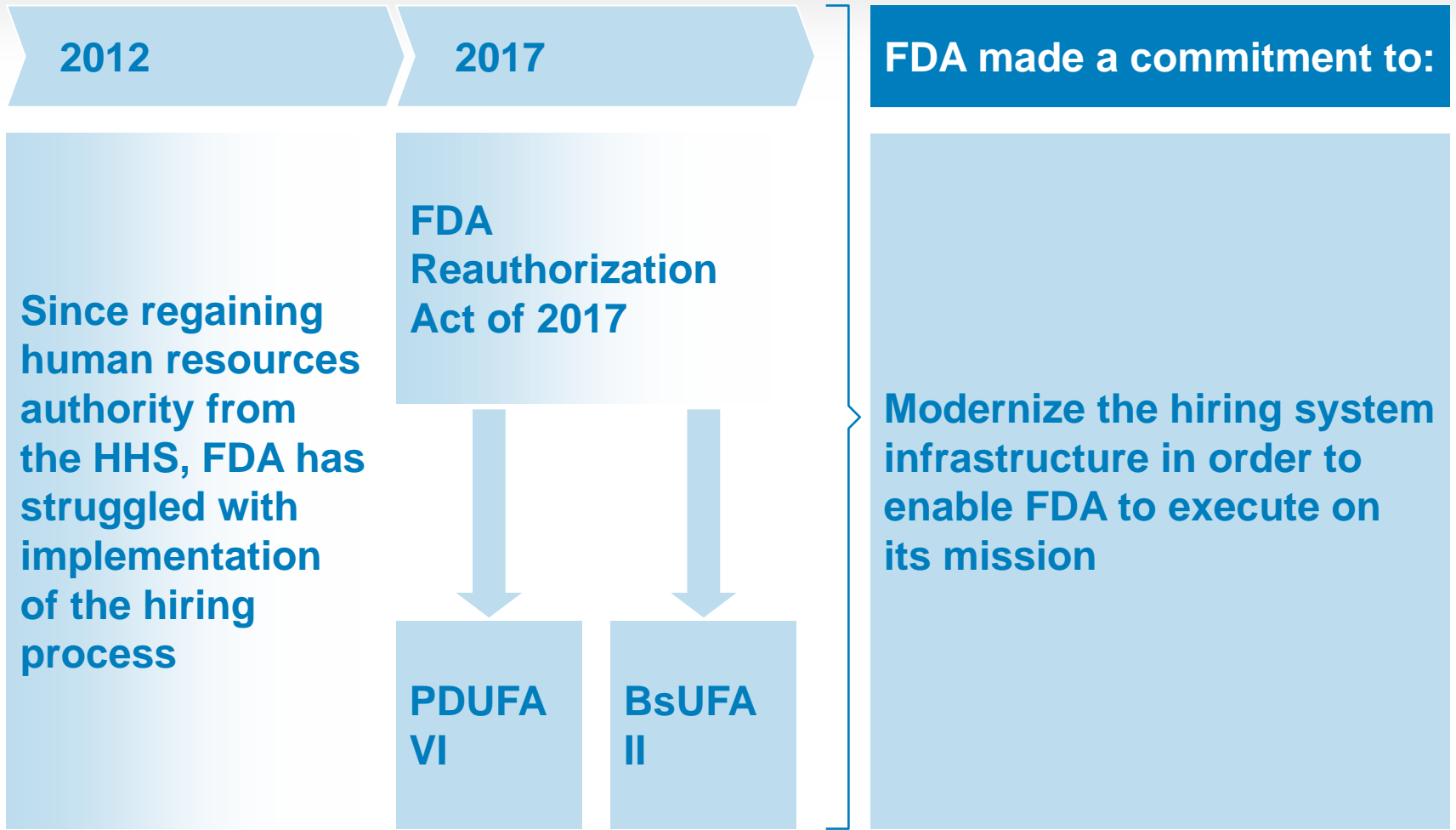
November 30 Public Meeting Agenda

Topic	Descriptions	Presenter	Time
Introduction	<ul style="list-style-type: none"> Welcome and introduction 	Rachel Sherman	9:00-9:10am
Hiring Assessment Findings	<ul style="list-style-type: none"> Objectives of the diagnostic assessment Sources of input Summary of primary findings of the current state 	Steven Berman	9:10-9:25am
PDUFA VI and BsUFA II Hiring & Retention Progress Report	<ul style="list-style-type: none"> Overview of key progress made to date Objectives moving forward 	Tania Tse and Melanie Keller	9:25-9:45am
Reimagined Hiring Pilot	<ul style="list-style-type: none"> Introduction to the reimagine hiring pilot approach Key objectives of the pilot and summary of how the pilot will be different than the current state 	Melanie Keller	9:45-9:55am
BREAK			9:55-10:15am
Public Discussion	<ul style="list-style-type: none"> Public comment from the audience 	Public	10:15-11:55am
Closing	<ul style="list-style-type: none"> Closing remarks 	Rachel Sherman	11:55-12:00pm

