March 2025

MDUFA Workforce Metrics Assessment

Assessment Report

Table of Contents

Executive Summary....3
Overview....3
Report Contents....5
MDUFA Workforce Metrics Assessment....6
Assessment Background and Objectives....6
Current MDUFA Workforce Measurement System....10
Overview of the MDUFA Program and Reporting Commitments....10
MDUFA Process FTE Overview....14
MDUFA Positions and Hiring Methodology Overview....20
Standards and Benchmarks....24
Key Findings....38
Recommendations....40
Recommendation 1: Implement a Comprehensive Framework for Workforce Metric Reporting....40
Recommendation 2: Centralize Workforce Reporting for Improved Communication and Transparency....41
Recommendation 3: Expand the Existing Governance Framework....42
Appendix I: Assessment Methodology....44
Methodology....44
Research Questions....45
Evaluation Framework and Benchmarks....48
Limitations and Considerations....49
Appendix II: Workforce Measurement in the Federal Government and the FDA....51
User Fee Program Definition....51
Workforce Measurement in the Federal Government....52
Key Terms....53
Appendix III: Technical Supplement....55
MDUFA Process FTE Methodology Summary....55
Analysis....57
Appendix IV: Glossary of Key Acronyms and Terms....63
Appendix V: Figures and Tables....65
Figures....65
Tables....65

Executive Summary

Overview

The U.S. Food and Drug Administration (FDA) is committed to safeguarding public health by ensuring the American public has timely access to safe, effective, and high-quality medical devices of public health importance. In 2002, Congress established a user fee program under the Medical Device User Fee and Modernization Act (MDUFMA) to provide additional resources for the regulatory review process. Under this program, medical device companies pay user fees to increase FDA capacity for activities related to the oversight and review of specific medical device applications. In return, the FDA commits to meeting performance goals and regularly reporting its progress to industry. Every five years, the FDA and the medical device industry renegotiate the terms of this agreement, which is sent to Congress to reauthorize. The latest reauthorization, Medical Device User Fee Amendments (MDUFA V), was enacted in September 2022.

To provide transparency to stakeholders and meet reporting requirements, the FDA reports on the workforce supporting the MDUFA program through two metrics: MDUFA Process Full-Time Equivalents (FTE) and MDUFA Hires.[1] These two metrics are the product of statutory requirements and negotiations between the FDA and industry representatives. As a part of the MDUFA V Performance Goals and Procedures for Fiscal Years 2023 through 2027 (**MDUFA V Commitment Letter**), the FDA and industry agreed to an assessment by an independent contractor of the methodologies and metrics used to represent the current FDA workforce completing MDUFA activities. The FDA engaged Eagle Hill Consulting (Eagle Hill) to:

- **Describe the purpose of workforce measurement in the federal government**
- **Describe the current MDUFA workforce measurement system**
- **Identify relevant benchmarks, standards, and assessment criteria for comparable workforce measurement systems**
- **Assess the MDUFA workforce measurement system in comparison to the assessment criteria**
- **Provide recommendations for improvement**

The assessment, which began in July 2024 and concluded in February 2025, relies on an evaluation model guided by seven targeted research questions and a robust assessment methodology. While the assessment aims to provide context for the MDUFA program as a whole, much of the analysis focuses on MDUFA V, including fiscal years (FY) 2023 and 2024. The assessment analyzes data from FDA IT systems, including time reporting, position management, and budgeting systems. The assessment also includes a gap analysis based on industry standards for workforce metrics and best practices from benchmarked user fee programs, both domestic and international. The overall analysis incorporates qualitative insights from FDA subject matter experts (SMEs), industry representatives, existing process documentation, and publicly available reports.

The current reporting framework for MDUFA activities meets reporting requirements and has the potential to be enhanced for greater transparency and insight into the workforce. Due to internal investments and refinement, CDRH and CBER's time reporting and HR systems are equipped to provide insights beyond those currently generated. These recent data system investments have improved FDA's workforce data collection and analysis capabilities. However, misalignment exists between the FDA and industry representatives due to a lack of consensus on definitions in reporting. Workforce reporting focuses on MDUFA Process FTEs and positions, capturing effort and hiring progress. The methodology for estimating MDUFA Process FTEs relies on assumptions that vary across Centers and Offices.

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[1] The FDA defines the Process FTE as a measurement of labor hours expended on MDUFA activities, FY 2023 MDUFA Performance Report to Congress (pg. 21). The Process FTEs do not describe individual people, but rather the cumulative staff time that support the program. MDUFA Hires track progress toward the MDUFA V hiring goals.

Executive Summary

This report provides **three recommendations** to further improve the effectiveness and transparency of the current workforce measurement and reporting. These recommendations prioritize actionable, applicable, and data-driven solutions to address remaining challenges by leveraging the FDA's existing IT infrastructure and available data. While these recommendations reflect feasible and realistic FDA capabilities, it is worth noting that implementation requires additional resources as well as collaboration and concurrence between FDA and industry, which may occur through the MDUFA reauthorization process. The ***Recommendations*** section provides context for each of the recommendations, including pain points, recommended activities, and implementation considerations.

Recommendation 1: Implement a Comprehensive Framework for Workforce Metric Reporting: The current MDUFA program's workforce reporting, while fully compliant with the requirements set with industry in the MDUFA V Commitment Letter, provides a limited view into the workforce completing MDUFA activities. To make the MDUFA program more transparent and easier to understand, the FDA and industry representatives should create a clear framework for reporting workforce metrics that connect MDUFA workforce information to performance goals.

This framework should delineate the roles necessary to complete MDUFA activities and the specific MDUFA activities required for each role. By focusing on MDUFA-related roles and activities, this framework would improve transparency into the workforce capacity of the Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Research (CBER), the Office of Inspections and Investigations (OII),[2] and Headquarters (HQ) staff supporting MDUFA activities. More transparency into capacity would enable greater accountability and stewardship of MDUFA user fees. The FDA can generate these metrics using much of its existing data, systems, and processes. Finally, in adhering to the Office of Personnel Management (OPM) and the Office of Management and Budget (OMB) best practices, the framework should include a continuous improvement process to realize the transparency and utility of the framework.

A more thorough framework capable of providing more precise insights into how workforce dynamics affect the overall program performance would help the FDA and industry make more informed decisions during program reauthorizations.

Recommendation 2: Centralize Workforce Reporting for Improved Communication: Currently, the MDUFA program's workforce-related reporting occurs in multiple reports issued at different times throughout the year. To improve communication and visibility across the MDUFA program, the FDA and industry should agree to centralize the MDUFA program's workforce-related reporting into a single comprehensive report or dashboard. The single report or dashboard should include current reporting requirements (i.e., MDUFA Process FTEs and MDUFA Hires) and can be expanded to include metrics determined by the framework in *Recommendation 1*. The FDA and industry should consider including total employee headcount for CDRH (i.e., beyond hires) and net increases, headcount by functional role, and distribution of functional roles to align with comparable FDA user fee programs and best practices from OMB and OPM. These documents should include clear definitions of terms used, intended uses, methodological notes that outline any limitations or considerations, and an easy-to-understand summary of key points related to the MDUFA commitments.

Recommendation 3: Expand the Existing Governance Framework: Currently, the processes and procedures for calculating the MDUFA workforce metrics are inconsistently documented. To make workforce reporting more consistent, comprehensive, and efficient, the FDA should build on current governance frameworks[3] to create a roadmap for the MDUFA program's workforce reporting. The FDA should continue to formalize and document internal processes, standardize data collection, enhance transparency, and improve real-time reporting across and within the Centers and Offices, all while streamlining the reporting workflow. Where possible, the FDA should continue to standardize MDUFA reporting processes (e.g., methodology for

[2] In October 2024, the FDA transitioned the Office of Regulatory Affairs (ORA) to Office of Inspections and Investigations (OII).
[3] The FDA has established a user fee governance board that can be used as a model for a MDUFA governance framework.

calculating MDUFA Process FTEs, time reporting requirements,[4] etc.), and examine general activities for inclusion in the MDUFA workforce metrics. By building on current governance frameworks, the FDA can create a robust roadmap for the MDUFA program's workforce reporting that preserves process know-how and enables straightforward communication.

Report Contents

The MDUFA Workforce Metrics Assessment provides background information about the assessment and outlines the findings in the following sections:

- ***Current MDUFA Workforce Measurement System*** outlines the methodology, inputs, and outputs of the current MDUFA workforce measurement system and provides findings from the analysis.
- ***Standards and Benchmarks*** includes the analysis of the MDUFA program compared with benchmark user fee programs and standards.
- ***Key Findings*** summarizes actionable insights from the analysis.
- ***Recommendations*** details the three recommendations for the FDA's consideration.

Additionally, the report includes five appendices:

- ***Appendix I: Assessment Methodology*** includes detailed documentation of the analysis methodology, including the assessment approach, analysis of data inputs, and research questions.
- ***Appendix II: Workforce Measurement in the Federal Government and the FDA*** includes a detailed description of workforce measurement in the federal government.
- ***Appendix III: Technical Supplement*** provides a detailed discussion of the assessment's analysis.
- ***Appendix IV: Glossary of Key Acronyms and Terms*** includes an acronym list and definitions of key terms used throughout the report.
- ***Appendix V: Figures and Tables*** includes descriptive captions for each figure and table used in the report.

[4] Each Center and Office that contributes to MDUFA activities has different processes and requirements for determining the MDUFA Process FTE. For example, HQ, which accounts for about 6% of the MDUFA program, does not have the same time reporting standards as the other Centers and Office.

MDUFA Workforce Metrics Assessment

Assessment Background and Objectives

The Food and Drug Administration (FDA) regulates medical devices for safety and effectiveness. Through the Medical Device User Fee Amendments (MDUFA), the FDA collects fees from manufacturers to enhance the timeliness and predictability of premarket device reviews. These fees support the FDA in meeting performance goals and implementing program enhancements. Four FDA Centers and Offices support the MDUFA program: Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Research (CBER), the Office of Inspections and Investigations (OII),[5] and Headquarters (HQ).[6] Each Center and Office carries out essential activities related to the review of device applications (i.e., the MDUFA process).[7]

The current MDUFA agreement, MDUFA V, establishes performance goals for fiscal years 2023 through 2027, including a requirement for an independent assessment of the MDUFA workforce metrics. This assessment aims to describe the metrics' context, purpose, and approach, and to report findings to the FDA, the medical device industry, and other stakeholders. It also provides recommendations for improvement, summarized in this report.

The assessment evaluated the current methodologies and metrics used to represent the FDA workforce completing MDUFA activities, comparing them against established standards, and offering recommendations for improvement. The report describes how the federal government and the MDUFA program measure their workforces and compare MDUFA to similar programs. It focuses on two key workforce metrics: **MDUFA Process FTE** and **MDUFA Hires**,[8] which are detailed in the following section. The report also addresses how the metrics support user fees and their reporting processes. To provide context and actionable recommendations, it considers inputs, outputs, context, and goals for workforce reporting.

The recommendations and conclusions are informed by qualitative and quantitative analyses completed in February 2025; quantitative data incorporated in the analysis is up-to-date as of the end of FY 2024. The report aims to provides clarity on the current MDUFA program's workforce reporting by describing the workforce completing MDUFA activities in context. It relies on the FDA's workforce data, existing methods, and reporting practices, with the evaluation criteria, data analysis, and insights reviewed by the FDA.

Assessment Scope

The current MDUFA workforce measurement system consists of the methodologies, data, and metrics available to represent the FDA workforce completing MDUFA activities. These methodologies, data, and metrics include positions and MDUFA Process FTEs, as discussed in the MDUFA V Commitment Letter.