Objectives

- 1 Provide background context for the diagnostic**
- 2 Present an overview of the current state of hiring at FDA**
- 3 Review the diagnostic findings**
- 4 Discuss the implications and recommendations**

Context



In the past several years, there have been poor outcomes across 5 dimensions



Timeliness



Quality



Accuracy

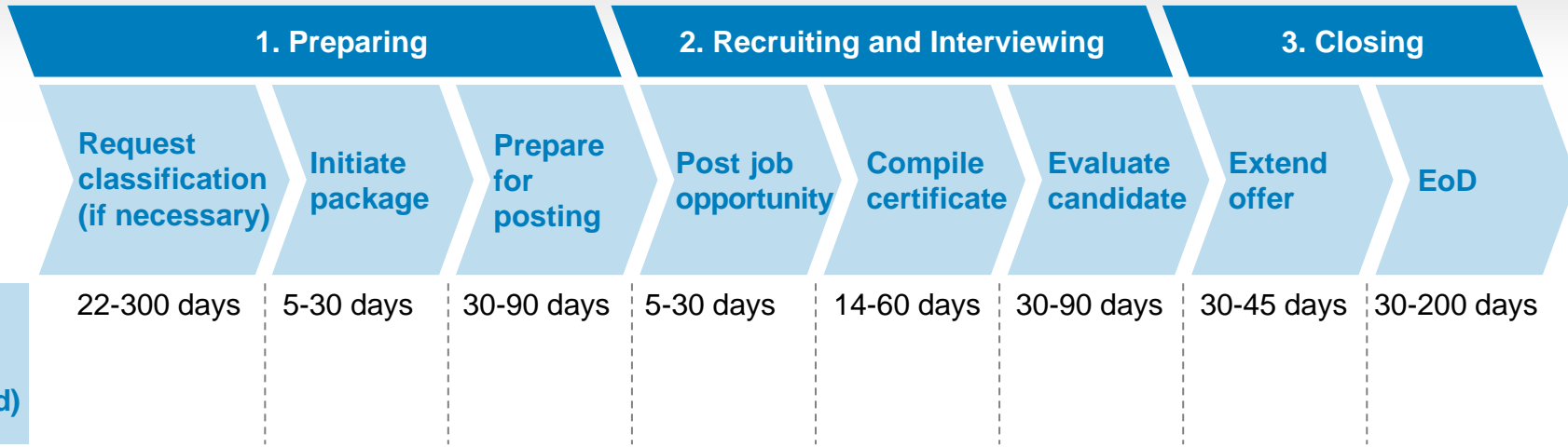


Customer service



Employee satisfaction

At a high level, the current state of hiring is wrought with lengthy timelines and high vacancy rates



Time to hire observed for positions filled in FY16-17
~150-550+ days

High vacancy rates
~14%

Low satisfaction rates with overall hiring process

Only ~12% of hiring managers surveyed are 'satisfied' or 'very satisfied'

Source: Data pulled September 2017 from CapHR, USA Staffing, Center databases

On the ground, there are numerous pain points from various stakeholders



Candidates

“

The hiring process was incredibly **frustrating**, not transparent and very **delayed**.

”



Hiring Managers

“

HR has a profound **disconnect to my Office's mission**. Timely recruitment does not seem to be a goal.

”



HR Specialists

“

There are **no [agency-wide] mandatory trainings** and there is a **lack of recognition and rewards**.

”

Source: Qualitative commentary captured in surveys administered to New Hires, Hiring Managers, OHR Specialists

A diagnostic of the root causes of the hiring process was performed

● Major ● Moderate ● Minor/No Gap

Severity of gap Criticality for success

Potential root cause of pain within existing hiring process

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



Summary of main findings

Findings

- 1 Process documentation is incomplete
- 2 Process suffers from substantial complexity
- 3 Unclear roles and responsibilities
- 4 Poor user friendly technology and systems
- 5 Lack of collaborative open dialogue

Implications

- Substantial variation in execution
- Poor timeliness and customer satisfaction
- Confusion and weak accountability
- Low efficiency and transparency
- Poor communication

Diagnostic results show that the process is not well-designed

Weak indicates room for meaningful process excellence improvement

Moderate indicates room for some process excellence improvement

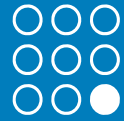
Strong indicates process is optimized across dimensions

A gap analysis against dimensions of process excellence revealed that the process is:

Dimension	Gold standard markers	Assessment	Current state
Simplicity	<ul style="list-style-type: none"> • Minimum number of steps • Minimum number of handoffs • Minimal time (from start to finish) 	Weak	<ul style="list-style-type: none"> • 52-58 steps • 24-25 handoffs • 190-845 days
Standardization	<ul style="list-style-type: none"> • Low variation in how similar cases are handled • Low variation in cycle time 	Weak	<ul style="list-style-type: none"> • Qualitative capture from hiring manager survey indicates high variability • 2 sigma process
Efficiency	<ul style="list-style-type: none"> • Minimizes amount of repeat work required for: <ul style="list-style-type: none"> – HR – Hiring managers – Candidate • Minimal wasted effort on non-value add work 	Weak	<ul style="list-style-type: none"> • Qualitative capture from hiring manager survey and focus groups with HR liaisons indicates low process efficiency
Demand management	<ul style="list-style-type: none"> • Enables continual performance management • Enables planning hiring timelines in advance 	Moderate	<ul style="list-style-type: none"> • See section 5.3.3 for evidence on limited data collection • Some continual classification for generic roles



Not simple



Not standardized



Not efficient

Source: Focus groups with HR professionals conducted September 2017

The hiring process at FDA is complicated



	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	Excessive steps
# of parties involved	5	4	4	5	1-2	4	9	4	Multiple parties involved
# handoffs	3	3	5	3	0-1	5	4	1	Too many handoffs
% of steps involving handoff	75%	75%	71%	75%	0-25%	36%	24-36%	25%	
# of approvals required	1	1	2	0	0	2	1	0	Numerous approvals required

Source: Focus groups with HR professionals conducted September 2017

There is significant confusion about roles and responsibilities

In 7 out of 10 process steps, only 50% of hiring managers are clear about their responsibilities

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%

Low clarity and weak accountability

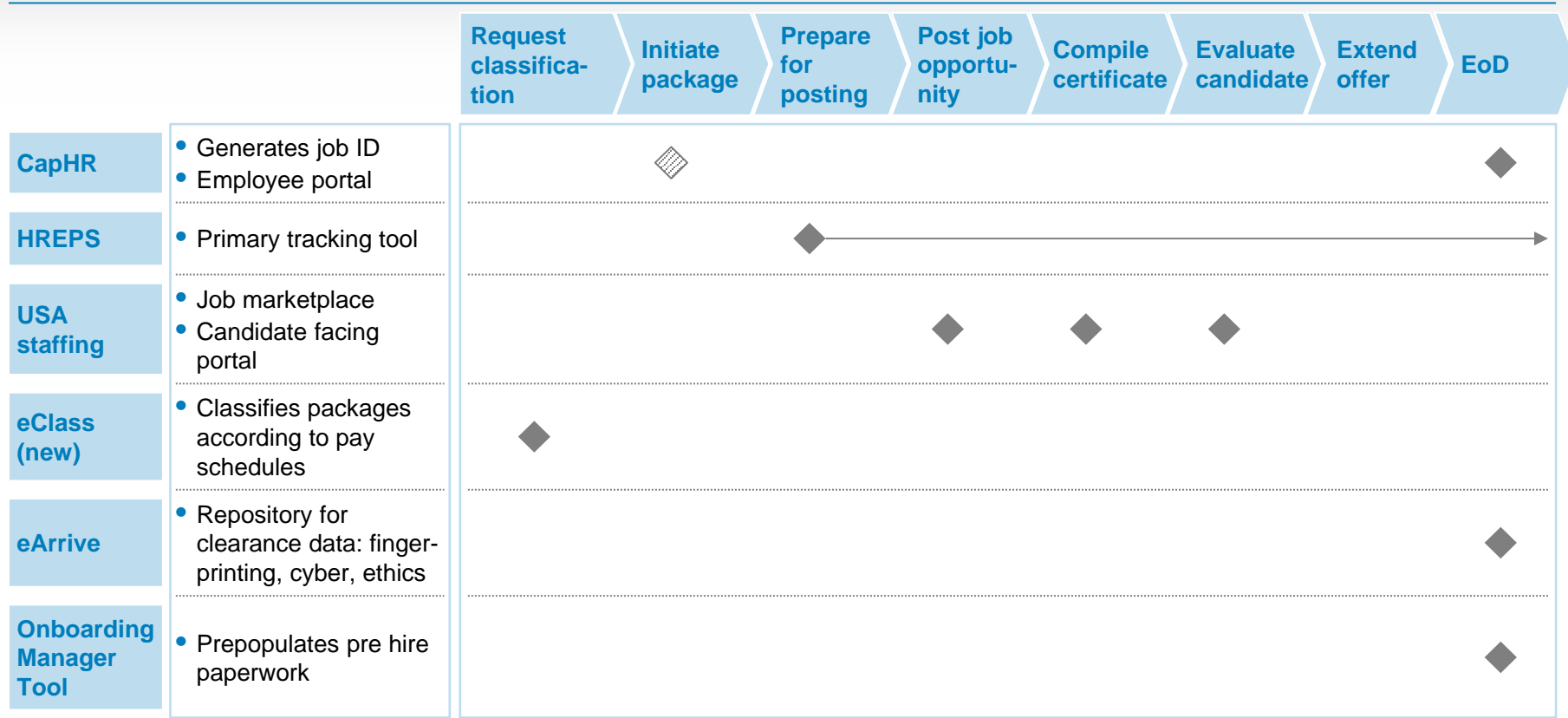


Source: CDER Hiring Manager Survey and focus groups with CBER and OHR

The current IT systems don't support the process

Center HR OHR

There are 6+ systems, each with limited integration and numerous pain points:



Not integrated 

Not automated 

Not efficient 

There is extremely limited data tracking of measurements which would enable performance improvement

Dimension

Current state of data tracking at FDA

Process timeliness



1-2 measurements (e.g., average time to fill by hiring authority)