In practice, the MDUFA workforce measurement system includes two primary metrics (MDUFA Process FTE and MDUFA Hires) that provide insights into resource allocation and use. The metrics stem from statutory requirements and MDUFA commitments negotiated between the FDA and industry, including the Federal Food, Drug, and Cosmetic Act (FD&C Act) and MDUFA V Commitment Letter. The FDA must report annually on MDUFA's workforce data, including changes to the number of MDUFA Hires and MDUFA Process FTE distribution by organization. Additionally, the FDA reports MDUFA V hires, changes in average FTE hours required to complete review of medical device application types, and the number of employees subject to time

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[5] In October 2024, the FDA transitioned the Office of Regulatory Affairs (ORA) to Office of Inspections and Investigations (OII).
[6] This component is referred to as the Office of the Commissioner (OC) in section 2001(b) of the Medical Device User Fee Amendments of 2022 and in the available MDUFA Annual Performance Report (as of February 2024). Internally, it is defined to include the Office of the Commissioner (OC), and OC components including the Office of Operations (OO), Office of Policy, Legislation, and International Affairs (OPLIA), and certain other central offices.
[7] FDA, MDUFA V Commitment Letter, p. 14
[8] The reporting requirement in the MDUFA V commitment letter is the number of "hires." The FDA uses a subset of tagged positions to track the roles created with increased resources from MDUFA commitments.

reporting requirements versus those who are exempt. The MDUFA V Commitment Letter includes commitments for annual and quarterly updates on hiring targets, financial plans, and progress toward goals.

This report focuses on how the FDA measures and reports on the part of the FDA workforce that completes MDUFA activities, primarily during MDUFA V. While requirements and methods may be similar to those used in previous MDUFA cycles, this assessment does not explicitly examine the history of the FDA workforce supporting MDUFA activities, previous reporting requirements, methodologies, or available data.

Assessment Approach

This assessment began with an extensive review of existing documents, benchmarks, standards and conversations with key SMEs. The findings from these activities informed the assessment's evaluation design matrix and criteria. Clear assessment criteria are important for a systematic and transparent evaluation process. The criteria measure how well the workforce measurement system meets its goals. It also helps to identify strengths, weaknesses, and areas for maturity. The criteria for this MDUFA Workforce Metrics Assessment are based on best practices and benchmarks from similar user fee programs. The assessment criteria aim to provide insights by analyzing key data sources against a set of standardized research questions, grouped into four major themes:

- Program scope
- Program tools
- Program benchmarks
- Program performance

The analysis primarily focuses on CDRH, as staff in CDRH account for about 85% of the estimated labor hours spent on the MDUFA program. The assessment also incorporates valuable insights from SMEs across all Centers and Offices involved in MDUFA activities. This analysis includes insights from:

- **Methodology Discussions**: Conducted five in-depth discussions with representatives from CDRH, CBER, HQ, and OII to refine the methodology for computing workforce metrics.
- **Industry Stakeholder Engagement**: Held three information-gathering sessions with industry stakeholders to provide a broad, contextual perspective.
- **Data Analysis**: Analyzed position data for 2,365 unique positions, corresponding to 2,161 distinct employees in FY 2023 and 2,264 in FY 2024. Additionally, analyzed time reporting data for 2,565 distinct employees, with 2,334 employees at CDRH in FY 2023 and 2,399 in FY 2024.[9]
- **Gap Analysis**: Conducted a comprehensive gap analysis to evaluate the MDUFA workforce metric system's structure and effectiveness against established benchmarks, standards, and best practices. Identified benchmarks from five FDA user fee programs and seven federal and international user fee programs, as well as six standards and guidance documents.

To identify sources of potential misalignment between the FDA and industry about the current workforce metrics, this assessment conducted a sentiment analysis of industry representatives' perspectives. The sentiment analysis was completed through direct engagement with industry and a review of meeting minutes from MDUFA IV and V user fee negotiation meetings. For example, the sentiment analysis showed continued confusion about the current workforce metrics, including methodology, inputs, interpretation, and context; MDUFA IV and V negotiations meeting minutes show industry representatives requested clarification for the MDUFA Process FTE methodology and connections to review positions on more than ten occasions. Although agreement could not be reached between the FDA and industry on the topic, the parties did agree to a commitment to conduct an independent assessment.

[9] Position data consists of a snapshot of CDRH employees as of the end of FY 2024, and includes all MDUFA-tagged positions, regardless of fill status, and filled non-MDUFA-tagged positions. Vacant, non-MDUFA positions are excluded due to ongoing Center staffing review. CDRH employee headcounts only include employees with an assigned position tag and does not include employees assigned to MDUFA on detail or employees that left CDRH prior to the end of the fiscal year; this accounts for the difference between official headcount numbers and the employee population for the assessment's time reporting analysis.

Despite the MDUFA Process FTE's usage as a measure of the level of effort currently supporting the MDUFA program, it is often perceived as a capacity or headcount measure. Industry representatives indicated in conversations that the FTE calculation is unclear and difficult to translate into concrete terms (e.g., number of individual employees). This mirrors the reauthorization discussions where industry representatives requested additional insights into the MDUFA Process FTE methodology and time reporting processes; FDA has noted that its efforts to address industry's requests did not result in resolution.

This report relies on time reporting and position data from FY 2023 and FY 2024, as it relates to MDUFA V reporting requirements. It is not meant to capture elements and dimensions, such as capacity, beyond those requirements. The FDA uses time reporting data and position records aligned to financial systems to report MDUFA metrics; however, the FDA has other business functions and reporting requirements that use the same data and are impacted by the same processes and methods for the workforce measures. Some of the observations and recommendations in this report consider related processes, procedures, and outputs affected by the FDA's approach to calculating MDUFA workforce metrics.

The data sources are directly tied to the MDUFA program's activities and intended impacts. The assessment uses this data to provide insights into how the program is performing against its goals and commitments. The data analysis aligns with the assessment's objectives and reflects outcomes, as recommended by the guidelines for aligning data with program goals.[10]

The Centers and Offices supporting MDUFA have improved data integration and reporting procedures during MDUFA IV and V. The analysis identified opportunities for greater clarity and understanding of workforce metrics. Transitioning from a reporting system based on MDUFA's current metrics to one based on a more comprehensive set of workforce capacity measures will empower the MDUFA program to better quantify total effort and effectively communicate success stories to stakeholders.

Limitations and Considerations

This assessment acknowledges real-world considerations and limitations. Including these factors provides transparency in the methodology and interpretation of the findings. Noting limitations does not imply errors or deficiencies, as the current MDUFA program's workforce reporting fulfills MDUFA V commitments and regulatory requirements. Recognizing limitations adds to the credibility of the assessment's underlying research. For example, the benchmark analysis considers workforce metrics from other user fee programs. However, the commitment goals and methodologies used by other FDA user fee programs differ. These differences are a result of several factors, including the scope of the user fee program activities, date of program inception, resulting maturity levels, and differing areas of focus for industry.

Additionally, a constraint with this assessment and many other qualitative studies is the varied expectations and experiences of the individuals involved in this assessment. The assessment includes perspectives from FDA SMEs and industry representatives.[11] While the individuals represent the main FDA Centers and Offices and industry organizations, the assessment is unable to capture every perspective with a stake in the MDUFA program.

Finally, data availability further constrained the evaluation process. As the MDUFA program has matured, reporting requirements and reporting capabilities have also changed. These changes and the limits of the underlying data infrastructure mean this assessment cannot evaluate the full history of the FDA workforce completing MDUFA work through the lens of today's reporting requirements. These challenges underscore the complexities involved in designing and implementing an effective program evaluation and highlight key

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[10] Administration for Children and Families (ACF), Office of Planning, Research, and Evaluation (OPRE). (2023). *Chapter 6: Project manager's guide to selecting data sources for program evaluation*. Office of Planning, Research & Evaluation.

[11] Eagle Hill engaged stakeholders from a number of internal FDA Centers and Offices, including CBER, OII, and HQ, as well as external industry stakeholders from the Medical Device Manufacturers Association (MDMA), American Clinical Laboratory Association (ACLA), and Advanced Medical Technology Association (AdvaMed).

considerations that have informed the structure of the assessment criteria. See ***Appendix III: Technical Supplement*** for more context and information. Acknowledging these considerations provides a more nuanced and realistic evaluation of the MDUFA Workforce Metrics.

Overview of Report

The ***Current MDUFA Workforce Measurement System*** describes the two key workforce metrics, including IT systems, reporting requirements, and methodologies. The ***Standards and Benchmarks*** section identifies criteria from similar programs and professional standards as it applies to this assessment of the MDUFA program. This assessment yielded nine **key findings** that offer essential insights into MDUFA workforce measurement. While these findings do not determine specific actions, they enhance understanding of the current landscape and contextualize the ***recommendations***. Additional information about the assessment methodology, workforce measurement background, technical details, key terms, and figures and tables are available in ***Appendices I-V***.

Current MDUFA Workforce Measurement System

The MDUFA workforce measurement system represents a framework for monitoring and reporting on the FDA's workforce supporting the process for the review of medical device applications. This system supports FDA Centers and Offices, including the CDRH, CBER, OII, and HQ, in meeting hiring and performance goals established in the MDUFA Commitment Letter.[12] The metrics included in the measurement system also fulfill the FDA's statutory reporting requirements and provide industry representatives, Congress, and the public with insights into resource allocation and utilization. The measurement system connects methods and processes across FDA. The metrics used, including the MDUFA Process FTE and MDUFA Hires, aim to track level of effort, hiring, and financial allocations.

Overview of the MDUFA Program and Reporting Commitments

Medical Device User Fee Program

MDUFA is the FDA's second oldest user fee program, beginning in 2002 after the passage of the Medical Device User Fee and Modernization Act (MDUFMA). Through four authorization cycles, MDUFA II (2007), MDUFA III (2012), MDUFA IV (2017), and MDUFA V (2022), the FDA and industry representatives negotiated and revised application fees for certain medical device submissions. The FDA and industry representatives also determine shared outcome goals and review performance goals and other commitments to enhance the medical device program during each reauthorization.

Device Application Review

- ✓ **The FDA and applicants hold pre-submission meetings and communications** (optional)
- ✓ **Applicants submit appropriate application and fee** to the FDA. Application requirements and fee amounts differ based on the submission (e.g., premarket approval application (PMA), 510(k), supplements)
- ✓ **The FDA conducts submission review** (e.g., acceptance review, regulatory and scientific review)
- ✓ **FDA communicates decision** to applicant

CDRH's Total Product Lifecycle (TPLC) approach combines premarket and postmarket activities within a single program to inform FDA's postmarket and compliance decisions by leveraging knowledge from premarket data. The TPLC approach integrates MDUFA process activities, defined in Section 737(9) of the FD&C Act as "activities that are included in the review of device applications," with non-MDUFA activities. MDUFA process activities (hereafter referred to as "MDUFA activities") are performed by staff to a varying degree throughout the Centers and Offices included in the MDUFA program. Staff commonly perform both MDUFA activities and non-MDUFA activities, which creates complexities associated with workforce reporting.

The MDUFA program also specifies three legal conditions (known as "triggers") that must be satisfied each year for FDA to collect and spend MDUFA user fees.[13] One legal condition requires a minimum spending from budget authority appropriations, excluding user fees, on the MDUFA program. Due to the trigger amount, user fees supplement, rather than replace, general revenue appropriations from Congress to fund review activities for medical devices. As a result, MDUFA activities – and the staff performing them – are funded through a mixture of budget authority (BA) appropriations and MDUFA user fees.[14]

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[12] FDA, MDUFA V Commitment Letter

[13] MDUFA user fees are collected at the time of device application submissions and through an annual establishment registration fee. While the funds contribute to payroll for FDA staff involved in the review process, every individual employee's salary is funded through a mixture of budget authority and user fee funds.

[14] User fees fund specific activities, rather than individual employees who complete those activities.

Current MDUFA Workforce Measurement System

Reporting Commitments

The FD&C Act provides the statutory framework for the regulation of medical devices and the assessment of user fees to support the FDA's medical device review process. Section 738A of the FD&C Act includes reporting requirements for the FDA. The MDUFA Commitment Letters include additional reporting requirements agreed to by the FDA and industry representatives.