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

Without data it is very difficult to make data-driven decisions, drive accountability, and improve the process



Source: 80 day tracker CDER-CBER FY17 – USA Staffing

The mindsets and behaviors observed do not contribute to a healthy and effective culture

The climate lacks...	<ul style="list-style-type: none">• Trust• Operational Discipline• Creativity
Motivation is poor without...	<ul style="list-style-type: none">• Focused Leadership• Personal Ownership• Rewards and Recognition
External customer orientation is weak towards...	<ul style="list-style-type: none">• Hiring Managers• Candidates
Unclear direction due to insufficient...	<ul style="list-style-type: none">• Shared Vision• Accountability• Employee Involvement

Source: Qualitative commentary captured in surveys administered to OHR Specialists, Hiring Managers

Together, the root causes drive poor outcomes across the 5 dimensions discussed earlier



Timeliness

6+ months wait for 70% of Mission Critical Occupation (MCO) hires



Quality

“The frustration of the process drives away the best candidates” – *Hiring Manager*



Accuracy

“The HR contact incorrectly spelled my name on the onboarding website and I was sent someone else's quals” – *New Hire*



Customer service

“I was not given updates as to the progress or where I was in the pipeline. This was very stressful because I was entertaining other job offers, and needed to provide responses to them” – *New Hire*



Employee satisfaction

Over 50% of CDER and CBER hiring managers report dissatisfaction with OHR communication of their recruitment and hiring strategy

Source: CDER, CBER Hiring Manager Surveys and New Hire Surveys

Overview of recommendations




Design and launch a controlled pilot, testing:

-  A new optimized process design minimizing handoffs
-  Reconfigured stakeholder roles
-  New sources of talent
-  Enabling technologies
-  Targeted investments in HR and human capital capability building
-  Reevaluation of hiring policies

Evaluate performance and iterate:

-  Identify metrics against five hallmarks of success:
 - Timeliness
 - Accuracy
 - Customer service
 - Employee satisfaction
 - Quality
-  Incorporate meaningful performance goals

Expand the pilot, while:

-  Creating a culture of mutual collaboration and accountability
-  Implementing appropriate IT systems
-  Evaluating options to optimize the organization

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Objectives

Indicates PDUFA VI or BsUFA II commitment

Indicates other hiring initiatives

- 1) **Implementation of position based management**
- 2) Transition to New Core HR IT Platform (EHCM)
- 3) **Development and launch of eClass**
- 4) **Implementation of corporate recruitment strategy**
- 5) Establishment of a dedicated Title 38 (medical officer) team
- 6) **Award of HR support contract**
- 7) **Scientific staffing team**
- 8) **User fee hiring goals**
- 9) **Continuous assessment of hiring and retention**
- 10) Targeted pilot testing a reimagined process (after the break)

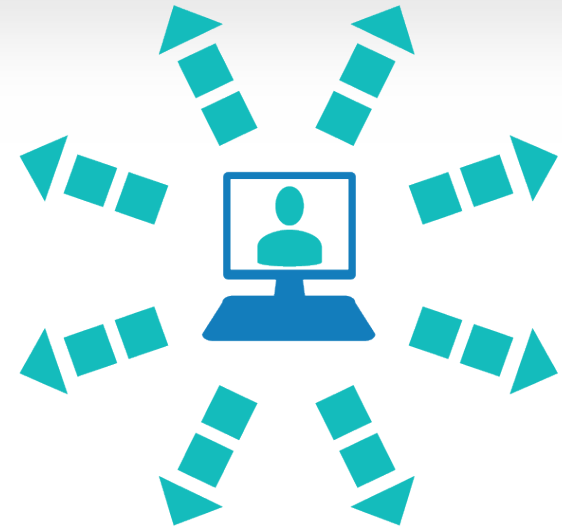
1 Position Based Management (PBM) – On-Going Effort

Complete implementation of an FTE-Based position management system capacity.

- In **June 2016** FDA began to capture information on all current filled and vacant positions for all Centers and Offices to establish a baseline
- Additionally, FDA worked to modify current financial systems, and existing HR databases to provide functionality to capture, track and manage positions
- OHR worked with OIMT to develop an Agency-wide automated Position Tracking System (PTS) as a current state solution being actively piloted at the National Center for Toxicological Research. **The PTS tool is available for use to all FDA Centers and Offices**
- As a long term solution, FDA anticipates the upgrade of core personnel systems (EHCM Project) currently in progress which includes additional position management capability. **Anticipate launch in August 2018**

2 EHCM Project Overview – On-Going Effort

Enterprise Human Capital Management (EHCM) will upgrade and streamline the current HHS HR IT infrastructure, provide additional functionality including a robust position management module, and provide employees and managers access to information through self service modules. EHCM implementation will positively **affect every FDA employee.**



IMPLEMENTATION GOALS



Valid and Reliable
workforce management,
pay and benefits data



Data Analytics to
bolster smart human
capital decision-making



Interoperability and security
Providing one enterprise-wide
platform configurable to FDA
specific business needs

3 FDA's eClass – On-Going Effort

Complete implementation of an online position classification system and establish a PD Library.