Workforce Metric Reporting Terms

Hiring Goals: Specific targets established in MDUFA V to support MDUFA-related activities.

MDUFA Hire: The first full-time employee onboarded to meet the MDUFA V hiring goal.

MDUFA Positions: The slots or roles allocated and created to accommodate and track MDUFA Hires.

First-Time Filled: The methodology establishing that once a MDUFA Hire employee occupies a designated position, that position is always considered filled in future reporting.

MDUFA Process FTEs: The measurement of labor hours expended on MDUFA activities.

The FD&C Act requires the FDA to track staffing levels, costs, and performance metrics to demonstrate the appropriate use of user fee resources and achievement of commitment goals[15] while providing transparency to Congress, industry representatives, and the public. In addition, the MDUFA V Commitment Letter establishes specific hiring targets and accountability measures. The MDUFA V agreement includes hiring goals; if certain performance goals are met, then hires – above the original hiring goal – are added. If the FDA does not achieve a percentage of the hiring goal, resources intended to support the new hires would be used to decrease fees in a future fiscal year. The hires are intended to fulfill MDUFA commitments and "support the process for the review of device applications.[16] These specific roles are allocated based on needs and linked to specific programmatic goals, such as premarket review efficiency or quality management. While vacancies due to attrition are tracked internally, the FDA uses a first-time filled methodology[17] to report on hiring goals externally.

The FD&C Act also requires the agency to report on FTEs funded through both user fees and BA across all divisions involved in the MDUFA program,[18] including CDRH, CBER, OII, and HQ. The FDA meets this goal by reporting on MDUFA Process FTEs. MDUFA Process FTEs are the measurement of total labor hours dedicated to MDUFA-related activities. Process FTEs are calculated using government standard budgetary practice of 2,080 annual work hours.[19] FTEs do not represent individual employees but, instead, are a representation of aggregate labor hours across all eligible activities. Supporting FTE calculations, the FD&C Act mandates reporting on employee time tracking requirements. Centers and Offices must report the number of employees subject to time reporting requirements versus those exempt.[20] Also included in the MDUFA V

[15] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 379j-1(a)(1)(A)(iv) (2024)
[16] FDA, MDUFA V Commitment Letter, p. 14
[17] A measurement approach where only the initial filling of a MDUFA-designated position counts toward annual hiring goals, regardless of subsequent vacancies or backfills of that same position. This allows the FDA to track progress against commitment goals without being penalized for normal staff attrition.
[18] ibid
[19] This calculation is derived from the OMB Circular A-11.
[20] ibid

commitment is an obligation for the FDA to perform complete time reporting to generate data that supports both workload analysis and capacity planning.[21]

Reporting Timeline Requirements

Based on statutory requirements and commitments made in MDUFA V, the FDA produces quarterly and annual performance reports and annual financial reports (see Table 1 below). Per MDUFA V, the FDA is also required to publish a five-year financial plan, with annual updates, that includes the agency's annual hiring targets. Information included within the MDUFA Program's performance and financial reporting includes:

- Changes in staffing levels, including the number of new hires, remaining vacancies, and FTEs funded by both user fees and BA
- Number of employees required to complete time reporting versus those who are exempt
- Analysis of changes in average FTE hours required to complete different types of device application reviews
- Detailed breakdowns of internal versus external hires and personnel compensation costs[22]

On a quarterly basis, the FDA must provide updates on progress toward annual hiring goals for the MDUFA program.[23] The FDA consistently meets these requirements. Table 1 highlights the workforce reporting requirements present within the MDUFA program.

Table 1: MDUFA Workforce Reporting Requirements

Source	Frequency	Reporting Requirements	Requirement Met?
FD&C Act[24]	Annual	Workforce data and analysis, including: • Changes in number of hires compared to MDUFA V commitments, and any remaining vacancies • Distribution of MDUFA Process FTEs (user fee vs. BA) by division/office (CBER, CDRH, HQ, OII) • The number of employees subject to time reporting requirements versus those exempt from such requirements for each organizational component (CDRH, CBER, OII, and HQ) • Changes in average FTE hours required to complete review of medical device application types Meeting with stakeholders to review and evaluate the implementation of the medical device user fee program	Yes
MDUFA V Commitment Letter[25]	Annual	Specific hiring targets established under the MDUFA V Commitment Letter	Yes
MDUFA V Commitment Letter[26]	Annual (five-year plan updated by end of Q2)	The FDA must publish a five-year financial plan that includes annual hiring targets. Updates by the end of the second quarter of each fiscal year must include: • Number of new MDUFA V hires by office	Yes

[21] FDA, MDUFA V Commitment Letter, Financial Transparency, and Hiring, p. 16
[22] FDA, MDUFA V Commitment Letter, p. 13
[23] FDA, MDUFA V Commitment Letter, p. 30
[24] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 379j-1(a)(1)(A)(iv) (2024)
[25] FDA, MDUFA V Commitment Letter, p. 13
[26] FDA, MDUFA V Commitment Letter, p. 13

Source	Frequency	Reporting Requirements	Requirement Met?
		• Number of hires made from outside versus within the Center • Number of unfilled positions • Changes in personnel compensation costs	
MDUFA V Commitment Letter[27]	Quarterly	The FDA must demonstrate the following: • Progress toward meeting annual hiring goals • Tracking and reporting on the hiring of internal experts, specifically for Real World Evidence-related reviews[28]	Yes

MDUFA Workforce Measurement Calculation and Reporting Process

As discussed above, the MDUFA program tracks and reports workforce commitments through MDUFA Process FTEs and MDUFA Hires. The following process map (Figure 1) was developed to represent the key activities for computing and reporting MDUFA workforce metrics. Four high-level phases were identified:

1. The FDA negotiates with industry to determine the number of hires and then CDRH allocates positions and tracks position metrics
2. CDRH analyzes aggregate time reporting data
3. CDRH calculates mass allocation (MA) percentage and process percentage
4. CDRH generates and publishes performance and financial reports

The sections below further explain and discuss these phases.

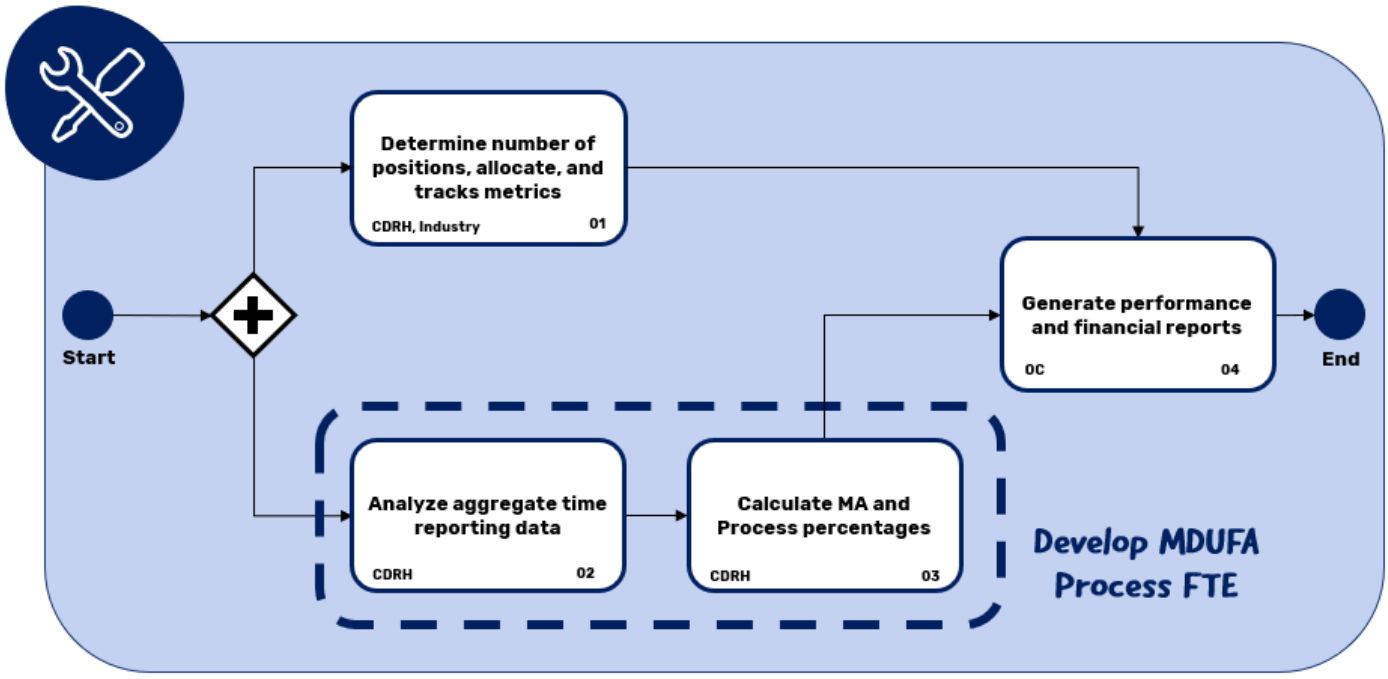

Figure 1: Process map outlining the key activities of CDRH's MDUFA FTE & Position Tracking process.

Review of IT Systems

The FDA employs multiple IT systems to track, validate, and report on MDUFA workforce metrics across Centers and Offices. Table 2 below provides a brief overview of the primary IT systems.

[27] FDA, MDUFA V Commitment Letter, p. 30
[28] FDA, MDUFA V Commitment Letter, p. 21

Table 2: FDA IT Systems Supporting MDUFA Workforce Metric Development

System	Description
Insight Time Reporting (ITR)	The ITR system is CDRH's, CBER's, and OII's platform for time reporting. Employees log the total hours they have worked each day aligned with appropriate codes, organized by activity. Each ITR code has a funding source that identifies whether the activity is 100% MDUFA allowable, not MDUFA allowable, or activity that supports MDUFA and non-MDUFA programs.
Integrated Budget and Acquisition Planning System (IBAPS)	IBAPS is a reporting tool that is integrated with Hyperion. MA percentages entered into Hyperion flow into IBAPS. In addition, the FDA Centers and Offices manually enter the process cost percentages derived from ITR data into IBAPS. IBAPS reports incorporate total spending and total FTEs[29] by funding source and applies the MDUFA process percentages by cost center to calculate total MDUFA Process FTEs and dollars spent in each cost center by fund type.
Hyperion	Hyperion is a financial modeling and planning tool used to calculate budgetary and allocation data. CDRH uses it to calculate MA percentages, and the resulting figures automatically flow from Hyperion into IBAPS for final reporting.
Position Management Systems	Centers maintain separate systems for position tracking: CDRH uses the CDRH Acquisition and Administrative Planning System (CAAPS), while CBER employs its Position Management System (Path HR).

The below sections provide further detail on the metrics and methodologies used to implement and monitor them, as well as their significance in workforce metric reporting.

MDUFA Process FTE Overview

The MDUFA Process FTE metric captures MDUFA activities performed across all Centers and Offices in accordance with MDUFA V commitments. This metric measures the level of effort expended to support MDUFA activities in terms of a paid staff year. These FTEs do not capture individual people, but rather the cumulative staff time spent to support the program. This metric should not be confused with headcount. The MDUFA Process FTE is computed following a detailed approach incorporating the OMB Circular A-11 definition of "FTE Employment".[30] This method for calculating time attributable to MDUFA activities is consistent with the other user fee programs. Since CDRH serves as the primary center for MDUFA work, this section provides an overview of CDRH's Process FTE methodology including key inputs, calculations, and reporting activities.

CDRH Time Tracking and Reporting

The primary input used in CDRH's Process FTE methodology is time recorded to MDUFA activities. At CDRH, employees use ITR to report working hours using specific activity codes. Activity codes are aligned to a funding source based on their statutory allowability, including:

- 100% MDUFA allowable (i.e., activities included in the "process for the review of device applications")
- MDUFA non-allowable (e.g., compliance-allegations activities, other user fee program activities, etc.)[31]

[29] FTE used in this context is the total worked hours (not including overtime or worked holidays) relative to regular straight-line hours (i.e., 2,080) and is how CDRH directly incorporates "FTE Employment" as defined by OMB. Total worked hours, or tour of duty, are generally capped at 2,080 hours per employee, as long as the employee is full time and works a complete year. It is important to note that this FTE value is distinct from the MDUFA Process FTE in that it is an intermediate input prior to applying the MDUFA process percentage.

[30] "FTE Employment," as defined by section 85 of the Office of Management and Budget (OMB) Circular A-11, reflects the total number of regular straight-line hours – not including overtime or holiday hours – worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for the purposes of defining "FTE Employment."

[31] Other user fee program activities in this context are associated with the Prescription Drug User Fee Act (PDUFA), Mammography Quality Standards Act, and Export Reform and Enhancement Act.

- General activity codes (e.g., policy development and hiring) that support both the MDUFA program and non-MDUFA programs

The data collected through ITR is aggregated at the cost center[32] level and used to calculate the following key values:

- **Process Percentage**: This calculation represents the proportion of hours within each cost center attributable to MDUFA-allowable activities. The process percentage determines the maximum amount of user fee funds that can be spent on payroll within a given cost center. It is also used to compute the Process FTE metric (see ***Process FTE Calculation*** for more information).
- **Process Cost Limits**: Derived from process percentages, process cost limits act as spending caps, ensuring that user fee expenditures within a cost center remain within allowable bounds. These limits are used to manage resource distribution effectively while maintaining compliance with statutory requirements.
- **Mass Allocation Percentage**: This dictates how funding is executed by fund type (e.g., BA, MDUFA, etc.). Mass allocation percentages are set within process cost limits and adjusted for funding needs, resource availability, and operational priorities. This is completed in alignment with the statutory spending trigger.

Employees working on MDUFA activities are paid using a mix of BA and user fee funds, based on MA percentages determined at the cost center level. The source for an employee's pay is not determined by their position or the amount of time they individually spend on MDUFA activities, but through the mass allocation percentage in their cost center. All employees contributing to the MDUFA program are paid from a mix of user fees and BA.

Process Costs and MDUFA Activities

As mentioned above, MDUFA activities fall into two categories of ITR activity codes: MDUFA-specific codes and general codes supporting MDUFA and other programs. MDUFA activity codes include necessary device application review activities such as premarket approval review and preapproval inspections. Time logged in MDUFA activity codes is 100% attributable to the MDUFA process. In this assessment, this time is referred to as 100% MDUFA time.

Other MDUFA activities are captured in general activity codes. These include additional and necessary activities for completing MDUFA tasks (e.g., policy-guidance development). However, hours recorded in general time categories may or may not be spent on MDUFA activities. To accurately capture this work in the MDUFA process percentage and MDUFA process cost limit, CDRH estimates the proportion of time reported in general codes attributable to the MDUFA process. The calculation uses the ratio of 100% MDUFA time to total time, excluding general time.[33] This estimated time is referred to as general MDUFA time. The general MDUFA time is then added to the 100% MDUFA time to determine the total time attributable to the MDUFA process. Total MDUFA time is used to compute the MDUFA process percentage (See Table 3).

[32] A budgetary and financial tracking unit used to aggregate and monitor expenditures of both BA funds and user fees. Cost centers are roughly organized at the division level. They serve as the core unit for which process percentages are calculated and financial allocations are tracked.

[33] This spreading proportion can be equivalently formulated as 100% MDUFA time relative to the sum of 100% MDUFA time and MDUFA non-allowable time (i.e., all other categories). This formulation is displayed in Table 3 for improved interpretability.

Table 3: Illustrative Example of MDUFA Process Percentage Calculation

User Fee / Budget Category	Total Time	Percent of Total Time	Spreading Percentage	General MDUFA Time	General Non-MDUFA Time	Time Post-Spreading	MDUFA Process Percentage
MDUFA	600	60%	*600/(600+250) = 71%*	*71%* X *150 = 106.5*		*600 + 106.5* = 706	71%
All Other Categories	250	25%	*250/(600+250) = 29%*		*29%* X *150 = 43.5*	*250 + 43.5* = 294	29%
General	150	15%					
Total	1,000	100%	100%	106.5	43.5	1,000	100%

Center-specific Variations

While CDRH and other Centers and Offices align on OMB's definition of "FTE Employment" for reporting final Process FTE outputs, there is variation in how process percentages are determined. Individual Centers and Offices calculate the process percentage differently to best reflect their unique operating contexts, workload planning, and reporting practices. As discussed in ***Process Costs and MDUFA Activities***, a portion of an employee's time is logged to general activity codes such as training, professional development, general and administrative work, and leave. CDRH includes all general activity codes when estimating MDUFA process time attributable to general activities. In contrast, CBER excludes certain general activity codes, such as leave.[34] This difference leads to minor variation in process percentages.

HQ and OII implement alternative approaches to workforce time trackinMDUg. HQ relies on financial reports rather than the time reporting system for FTE calculations. OII has historically relied on its Field Accomplishments and Compliance Tracking System (FACTS) for activity-based tracking of MDUFA work. However, the Office is working to mature tracking capabilities as it integrates ITR into its workforce measurement and reporting system. OII began using ITR in FY 2022 to capture MDUFA-specific data, introducing designated codes that allow employees to attribute their work to MDUFA.[35] Operational staff still use FACTS to record the granular details of inspection activities while also using ITR to log overall time spent on MDUFA and other administrative tasks.

Reporting Activities and Data Checks

To compile MDUFA process time into the reported Process FTE metric, CDRH follows a standardized reporting process (see Figure 1, above). This process begins with manually entering mass allocation percentages and process cost limits into the financial planning and modeling systems, Hyperion and IBAPS. These systems aggregate and reconcile data to support the generation of internal financial reports.[36] The MDUFA Process FTE metric is an output of these reports as it incorporates time attributable to MDUFA activities in terms of a paid staff year devoted to the MDUFA program.

CDRH regularly reviews these internal financial reports and makes data-driven adjustments to mass allocation percentages to ensure all BA funding is fully utilized. It also reviews process percentages in IBAPS on a quarterly basis. Additionally, CDRH works to minimize the number of adjustments made during these reviews through routine audits.

CDRH maintains high compliance with time reporting requirements, including standards in employee performance plans; therefore, underreporting is rare. In the event there are any underreported hours, the

[34] CBER also has other calculation-specific nuances not discussed here. The methods rely on a specific selection of activity codes attributable to the MDUFA process.
[35] OII also has ITR codes used to identify PDUFA, BsUFA, and GDUFA activities.
[36] The primary role of these internal financial reports is reconciling payroll data and ensuring that expenditures align with statutory funding guidelines. Additionally, they help determine the proportion of MDUFA resources that are necessary to support FDA's centralized services (e.g., IT services).

CDRH ITR team uses historical averages to estimate and allocate the remaining hours and time codes. CBER also compares their current reporting data against previous months to verify calculations and identify any significant variations that require additional investigation. Reports go through a formal quarterly certification process with HQ. Finally, after validation and adjustment, FDA compiles applicable reporting information (e.g., the MDUFA Process FTE metric) into the MDUFA program performance and financial reports. Reports including the MDUFA Process FTE metric are posted publicly on an annual basis.

Process FTE Calculation, Assumptions, and Limitations

At a high-level, the MDUFA Process FTE calculation (Figure 2) can be broken down into two main components related to MDUFA process percentage and reporting activities.[37] The first involves the process percentage calculations covered in ***CDRH Time Tracking and Reporting***. This part of the methodology is where the hours attributable to MDUFA activities are collected, analyzed, and synthesized for use in the CDRH reporting process. The second component is completed via the steps outlined in ***Reporting Activities***. This portion of the methodology involves reconciling MDUFA process time with available funding per statutory guidelines and culminates in the reported Process FTE metric.[38] Additionally, it is important to note an additional term included in this methodology overview: FTE. This term represents the total worked hours (not including overtime or worked holidays) per FTE (i.e., 2,080), consistent with OMB's definition of "FTE Employment". It is a standardized input used across all MDUFA-associated Centers and Offices to convert the MDUFA process percentage into FTE terms for reporting purposes.

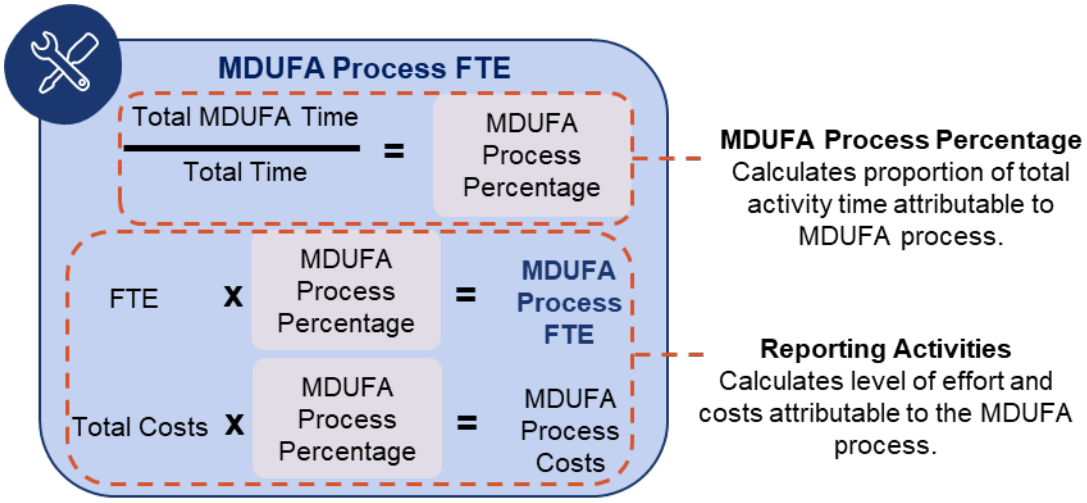

Figure 2: High-level description of MDUFA Process FTE calculations. Calculations are broken up into two distinct components: the MDUFA Process Percentage and Reporting Activities.

In reviewing the methodology for calculating MDUFA Process FTEs, and its role in MDUFA reporting requirements, this assessment found that the metric sufficiently meets reporting requirements. The methodology is based on certain assumptions and limitations to effectively estimate the MDUFA process percentage. These assumptions and limitations are directly linked with specific calculation steps in the MDUFA Process FTE methodology (Figure 3). Also, in many cases, they help balance the trade-off between providing sufficiently granular estimates and methodological rigor. The assumptions and limitations can best be summarized as follows:

[37] The calculation overview provided is a high-level simplification of the MDUFA Process FTE methodology. Due to the nuances associated with computing the Process FTE metric at scale (i.e., across all cost centers) as well as organizational variation (e.g., support organizations versus non-support organizations), the full details of CDRH's Process FTE calculations are considerably more complex. However, this high-level summary helps build intuition around the key inputs, mechanics, and interpretation of the metric.
[38] MDUFA process costs are also calculated as a part of the reporting activities component; however, they are communicated primarily through the MDUFA Process FTE metric.

Current MDUFA Workforce Measurement System

Assumptions:

- *Labor Distribution Assumption*: General time attributed to MDUFA activities is distributed proportionally based on total non-general time reported in each individual cost center (i.e., it does not vary by functional role).[39]
- *General Activities Assumption*: All general activity codes are included when calculating the proportion of general time associated with MDUFA activities.

Limitations:

- *Overtime Limitation*: Overtime hours can only be included in the Process FTE metric through the MDUFA process percentage.