- OHR established a SharePoint PD library to provide Centers and Offices ready access to classified PDs available for use or modification.
- FDA's PD Library contains 9,834 searchable PDs for various positions at multiple grade levels.
- OHR developed eClass, an automated tool that streamlines and enhances FDA's classification and hiring process.
- eClass functionality allows position descriptions to be created, edited, approved, published, viewed, reported on and archived in a PD library.



3 eClass Launch Schedule

Beginning on October 17, 2017 eClass is being introduced Center-by-Center Agency-wide over the next two months.

eClass Introduction Includes:

- Training from experienced instructors
- A step-by-step classification process that integrates FDA processes with eClass
- Information on where to find recorded training, user manuals, deliver feedback and request assistance

eClass Phase	“Go Live Week”	Center/Office
1	October 16-20	ORA, OIP, OGROP
2	October 30-November 3	CDER, CTP, CBER
3	November 13-17	CFSAN, OFVM, OHR, OC, OMPT, NCTR, CVM
4	November 27-December 1	CDRH, OO
5	December 11-15	TBA

4 Corporate Recruitment (CRT) 2.0 – On-Going Effort

Complete implementation of corporate recruitment for key scientific and technical disciplines commonly needed across offices engaged in the human drug review program.

In 2015, OHR first implemented a Corporate Recruitment hiring strategy in response to the growing hiring needs of FDA.

Goals Include:

- Expediting the hiring process, and reducing paperwork for commonly filled mission critical positions.
- Creating access to a consistent pool of highly qualified applicants on a regular schedule.
- Leveraging technology and automation.

Corporate Recruitment is currently being utilized for 5 key scientific occupations Agency wide

4 Upcoming CRT Cycle

Current CRT Occupations	Launch Date	Hires to Date	Next Hiring Certs Issued
Mathematical Statisticians	June 2015	52	1/19/2018
Statisticians	December 2015	8	1/19/2018
Pharmacologists	June 2016	21	1/9/2018
Toxicologists	June 2016	7	1/9/2018
Chemists	July 2016	31	2/21/2018
Biologists	Expected March 2018	n/a	n/a
Microbiologists	Expected March 2018	n/a	n/a

5 Dedicated Title 38 (Medical Officer) Team - Completed

FDA stood up the Title-38 team in June 2015 to improve the timeliness and consistency of Title-38 hiring, and monitor physician credentials for 800 medical and dental officers agency-wide

Accomplishments to Date:

Developed a 10-business day work flow to issue tentative job offers to selected candidates resulting in an 80% decrease in the time to hire Medical Officers and Dental Officers.

To date filled 117 positions using this streamlined process.

Partnered with FDA's Physician Compensation and Credentialing Board (PCCB) to track, monitor and advise on pay increases to ensure appropriateness and equity in physician pay across the Agency.

Currently tracking and monitoring medical credentials for 800+ employees to ensure compliance with T38 requirements.

6 Augmentation of Hiring Staff Capacity & Capability – Completed

FDA will engage a qualified contractor to provide continuous support throughout PDUFA VI & BsUFA II to augment the existing FDA HR staff capacity and capabilities.

- **On July 7, 2017, FDA awarded a multi-vendor 5 year contract with a \$49M ceiling to support current and future OHR initiatives including meeting user fee hiring goals**

7 Scientific Staffing Team for Medical Product Centers – Ongoing

Establish a staff that will conduct continuous recruiting, staffing, and retention of scientific, technical and professional staff

- ✓ Team is 50% staffed – plan to achieve 100% by March 2018
- ✓ National search for an Associate Director for Scientific Staffing underway

Goals Underway:

- Develop FDA recruitment branding campaign and deploy social media strategy
- Create targeted strategy for scientific staffing activities that align with Center priorities
 - Recruitment ambassadors
 - On-campus scientific recruiting events
 - Strategic relationships with academic and professional associations
 - Maximize FDA recruitment activities at conferences
 - Target graduate programs with STEM focus
- Improve retention of mission-critical jobs, such as math statisticians and medical officers

8 User Fee Hiring Goals (PDUFA VI and BsUFA II) - Ongoing

Metric goals for targeted hires within the human drug and biosimilar biological product review program staff

		FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
PDUFA VI Hiring Goals	CDER	43	57	45	17	9
	CBER	16	8	7	1	0
	Other FDA	12	9	6	0	0
	Total FTE	71	74	58	18	9
BSUFA II Hiring Goals	CDER	15				

9 Continuous Assessment of FDA Hiring and Retention – Ongoing

Comprehensive review of current hiring processes and hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in human drug review program staff hiring.

<u>Commitment</u>	<u>Deadline</u>
Initial baseline assessment, published study report, and public meeting	December 31, 2017 - Completed
Operationalize recommended enhancements	December 31, 2018
Interim assessment published report	March 31, 2020
Interim assessment public meeting	June 30, 2020
Final assessment published report	December 31, 2021
Final assessment public meeting	March 30, 2022

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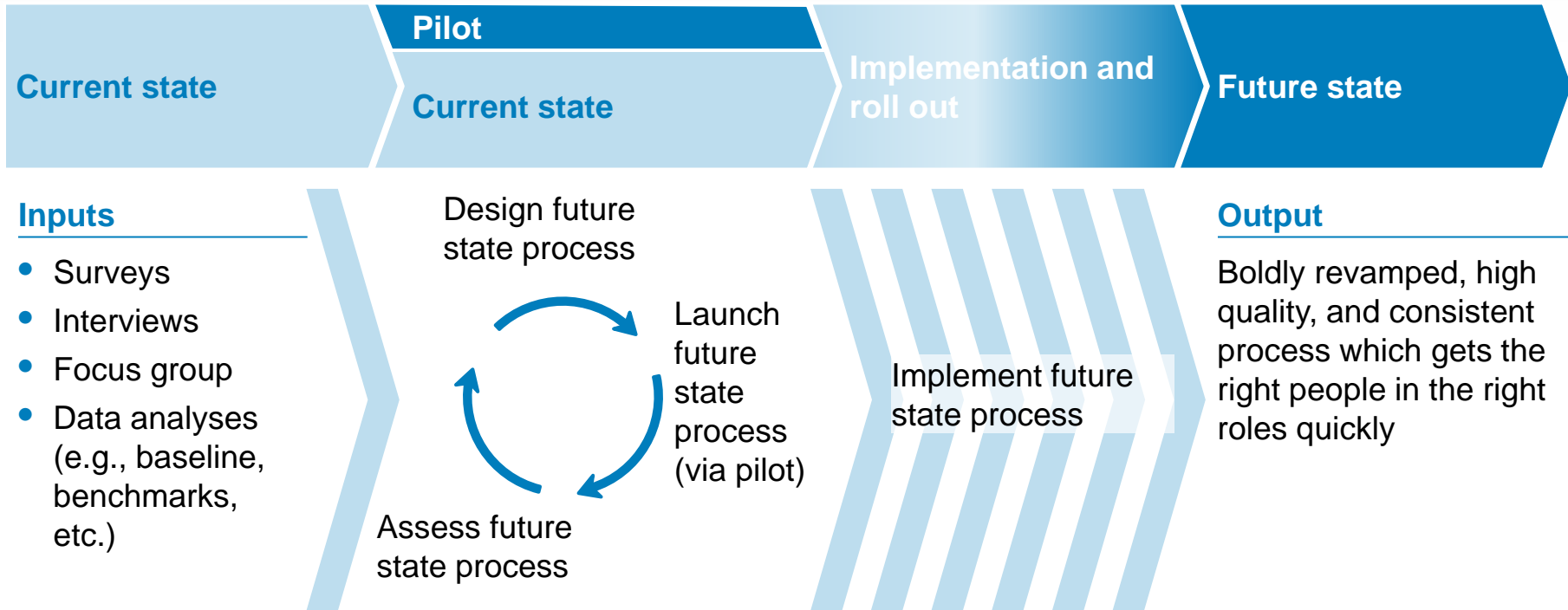
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Objectives

- 1 Provide an overview of the pilot scope and objectives**
- 2 Discuss the approach taken to redesign the hiring process**
- 3 Share the path forward for finalizing the design and implementing the pilot**

The pilot is a mechanism for designing, testing, and refining the future state design while maintaining the existing workflow

Schematic of the role of the pilot in getting from current state to future state

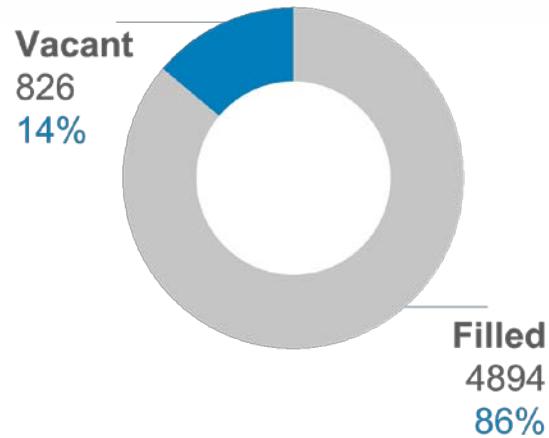


“The purpose of the hiring pilot is to **recruit and retain a world-class workforce**... by piloting new hiring **procedures** – based on **new systems** – that are designed to **directly support FDA hiring objectives**”

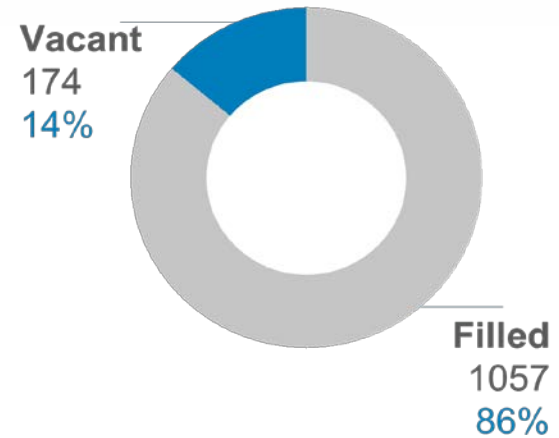
– Dr. Scott Gottlieb

The initial pilot will include ~145 packages and is designed based on the project team's objectives