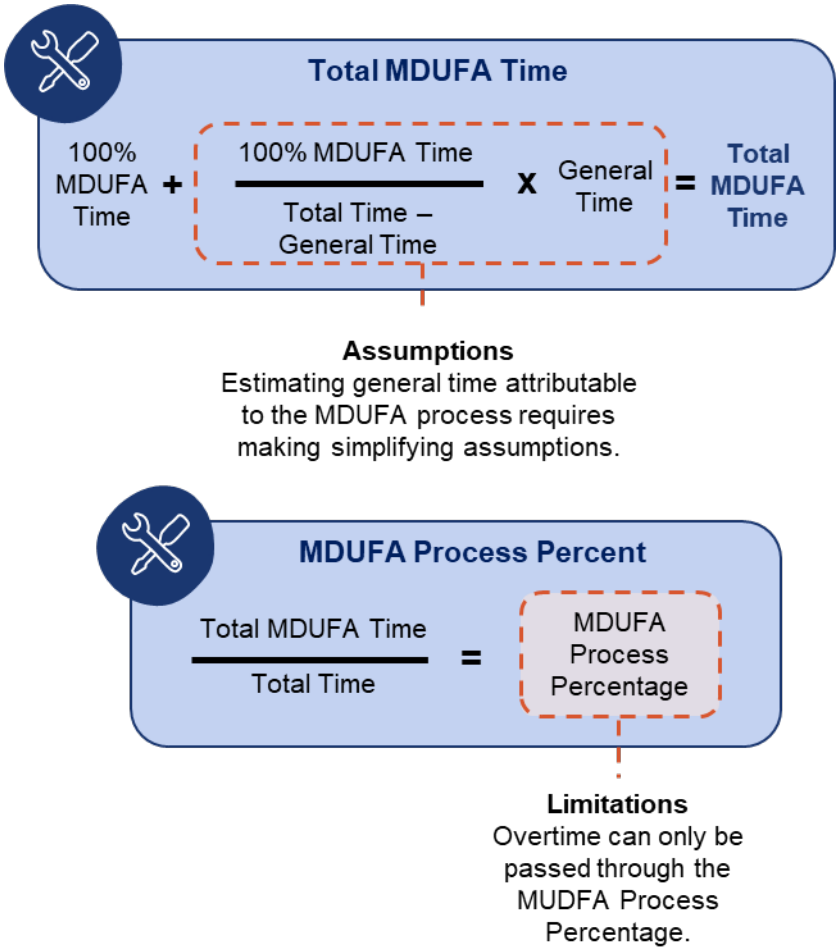

Figure 3: High-level description of Total MDUFA Time and MDUFA Process Percent calculations as well as associated assumptions and limitations.

The labor distribution assumption and general activities assumption relate to how general time attributable to MDUFA activities is estimated. These simplifying assumptions support calculating general MDUFA time at the cost center level by smoothing some employee specific variation (e.g., differences in roles). In the case of the general activities assumption, it also differs from assumptions made by other Centers that estimate MDUFA process time (e.g., CBER excludes certain activities such as leave). The overtime limitation, in contrast, is primarily a function of the statutory requirements involved in reporting the MDUFA Process FTE metric. The FTE term in the MDUFA Process FTE methodology (Figure 2) must follow OMB guidelines using straight-line hours, meaning it excludes overtime and holiday hours worked. Therefore, any overtime completed in a given cost center can only be passed through to the final reported Process FTE metric via the MDUFA process percentage. Ultimately, this means that the significant hours worked above the standard tour of duty are not fully included in the Process FTE. Additionally, depending on what activities are included, the impact on the process percentage is skewed. For a more detailed, technical discussion of the mechanics of these assumptions and limitations see ***Appendix III: Technical Supplement***.

Discussion and Opportunities for Improvement

Overall, this assessment found that the MDUFA Process FTE metric meets reporting requirements and measures MDUFA process level of effort as intended. However, after extensive analysis and review of applicable documentation, there were clear opportunities for improvement, particularly with respect to

[39] An important note regarding the interpretation/mechanics of this assumption vary depending on the type of cost center (e.g., support organization cost centers use a center-wide average for general time spreading).

communication and alignment between MDUFA program stakeholders on interpretation of the metric. This alignment is key to the continued success of the MDUFA program.

Workforce Metric Reporting Outcomes

Current reporting meets statutory requirements but does not provide insights into the specificity of objectives/goals.

The sentiment analysis from direct conversations with industry representatives and review of meeting minutes from MDUFA IV and V user fee negotiation meetings helps to clarify the external views of the MDUFA program's reporting practices.[40] The MDUFA Process FTE methodology was the primary source for many of the interpretation issues identified in the sentiment analysis. Although the Process FTE metric is intended to convey MDUFA process level of effort, it is not always communicated nor interpreted as such. The sentiment analysis shows the MDUFA Process FTE is often seen as an approximate measure of headcount or capacity. This is distinct from the level of effort framing that CDRH intends, leading to misalignment in expectations between internal and external stakeholders on the information the metric should convey. Additionally, the Process FTE methodology requires multiple separate internal reports to assemble and there are no formal SOPs available for certain internal reporting process steps, further complicating communication and understanding by industry.

Additionally, the assumptions and limitations inherent to the Process FTE metric can further compound stakeholder misalignment. Although these assumptions and limitations are helpful in simplifying the metric calculations or a result of statutory requirements, they also mean Process FTEs do not account for certain workforce nuances that are typically included in formal measures of capacity. Cost center estimates of general time may not fully incorporate differences in employee roles and include some non-work activities such as leave.[41] In contrast, formal capacity measures estimate FTE needs by role and only focus on productive hours (i.e., time dedicated to mission-focused workload). These differences are reasonable given the intent and scope of the Process FTE metric but indicate a need for careful communication to avoid misinterpretation. Lastly, the overtime limitation potentially impacts how additional MDUFA attributable hours beyond tour of duty translate to Process FTEs. In some cases, this translation may not occur as intended due to the mechanics of the Process FTE methodology calculations. These considerations present an opportunity for the FDA and industry to consider additional reporting to provide a comprehensive view of the CDRH workforce completing MDUFA activities.

This assessment's findings highlight the need for more careful communication of the MDUFA Process FTE metric as strictly a measure of level of effort. Furthermore, stakeholders who promote the growth and maturity of the MDUFA program cannot rely on the Process FTE metric to gain a full picture of FDA workforce completing MDUFA activities. Additional and more comprehensive metrics that measure program output can help internal partners and external interested parties to tell success stories and advocate for the MDUFA program.

[40] External views are those provided by industry stakeholders interviewed for the purposes of this assessment. Views of these stakeholders are treated as representative; however, they may not fully capture all external views related to reported MDUFA program metrics.

[41] For a technical discussion of the how these assumptions and limitations impact the outputs of the Process FTE methodology, see Appendix III: Technical Supplement.

MDUFA Positions and Hiring Methodology Overview

To address hiring goals established under MDUFA V, CDRH and CBER use position-based management systems to facilitate tracking and enable reporting on progress toward meeting these goals (Table 4). MDUFA-tagged positions are used to track the number of individuals hired, the change in the number of individuals hired as agreed in the MDUFA V Commitment Letter, and the number of remaining vacancies. In reporting on these hires, the MDUFA program uses various IT systems. The systems assign position "tags" that designate roles as MDUFA positions. These position tags can be reallocated or reassigned when positions change within the organization, with some restrictions on executive roles. The FDA internally tracks position vacancies due to attrition.

Table 4: MDUFA V Minimum Hiring Goals

Fiscal Year	Hiring Goal
FY 2023	144
FY 2024	42
FY 2025	24

Position Tracking and Reporting Methodology

CDRH and CBER use different systems to track these positions and associate hires with their respective user fee reauthorization. CDRH employs the CDRH Acquisition and Administrative Planning System Human Resource Position Based Management (CAAPS HR-PBM) to monitor position status, and CBER uses the Path HR system. In both systems, positions are specifically tagged as MDUFA positions to enable tracking against hiring commitments. Prior to MDUFA V, the MDUFA program solely engaged in informal reporting against hiring targets, as it did not have formal hiring goals requiring position tracking or specific IT systems capable of tracking positions at that level within FDA.[42]

The number of MDUFA hires is determined during the user fee negotiation process, establishing annual hiring targets. Internal allocation of new hires is determined by CDRH leadership, following the MDUFA Commitments and aligning to organizational needs (e.g., premarket review, quality management, etc.). Once allocated, the Office of Management's (OM's) Division of Financial Management (DFM) then creates the associated positions within CAAPS HR-PBM. OM's Division of Workforce Management (DWM) then works with program offices to complete the hiring process.[43]

To address the MDUFA hiring commitments, the FDA reports on progress toward meeting hiring goals using the first-time filled methodology.[44] When a position is filled for the first time, it is counted toward the annual hiring goal and is no longer considered vacant. While CDRH and CBER tracks staff attrition, there is no existing requirement to report on subsequent vacancies resulting from attrition, and the position maintains its "filled" status for MDUFA reporting purposes independent of the position's current fill status.

MDUFA-Tagged Positions and User Fees

The MDUFA Process FTE is the workforce metric directly connected to the user fee and budget authority spending, as discussed in greater detail in ***MDUFA Process FTE Overview***. As a standalone metric, MDUFA Hires have a limited impact on the execution of user fee funds. The MDUFA V Commitment Letter includes a fee adjustment related to the established hiring goals. If the FDA does not achieve a percentage of the hiring goal, resources intended to support the new hires are reallocated to decrease registration fees. The FDA met the hiring goal in FY 2023 and FY 2024 and therefore a fee adjustment was not required.[45]

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[42] Prior to CAAPS, CDRH personnel systems focused on individual employees rather than specific positions. Due to normal evolutions of the organization and movement within individual employee's careers, following a specific position over time is difficult.
[43] Standard hiring procedures are used to meet MDUFA hiring goals. CDRH applies a dynamic approach to tracking positions as the specifics of a position (e.g., title, job series, office) are subject to change over time. DFM deactivates and archives unused tags and new tags must be issued for future positions rather than reopening archived ones.
[44] As of January 2024, CDRH does not have formal work instructions or SOPs for position tracking and management in CAAPS HR-PBM.
[45] This is based on unpublished performance data and may be subject to change.

Current MDUFA Workforce Measurement System

More broadly, regardless of whether an employee is considered a MDUFA Hire, the source of their pay is not determined by their position, but rather through the MDUFA MA percentage. No individual employee is paid from 100% user fees funds based on their position or the work they complete. Additionally, the position tag does not determine employees' roles within the FDA; there is no formal MDUFA staff, only employees who perform activities contributing to the MDUFA program. An employee in a tagged position is not asked or expected to dedicate a predetermined amount of time to 100% MDUFA allowable activities. Further analysis of the FDA's systems indicates the amount of time reported in 100% MDUFA allowable activities varies by employee.

Filled and Vacant MDUFA-Tagged Positions

The assessment conducted a snapshot analysis of data related to MDUFA-tagged positions as it relates to staffing and total level of effort.[46] Currently, MDUFA-tagged positions make up less than 20% of the workforce in CDRH (see Figure 4). It should be noted that this figure is largely a product of MDUFA position tracking system capabilities not being available until MDUFA IV. Therefore, pre-MDUFA IV positions have not been tagged. As such, the number of employees who work on MDUFA activities (identified using time reporting data) is significantly higher than the number of MDUFA-tagged positions. All other positions are tagged as general or aligned to the initial non-MDUFA funding sources. CDRH reported that there were 2,161 and 2,243[47] employees on board in FY 2023 and FY 2024, respectively, compared to the 393 and 447, respectively, MDUFA-tagged positions during the same period.