CDER: ~110 packages



CBER: ~35 packages



- Enable **rapid testing** of hypotheses
- Use the pilot to **deliver priority, short-term wins**
- Act as a testing ground for novel, reimagined processes with an **eye towards future expansion**
- **Challenge conventional wisdom** and do not get 'bogged down' in organizational history or structure

Our approach to reimagining the hiring process will leverage several sources of insight

Data and analyses from prior work

Extensive surveys, focus groups, and interviews covering perspectives from across the Agency were completed and will form the factbase for understanding what needs to be fixed



Policy assessment

A mandate and policy assessment will form the guardrails for what we can and cannot build into the reimagined design



Customer perspectives

Focus groups with customers (hiring managers and new hires) will ensure the reimagined process meets their needs



**Best thinking
for a truly
reimagined
process**

External benchmarks

Learnings from within FDA (e.g., CTP) and external organizations (e.g., NASA, NOAA) will be gathered to identify the most innovative ways to recruit and hire in public sector

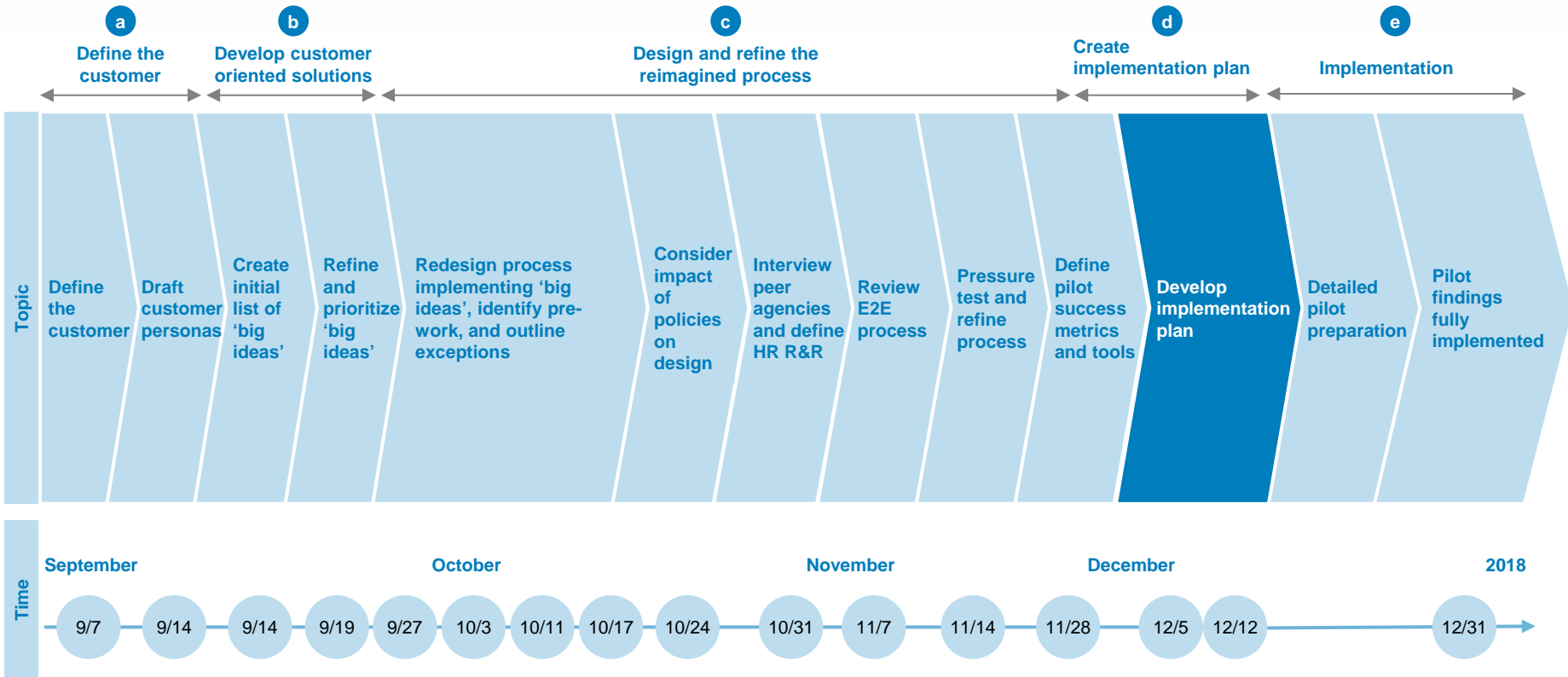


Network of experts

Expertise in human capital excellence, lean process optimization, automation, and design thinking will be leveraged to brainstorm the potential solution space

Where we are in the pilot design process – next we will develop the implementation plan