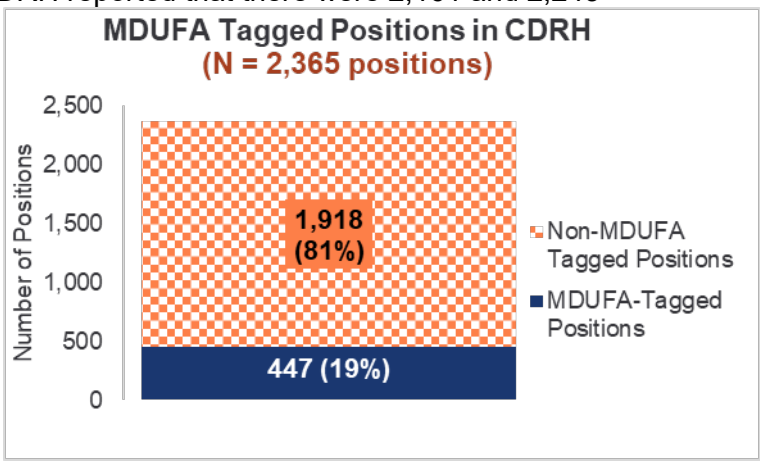

Figure 4: MDUFA tagged positions account for less than 20% of all positions in CDRH.

This assessment considers other role- and people-based metrics as an opportunity to provide insights into the MDUFA program's level of effort. Hiring goals are important to increase program level of effort, along with the volume of application review. However, the current workforce measurement system provides insight into the total level of effort in the MDUFA program using only the MDUFA Process FTEs. Additionally, the timing of hiring affects MDUFA hires' overall impact on MDUFA Process FTEs. Hires made in the middle of the fiscal year will naturally not have the same level of impact on the MDUFA program's total level of effort as a MDUFA hire onboarded at the beginning of the fiscal year. These nuances can make it difficult to quantify the total impact caused by changes in headcount (Table 5). It is unclear how meeting MDUFA hiring goals translates to a proportional increase in total level of effort.

[46] This analysis showed that of the 396 MDUFA IV and V and 51 Total Product Life Cycle (TPLC) Advisory Program (TAP Pilot) positions, the vast majority of MDUFA-tagged positions are filled. As of the end of FY 2024, 13% of MDUFA-tagged positions and 14% of TAP Pilot positions are vacant.

[47] These figures represent CDRH on-board levels at the end of the fiscal year, excluding new hires resulting from reorganizations.

Table 5: Comparison of Count of MDUFA-Tagged Positions, Employee Count, and MDUFA Process FTEs

FY	MDUFA-Tagged Positions Count	MDUFA-Tagged Positions Net Change (n)	MDUFA-Tagged Positions Net Change (%)	CDRH Headcount Reported Figure	CDRH Headcount Net Change (n)	CDRH Headcount Net Change (%)	CDRH MDUFA Process FTEs Reported Figure[48]	CDRH MDUFA Process FTEs Net Change (n)	CDRH MDUFA Process FTEs Net Change (%)
May 2022[49]	213	-	-	1,945	-	-	1,373	-	-
FY 2023	393	180	84.5%	2,161	216	11.1%	1,466	93	6.8%
FY 2024	447	54	13.7%	2,243	82	3.8%	1,593[50]	127	8.7%

Discussion and Opportunities for Improvement

The CAAPS HR-PBM system is an invaluable resource for CDRH as the system provides a significant level of detail for each position and employee in a robust and user-friendly manner. CAAPS HR-PBM contains records for all MDUFA-tagged positions created for MDUFA IV and V, including funding sources and the current and previous (as applicable) employees occupying the position. However, CAAPS HR-PBM does not identify specific roles and activities for each position, as these are considered subject to change based on position needs, and limitations stemming from the evolving nature of the position tracking system meant that data required for a historical analysis was unavailable for this assessment.[51]

The current hiring and position tracking methodology, and its embedded assumptions and limitations, has proven to be a challenge for industry in attempting to understand the MDUFA Program's resource and staff allocation. Despite FDA's ongoing efforts to clarify misconceptions around methodology and reporting, discussions with industry representatives and a review of meeting minutes from MDUFA IV and V Reauthorization Meetings reveal that industry representatives wanted to know more about the impact of hiring and vacancies on large carryover balances. Industry also expressed concerns with lack of insight into the distribution of positions and their current fill status. While they appreciated that progress has been made in these areas, reporting provided very little additional information about the individuals hired within those positions and the overall increase in capacity. However, it should be noted that this information was not required under MDUFA IV or V.

By reporting more complete and meaningful personnel metrics, MDUFA reporting can simplify hire-based reporting and reduce opportunities for further confusion. These personnel metrics include and are not limited to the total number of FDA employees who work on MDUFA activities, changes in total CDRH headcount, role-based information for the employees working on MDUFA activities, and more dynamic hiring goal reporting.[52] While these metrics are not currently represented in MDUFA performance reporting, CDRH's IT infrastructure is able to provide insights into some of these areas of interest. ***Appendix III: Technical Supplement*** offers additional insights and frameworks for quantifying the impact of time reporting tendencies of the FDA workforce completing MDUFA activities.

[48] The CDRH MDUFA Process FTE does not include the Working Capital Fund (WCF) Split.
[49] May 2022 represents the established baseline for MDUFA V. The purpose of this baseline is to exclude MDUFA V pre-hires from the total count.
[50] This figure is based on unpublished performance data, that does not include the WCF Split and is subject to change.
[51] While position data is unavailable prior to MDUFA IV, context for MDUFA V hiring decisions is provided in past MDUFA V Five-Year Financial Plans.
[52] Personnel metrics and hiring goal reporting were generated in a benchmark analysis of a number of FDA Centers, user fee programs, and standards and best practices including CBER, CDER, PDUFA, BsUFA, ISO 30414 and OPM workforce planning guidelines. Additional details on this analysis can be found in the Standards and Benchmark section.

Current MDUFA Workforce Measurement System

The use of position tracking via CAAPS HR-PBM was intended to provide greater transparency into the FDA workforce completing MDUFA activities by tracking against hiring goals. However, the limitations in the current position tracking system and the hiring goal reporting methodology mean that the resulting position metrics paint an incomplete picture of program capacity. Due to the dynamic nature of employee roles and responsibilities within a given position, lack of alignment between MDUFA-tagged positions and total CDRH headcount and an unclear connection between employee headcount and program capacity, it can be difficult to develop a holistic understanding of intended capacity gains. If CDRH and Industry agree that capacity metrics are needed, the current MDUFA position tracking should be adapted to a more specific role- and activity-based tracking system. The versatility of CAAPS HR-PBM means it is well suited to provide more granular and targeted insights. Additional metrics may provide a clearer picture into the relationship between position allocation and program performance.

Standards and Benchmarks

This assessment conducted a benchmark analysis[53] of the MDUFA workforce metrics system, focusing on 18 standards and benchmarks to document strengths, areas for improvement, and potential for system maturity. Table 6 outlines the specific standards and benchmarks used in this analysis, providing a clear foundation for understanding the areas where the MDUFA program aligns with best practices and where opportunities for adjustments exist.

- **Food and Drug Administration User Fee Programs**
  - Prescription Drug User Fee Act (PDUFA)
  - Generic Drug User Fee Act (GDUFA)
  - Biosimilar User Fee Act (BsUFA)
  - Animal Drug User Fee Act (ADUFA)
  - Animal Generic Drug User Fee Act (AGDUFA)
- **U.S. Federal Government and International User Fee Programs**
  - Nuclear Regulatory Commission (NRC) License Fee Program
  - Animal and Plant Health Inspection Service (APHIS) Agricultural Quarantine and Inspection Program
  - Environmental Protection Agency (EPA) Hazardous Waste Electronic Manifest Establishment Act
  - Federal Energy Regulation Commission (FERC) Electric Assessment Fees
  - Health Canada Medical Devices Directorate (MDD) Medical Device License Fees
  - Australian Therapeutic Goods Administration (TGA) Medical Device Application Fees
  - European Union European Medicines Agency (EMA) Medical Device Registration Fees
- **Standards and Best Practices**
  - ISO 30401, Human resource management: Guidelines for internal and external human capital reporting
  - Federal Chief Data Officer (CDO) Council Recommendations for Implementing HR Dashboards
  - Government Accountability Office (GAO) Guidance on User Fee Programs
  - OPM Workforce Planning Guide
  - OMB Circular A-11
  - GSA President's Management Agenda - Workforce Priority Data

Summary of Comparable Benchmarks and Standards

The MDUFA workforce measurement system, as detailed in the ***Current MDUFA Workforce Measurement System*** section of this report, serves as the current framework for monitoring and reporting on the FDA's workforce supporting medical device review and regulation activities. This system plays a crucial role in fulfilling MDUFA's hiring goals, commitments, and statutory reporting requirements. It uses workforce metrics that track areas such as level of effort, hiring progress, and financial allocations.

In this context, this assessment analyzed a range of FDA user fee programs, U.S. federal government and international user fee programs, and relevant standards and best practices, focusing on identifying key similarities and differences. It is necessary to recognize that user fee programs, including MDUFA, are negotiated during reauthorization periods between federal agencies and their respective industry representatives. Both parties share responsibility for establishing and advancing broader goals and initiatives within these programs. This collaborative framework therefore influences the development and execution of

[53] Understanding the role of standards and benchmarks in assessment frameworks is essential for evaluating user fee programs. Within the context of this benchmark analysis, a benchmark serves as a measurable reference point for performance comparison, while standards and best practices are widely accepted guidelines for performance or quality.

commitment letter language, program goals, and wider initiatives, aligning them with the goals of both the user fee program and the industry it regulates.

The following key similarities and differences were identified during the benchmark analysis conducted:

Summary of Benchmark Analysis

Similarities:

1. Common structure for user fee agreements
2. Use of similar workforce metrics like FTE
3. Use of activity-based time reporting systems to track and report on workforce data

Differences:

1. Program structure across the FDA user fee programs and regulated commodities
2. Use of Workforce Capacity Planning
3. Calculation of certain key workforce metrics such as FTE and vacancies
4. Use of publicly accessible dashboards and easily accessible reports to report on program commitments

It is important to note that the benchmarked programs inherently differ in their levels of program maturity, specific objectives, and the diverse perspectives of the industry representatives involved. Some programs may be well-established, while others might still be in the early stages of implementation. The level of program maturity can significantly impact its structure, scope, and reporting effectiveness. Additionally, different objectives – whether focused on regulatory efficiency, program maturity, or resource allocation – can lead to distinct priorities set by each program. The perspectives of industry representatives also vary, as each program serves a unique sector with its own set of challenges and expectations. These factors contribute to the complexity of comparing programs, as the goals and processes of each are shaped by the distinct contexts in which they operate. As such, identified similarities or differences between MDUFA and other benchmarks do not imply a positive or negative evaluation of the MDUFA workforce measurement system.

By examining these benchmarks through the lens of the MDUFA workforce metrics system, this analysis offers insight into how different programs approach workforce management, efficiency tracking, and data utilization. It highlights both the commonalities and distinctions in their structures and practices, providing a clearer understanding of how these frameworks support or challenge the effective execution of program goals.

FDA User Fee Programs

The FDA user fee programs, including MDUFA, rely on fees collected from industry manufacturers to support the development of regulatory operations and policies. In addition to MDUFA, the FDA oversees several other user fee programs, each focused on different regulatory areas. These programs include: PDUFA, GDUFA, BsUFA, ADUFA, and AGDUFA. These programs all share a common goal of improving regulatory efficiency, advancing public health, and ensuring timely product reviews. Despite their shared mission and management under the same organizational umbrella, these user fee programs differ in their respective regulatory focus, fee structures, and their individual performance goals. However, their similarities make them comparable benchmarks for assessing the MDUFA workforce metrics system. The following comparison highlights both the commonalities and distinctions in how these programs operate, offering insights into the strengths and challenges within the FDA's broader regulatory framework.

This analysis acknowledges that the reporting, goals, and commitments included in this report are not the only related initiatives in the programs and organizations. Much of the benchmarking analysis uses publicly available information, including commitment letters. By agreeing to the goals in the commitment letters, industry and government representatives indicate these actions are a high priority and provide increased transparency.

Standards and Benchmarks

Similarities

The FDA user fee programs share several key similarities with MDUFA, making them comparable benchmarks for comparison. These similarities include a common program structure for user fee agreements, the use of similar workforce metrics like the Process FTE metric, and the reliance on time reporting systems to track workforce data. All these programs are structured to enhance regulatory efficiency while maintaining regulatory standards, and they use similar approaches to report on workforce performance, funding allocations, and progress towards hiring goals. These shared practices enable effective monitoring and performance evaluation across programs, providing insights for assessing the MDUFA program's operations and metrics.