Next session



The team took a customer-focused approach to reimagining the hiring process

Hiring Managers



Candidates

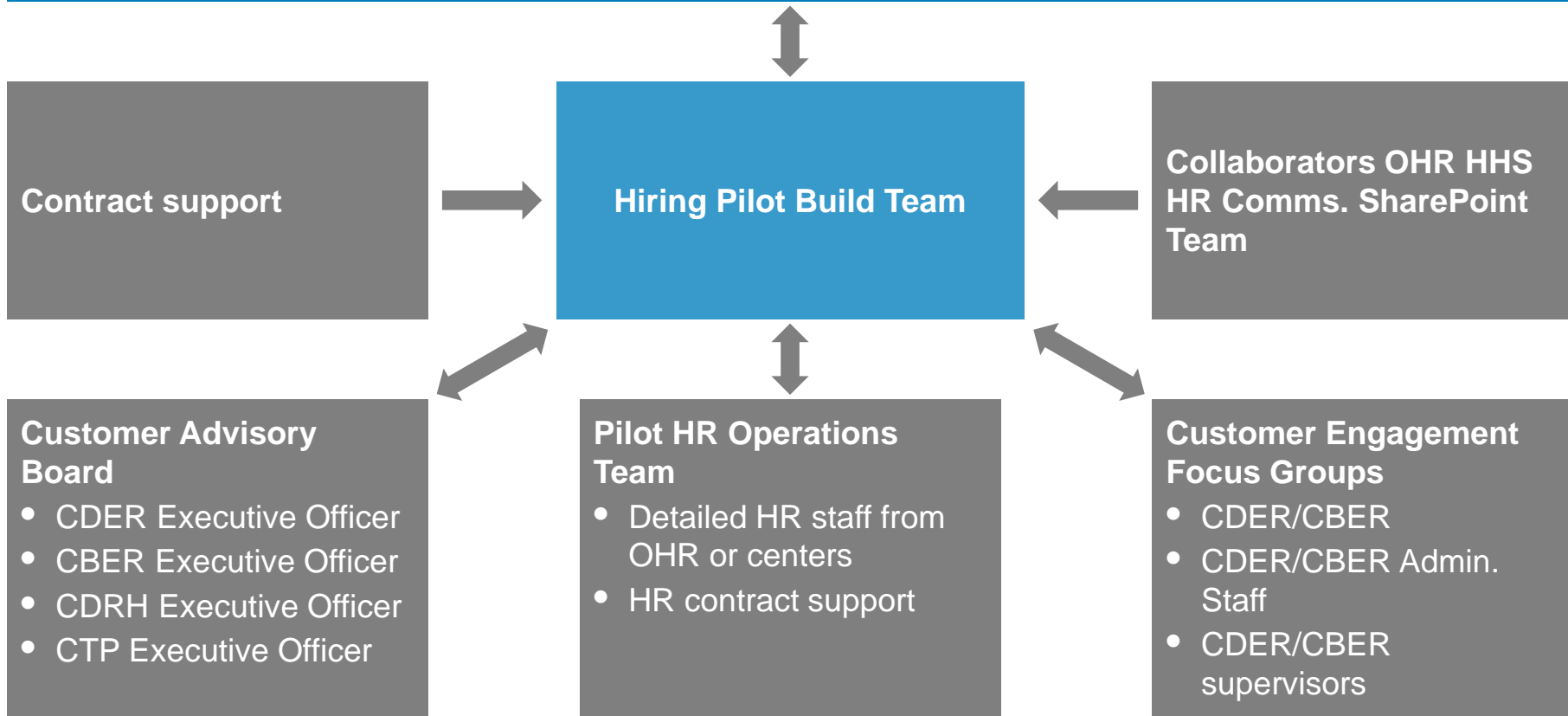


- The first step in our customer-focused approach was to **develop personas for the hiring managers and candidates**
- We created personas through **in-depth interviews and focus groups** from mid-2016 through mid-2017
- The team focused on **understanding their pain points** and **what parts of the hiring process bring them the most value**

Governance for the modernizing hiring pilot

CDER/CBER Hiring Pilot Steering Committee

CDER Center Director, CBER Center Director, COO, Principal Deputy Commissioner, Acting Associate Commissioner for Scientific & Clinical Recruitment



The pilot process will be fundamentally different from the current state with an eye towards the 5 dimensions of success



Timeliness

- **Parallel processing**
- **Reduced time** for end-to-end hiring process



Accuracy

- Ongoing performance and **process management**
- Enablement of rapid, **real-time issue escalation** and correction



Employee satisfaction

- **Rewards** and **recognition**
- Adequate **trainings** and **documented SOPs**



Quality

- **Better-fit candidates** in the **right roles** at the **right times**



Customer service

- Hiring managers have a designated, **single point of contact** who acts as interface with the 'HR engine'
- Customer service **feedback** from **hiring managers**

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Public Comment Period



We will now open the floor to public comments from the audience



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Thank you for your time

If you have any further comments/questions, please contact #TeamHiring via the docket (open until Jan 15, 2018) at:

- <https://www.federalregister.gov/documents/2017/11/02/2017-23899/assessment-of-food-and-drug-administration-hiring-and-retention-public-meeting-request-for-comments>

Please find the FR Notice including a link to the public report here:

- <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm577055.htm>