Program Structure
User fee programs within the FDA, including MDUFA, are structured around periodic negotiations between the FDA and industry representatives, with user fees being collected during an agreed-upon 5-year reauthorization cycle. The collected funds are allocated to specific program needs, which are clearly defined and agreed upon in their respective commitment letters. These commitment letters outline program goals, objectives, and performance expectations that are critical to the success of the user fee programs. All FDA user fee programs adhere to similar standards for reporting on performance and financial goals. These standards are designed to promote transparency and to align user fees with the intended program objectives. Each program is required to justify these financial allocations through detailed analyses, typically included in the annual performance and financial reports. This common approach to performance and financial reporting allows for consistent evaluation across different programs. It also promotes accountability and continuous improvement in regulatory efficiency.

Workforce Metrics
The workforce metrics systems of the programs listed above are also very similar to MDUFA's workforce system. Workforce metrics such as the Process FTE metric are used across all the programs listed above to demonstrate work effort. The workforce measurement systems of these identified programs are closely aligned with MDUFA's system per agency-wide standards, demonstrating a consistency in how workforce metrics are evaluated and reported. In all the examined programs, there is evidence of internal workforce capacity planning measures, which serve a mutual goal of using workforce metrics to enhance and build capacity. This shared objective is reflected in how workforce metrics, such as FTE measures, are employed across the programs. The FTE metric is not used as a simple count of employees but as a more nuanced measure of the actual work effort invested in the program.

A key feature of the FTE usage within these programs is that all these user fee programs are mandated to report on the number of FTEs funded by both the BA and user fee funds in their annual financial reports. User fee programs within the FDA, such as MDUFA, utilize activity codes to track the allocation of these funds. Hours reported within these activities codes (whether they are user fee allowable codes or general codes) can be funded by either BA or user fee funds.[54] This promotes transparency and accountability in how funds are allocated for workforce management and highlights the partial reliance on user fees to maintain workforce levels. Moreover, each program's commitment letters outline hiring goals, which underscore the importance of meeting specific workforce targets. These goals typically focus on the number of new hires by office, internal versus external hires, and the number of unfilled positions.[55] This approach further reinforces the programs' shared goal of workforce development, enabling them to be equipped with sufficient and qualified personnel to meet their mission objectives. It also establishes that the calculation of workforce metrics across different programs is consistent and reliable, further supporting the objectives of the program.[56] In essence, the

[54] The types of activities included within user fee allowable work are similar between the FDA use fee programs; however, the scope of activities may be inherently different due to Center structure and user fee-specific work.
[55] Other user fee programs within the FDA, such as PDUFA and GDUFA, also currently follow a first-time filled methodology when reporting on hiring goals. This methodology establishes that once an employee occupies a designated position, the position maintains its "filled" status for MDUFA reporting purposes, independent of the p osition's current fill status.
[56] Although these programs do not describe in great detail the exact methodology used to calculate metrics such as FTEs, conversations with stakeholders at the various Centers and Offices indicate that there is a standardized approach based on government standards and best practices.

integration of workforce metrics, such as FTEs, within these programs highlights a collective effort to strategically measure the program's workforce, supporting both immediate operational needs and long-term program sustainability.

Time Reporting Systems
The consistent use of activity-based time reporting systems[57] enables these user fee programs to gather accurate workforce data and assess performance metrics. When linked to outputs reported from work product tracking systems, time tracking systems provide insights into the activities performed by the current workforce and how user fee funded time is utilized within the FDA; this enables the program to address inefficiencies and align workforce activities to program needs. Currently, MDUFA, PDUFA, BsUFA, and GDUFA all utilize ITR within CDRH, CBER, CDER, and OII. The Center for Veterinary Medicine (CVM) currently utilizes an activity-based time reporting system called Activity Time Reporting (ATR), which serves a similar function within the ADUFA and AGDUFA programs. The retrieval and analysis of workforce data is essential to management of user fee resources; therefore, the use of near identical systems by other FDA user fee programs demonstrates a similar level of commitment to data use and analysis.

Overall, demonstrated consistency in user fee structure, utilization of time reporting and similar workforce metrics allows the FDA to use these user fee programs as reliable benchmarks when assessing the efficiency and accuracy of the MDUFA workforce metrics system.

Differences

While the FDA user fee programs share several similarities with MDUFA, there are key differences. These differences include inherently different programmatic structures, commitments for resource capacity planning (RCP) and IT modernization, and the use of accessible reporting in some user fee programs. For example, PDUFA, BsUFA, and PDUFA follow a structured and linear product lifecycle, while MDUFA utilizes a more iterative process in the form of TPLC, which requires continuous regulatory oversight. These lifecycle differences affect the allocation and measurement of personnel within these programs, which has impacts on measurement and reporting capabilities. Programs like PDUFA, GDUFA, and BsUFA also have outlined workforce capacity planning and IT modernization efforts in their commitment letters as a part of a joint agreement reached with their respective industry representatives. MDUFA, in comparison, does currently have several IT initiatives underway that serve to support the MDUFA program broadly but does not include RCP or capacity planning-related IT initiatives in its commitment letter. The FDA proposed that MDUFA V include a capacity adjuster to address the risk that unanticipated, sustained increases in MDUFA workload could negatively impact the program's ability to meet performance commitments; this was first proposed during MDUFA IV negotiations. However, as of MDUFA V, RCP was not implemented within the MDUFA program.[58] Another key difference lies in the reporting methods used across these programs. Other FDA user fee programs provide publicly accessible, easily navigable information related to their commitments on the FDA website in the form of dashboards or webpages, offering clear and digestible data, such as net hiring data relative to their hiring goals. In contrast, MDUFA's reporting is currently embedded in long, standardized performance and financial reports, which meet standard reporting guidelines.

It is important to note that commitment letters for these programs vary in the level of detail provided and may not capture the entire scope of work being performed, and that these differences in capabilities are the result of user fee reauthorization negotiations and the maturity of those programs over time, which can vary significantly, as previously mentioned. Although there are differing levels of program maturity, these distinctions highlight differences in the visibility of programmatic structure, workforce capacity planning, and

[57] Activity-based time reporting systems are managerial cost accounting tools that are distinct from the universal time and attendance reporting systems directly tied to payroll within the FDA.
[58] FDA. (2021, May 29). FDA – Industry MDUFA V reauthorization meeting, the FDA's proposal related to development of a capacity adjuster (p. 5)

reporting methodologies within these programs and how they affect the overall external perception of the programs and their workforce measurement systems.

Program Structure

Differences between the MDUFA program and other FDA user fee programs impact how each program captures and reports workforce metrics. The different Centers in FDA reflect these nuances in lifecycle approach in their organizational structures. CDRH centralizes staff executing on review and monitoring activities in line with its TPLC approach within the OPEQ super office. In CDER, for example, reviewers throughout the drug lifecycle are organized in several super offices aligned to their role and/or user fee program in the drug lifecycle (e.g. Office of New Drugs, Office of Compliance, Office of Surveillance and Epidemiology). Since the same staff within OPEQ may perform both MDUFA allowable and MDUFA non-allowable activities, isolating workforce resources is challenging. CDRH's centralized structural model reinforces the need for workforce metrics that represent aggregate level of effort for allowable activities, and ultimately a capacity adjuster is likely the best mechanism for providing adequate transparency of capacity within OPEQ and CDRH broadly.

Total Product Lifecycle

CDRH operates under the Total Product Lifecycle (TPLC) model, which involves oversight of new product development and marketing, manufacturing quality, safety surveillance, and iterative product updates to meet the regulatory needs of rapidly evolving medical technology products.

Another nuance in these different product lifecycles relates to user fee funding for postmarket activities. The MDUFA program excludes more costs related to postmarket activities, such as surveillance and compliance, as compared to the drug related user fee programs. In effect, PDUFA, GDUFA and BsUFA fund a greater proportion of all activities associated with their overall programs than MDUFA does. This impacts the workforce reporting through the Process FTE as the process activities allowable for each program are therefore different.[59] Ultimately, while the FDA intentionally considers product lifecycles in its regulatory approaches for both drugs and devices, these product lifecycles have unique considerations which effect the methodology used to calculate and report on of workforce metrics.

Resource Capacity Planning and IT Modernization Commitment

Another difference between the FDA user fee programs and MDUFA is the methodologies, data, and metrics available to represent their workforce, namely the participation in the current RCP implementation plan. RCP is a systematic approach to quantifying the number and type of resources needed to optimally address forecasted workload.[60] The RCP and Modernized Time Reporting Implementation Plan, which the FDA committed to under PDUFA VI, BsUFA II, and GDUFA II, established an RCP capability and modernized time reporting plan to better anticipate and address resource demands in the user fee programs. Three of the four benchmark user fee programs (PDUFA, BsUFA, and GDUFA) include specific goals for RCP within their Commitment Letters and detailed plans for capacity planning adjustment methodologies as part of this implementation effort. This allows for the adjustment of user fee revenues to account for forecasted increases in resource needs such as hires. By using RCP, these programs are better able to predict the workforce resources, such as hires, needed in real time. RCP methodologies also capture total time worked, regardless of time above tour of duty (see the ***MDUFA Process FTE Methodology Summary*** section for more discussion about the overtime limitation). These programs are also required to demonstrate the integration and maturity of RCP, as well as modernized time reporting as a part of this implementation plan.

Resource Capacity Planning

Utilizing RCP, such as a capacity adjuster, can help user fee programs optimize the use of user fee funds. It results in an increase in capacity, when needed, to meet performance goals.

[59] Although these programs do not describe in great detail the exact methodology used to calculate metrics such as FTEs, conversations with stakeholders at the various Centers and Offices indicate that there is a standardized approach based on personnel allocation or activity tracking.

[60] U.S. Food and Drug Administration. (2023, March). Resource capacity planning and modernized time reporting implementation plan.

Standards and Benchmarks

This report influences workforce strategies and provides transparency into the process. Currently, the MDUFA program does not use a capacity planning adjuster to adjust user fees based on workload and does not have an IT modernization plan explicitly aimed at maturing IT systems to implement RCP. The RCP and modernized time reporting implementation plan does mention the intention to incorporate MDUFA into future planning, but as of 2024, MDUFA has no formal role in the plan at this time. According to MDUFA V Reauthorization meeting minutes, the FDA initially sought to integrate RCP and a capacity planning adjuster into its framework to improve resource and capacity management during the re-authorization cycle. However, an agreement with industry representatives and the FDA was not reached due to conflicting views about funding new hires that may arise from the adjuster.[61]

Despite this, CDRH continues to explore other strategies to address capacity challenges within MDUFA. An ongoing commitment in the MDUFA V Commitment Letter states that the FDA will continue to perform activity-based time reporting, so data from time reporting can be used to conduct general workload analysis and capacity planning. CDRH has made significant improvements and advancements with its existing IT systems, such as ITR and CAAPS, in the absence of an IT modernization plan in the MDUFA commitment letter. However, there is no public reporting on an RCP methodology used within the MDUFA program that demonstrates a link between gathered ITR data and capacity planning. Any future inclusion of RCP or reporting on RCP implementation or IT modernization would require further collaboration and consensus between the FDA and industry representatives. As a result of the differing interests and reauthorization schedules of these user fee programs, MDUFA may have a different structure to their capacity planning methodologies compared to other FDA user fee programs, which affects the understanding of the workforce measurement system.

Digestible Reporting

Another key contrast lies in how FDA user fee programs report on commitment goals such as hiring updates, which is stipulated in the financial transparency section of multiple commitment letters. While other user fee programs within the FDA also follow a standard first-time filled methodology to reporting filled positions, PDUFA and BsUFA release center-wide (i.e., CDER and CBER) quarterly net hiring data and hiring updates on the FDA website in an easily accessible dashboard. This dashboard structure is located on the "For Industry" section of the FDA website.

In contrast, the MDUFA commitment letter does not include language regarding a requirement for additional web posting beyond its required annual reports. The MDUFA program currently only provides quarterly hiring updates to industry representatives verbally as well as annual reports. When compared to other FDA user fee programs that report metrics using a wider set of mechanisms such as web posting, industry representatives have fewer insights into workforce goals. It is worth noting that the FDA prioritized increasing the readability of the annual MDUFA reports as of FY 2024 by streamlining the data provided to resolve industry concerns, and that implementation of additional reporting mechanisms such as a dashboard may require financial investment by the program. However, a dashboard or dedicated website in addition to required reporting would provide industry representatives, Congress, and the public with easily accessible and real-time data on hiring updates.

Digestible Reporting

Publishing important workforce metrics, such as hiring updates, in a transparent dashboard structure aids programs like PDUFA and BsUFA in providing regular and digestible updates to their industry stakeholders.

[61] FDA. (2021, May 29). FDA – Industry MDUFA V reauthorization meeting, the FDA's proposal related to development of a capacity adjuster (p. 5); FDA. (2021, June 16). FDA – Industry MDUFA V reauthorization meeting, Industry's Principles and Proposals and Response to FDA's Proposals (p. 4)

Standards and Benchmarks

U.S. Government and International User Fee Programs

Several U.S. federal government and international user fee programs were selected as benchmarks for comparison with the MDUFA workforce metrics system. These programs were selected because they are regulatory in nature, share a common mission of ensuring public health and safety, and provide publicly accessible performance and financial reports, making them valuable benchmarks for MDUFA. These programs include:

- The Nuclear Regulatory Commission (NRC) License Fee Program,
- Animal and Plant Health Inspection Service (APHIS) Agricultural Quarantine and Inspection User Fee Program,
- Environmental Protection Agency (EPA) Hazardous Waste Electronic Manifest Establishment Act User Fee Program,
- Federal Energy Regulatory Commission (FERC) Electric Assessment Fee Program,
- Health Canada Medical Devices Directorate (MDD) Medical Device License Fee Program,
- Australian Therapeutic Goods Administration (TGA) Medical Device Application Fees, and
- European Medicines Agency (EMA) Medical Device Registration Fees.

These benchmarks offer valuable perspectives on user fee structures, performance reporting, and workforce metrics, providing useful comparisons for evaluating the MDUFA program's effectiveness and operational practices.

Similarities

The MDUFA program shares similarities with various U.S. government and international user fee programs, particularly in terms of purpose, structure, workforce metrics, and data management. Like MDUFA, these programs – such as those for EPA, NRC, and Health Canada's MDD – collect fees to fund regulatory activities. Workforce tracking across these programs often involves FTE metrics to monitor staffing levels. Furthermore, these programs use IT and HR systems to manage workforce data, akin to MDUFA's reliance on platforms like ITR and CAAPS for workforce tracking and performance evaluation.

Program Purpose and Structure
The MDUFA program and several benchmark user fee programs share a common purpose: to collect fees from stakeholders, such as industry participants, to support regulatory activities. These programs typically follow a similar structural framework, where fees are calculated based on the volume of applications or services provided. For instance, the EPA's Hazardous Waste Management System User Fees, which supports the Electronic Hazardous Waste Manifest System, as well as the fees associated with the Clean Water Act and the Clean Air Act, are structured around the volume of regulatory services rendered. Similarly, the NRC and Australia's TGA have fee structures based on the volume of applications and services, ensuring that the costs of regulatory oversight are aligned with the workload required for each program. In addition to these fee schedules, many of these programs also incorporate performance requirements, so that the funds collected are used efficiently and that the regulatory processes they support meet specific standards. This shared structure across MDUFA Offices and Centers, and these other programs help to maintain consistency and transparency in how fees are levied and used, promoting fairness and accountability in regulatory activities.

Workforce Metrics
Several benchmark user fee programs, including those from the EPA, FERC, NRC, APHIS, and Health Canada, report on performance and workforce metrics in ways that are similar to the MDUFA program. A common approach among these programs is the use of the FTE metric to represent their workforce, allowing for a standardized measure of staffing levels and the capacity to perform regulatory tasks. For example, the EPA and FERC include workforce data in their financial and performance reports, tracking FTEs to evaluate the effectiveness and efficiency of their programs. Similarly, the NRC tracks staffing levels using FTEs as part of its budget reporting process, which is akin to the FDA's approach of monitoring the workforce completing MDUFA activities through FTE metrics. This consistent use of FTEs across multiple programs enables easier

comparison of workforce resources and ensures that staffing aligns with the workload and regulatory responsibilities of each program.

Data Management
The user fee programs selected for benchmarking generally rely on IT and HR reporting systems to manage workforce data, similar to the FDA's use of systems such as ITR, CAAPS, and Path HR system. For example, the MDD uses an integrated IT system to track workforce data related to medical device licensing, which mirrors the FDA's approach in managing workforce information for the medical device program. Additionally, the TGA employs data management systems to monitor staffing needs and workloads associated with device registrations, aligning with the way MDUFA tracks staffing and regulatory activity within its own medical device program. These systems help ensure that workforce data is accurately captured, enabling each program to optimize resources and align staffing with regulatory demands.

Differences

The programs discussed also have minor differences in reporting transparency on workforce metrics, with the FDA's MDUFA program standing out for its comprehensive workforce reporting as required by the FD&C act and more robust involvement with external industry representatives. The FDA regularly provides annual reports on workforce metrics and actively engages industry representatives on a more routine basis. In comparison, programs like the NRC, APHIS, EPA, FERC, Health Canada, and EMA offer more limited transparency on workforce metrics and focus engagement primarily on industry representatives, with fewer opportunities for public participation. While these programs provide useful benchmarks, the MDUFA program leads in workforce reporting and industry engagement, though opportunities remain to further enhance these areas.

External Reporting Transparency
As part of the MDUFA program, the FDA provides routine annual and quarterly performance reports and engages with industry representatives during routine quarterly meetings. The MDUFA program also releases information about user fee allocation, performance outcomes, workforce metrics, and hiring updates to industry representatives, allowing for monitoring and assessing the effectiveness of the program over time. In comparison, other regulatory programs such as the NRC License Fee Program, the APHIS Agricultural Quarantine and Inspection User Fee Program, and the EPA's Hazardous Waste Electronic Manifest Establishment Act User Fee Program offer some degree of reporting transparency on workforce metrics but fall short of the level of detail in the MDUFA program's reporting. These programs typically provide basic financial and performance data, but they do not produce as frequent or comprehensive reports on detailed workforce metrics as in the MDUFA program.[62] The annual performance and financial reporting on workforce metrics that defines the FDA and specifically the MDUFA program's transparency practices is unique compared to these benchmarks. Additionally, external engagement in programs like FERC's Electric Assessment Fee Program, Health Canada's Medical Device License Fee Program, Australian Therapeutic Goods Administration (TGA) Medical Device Application Fees, and the EMA's Medical Device Registration Fees tend to engage industry less frequently than the FDA.[63] While these programs do engage with industry and conduct periodic consultations, they do not provide the same extensive opportunities for participation or ongoing dialogue.

External Reporting Transparency

The MDUFA program stands out for its high level of reporting transparency and comprehensive external partner access when compared to similar US and International government user fee programs.

[62] The aforementioned programs do provide basic annual financial and performance reporting, but do not provide quarterly reporting or the level of reporting detail that is seen within the MDUFA program.

[63] Health Canada, EMA, and FERC all hold annual meetings or occasional ad-hoc industry consultations, but the FDA, as a part of MDUFA program, holds quarterly meetings and regular ad-hoc industry consultations.

Standards and Benchmarks

Standards and Best Practices

Government standards and best practices also play a critical role in guiding organizations on how to effectively structure and report on their workforce systems. Aligning workforce planning and reporting with recognized industry guidelines may improve efficiency and accountability. The following key standards and best practices guide this analysis including:

- ISO 30414: human resource management – guidelines for internal and external human capital reporting
- Federal CDO Council recommendations for HR dashboards
- GAO guidance on user fee programs
- OPM workforce planning guidelines
- OMB Circular A-11
- GSA President's Management Agenda for workforce data

These standards and best practices were chosen for their focus on workforce management and their application within the government regulatory context. The identified standards and best practices share a common emphasis on promoting transparency, data-driven decision-making, and the alignment of workforce strategies with organizational goals. These standards provide a structured approach to managing and reporting workforce metrics, making them comparable benchmarks for reviewing the MDUFA program's workforce reporting practices. By comparing MDUFA's current workforce metrics system to these recognized frameworks, the analysis identifies areas where processes align with or diverge from established best practices, offering insights into potential improvements in planning and reporting.

Similarities

The MDUFA workforce metrics system aligns with key standards and best practices by tracking essential data and calculating metrics using standardized methodologies to accurately inform decision-making. Additionally, the use of robust and complex HR reporting systems reflects the best practices by providing a comprehensive view of workforce performance and ensuring comparability over time, which supports the evaluation of human capital return on investment (ROI) and overall workforce effectiveness.

Workforce Metrics
Several of the selected standards and best practices emphasize the need for high-quality, reliable data to effectively track and forecast workforce needs. These standards stress the importance of clear, consistent methodologies for collecting data and calculating these metrics to promote accuracy, transparency, and comparability across different programs and organizations. In alignment with these principles, the MDUFA program leverages similar metrics to maintain and assess its workforce needs. Specifically, the FDA utilizes the Process FTE metric, which is calculated and reported following established guidelines, such as those outlined in OMB Circular A-11 and ISO 30414. These practices align with government workforce data collection and reporting standards and demonstrate a commitment to measuring and managing workforce needs, enabling the program to meet its goals and perform effectively.

HR Reporting Systems
A common thread across workforce planning standards is the need for organizations to establish comprehensive HR reporting systems that can evaluate human capital ROI and assess the effectiveness of workforce strategies, with an emphasis on ensuring comparability across organizations and sectors. The MDUFA program has made significant strides in enhancing and improving its IT systems to meet these standards. The program currently uses several HR reporting systems, such as ITR and CAAPS HR-PBM, to collect and analyze data about the workforce performing MDUFA activities. These systems are designed to provide standardized, actionable data that allows the FDA to track workforce performance and trends over time, making it easier to compare results year over year. This improved data collection capability enables the FDA to make informed decisions regarding workforce planning and resource allocation. In addition to these improvements, the FDA's approach aligns with OPM workforce planning guidelines, which call for data-driven strategies to address both current and future workforce needs. Within this framework, CDRH and CBER use HR reporting systems to plan and manage their workforce needs effectively.

Differences

Key differences between the MDUFA workforce metrics system and established standards and best practices are evident in the areas of transparent reporting and metric methodology. The standards and best practices analyzed frequently highlight clear, regularly updated performance data that is easily accessible and understandable to a wide audience to facilitate transparent, benchmarkable reporting. Additionally, the standards offer metric methodology guidance and outline how metrics can provide an accurate view of workforce capacity and potential staffing challenges. These areas of focus highlight potential improvements to be made in the MDUFA workforce metrics system.

Accessible Reporting

Standards and best practices emphasize the need for workforce reporting that is easily understandable to a wide audience and allows for benchmarking against similar organizations. For example, PDUFA, BsUFA, and other user fee programs provide publicly accessible dashboards and webpages that include performance data, such as hiring updates, and offer the ability to compare performance against other user fee programs. Guidance documents like the GAO Guide on User Fees and OMB Circular A-11 also stress the importance of providing clear, accessible, and regularly updated data on performance and program costs to increase transparency and ensure that fees remain aligned with program activities. The MDUFA program currently adheres to the reporting requirements stipulated in the MDUFA V Commitment Letter, as well statutory requirements and Agency-level decisions on how to organize information consistently across the user fee programs. The MDUFA V Commitment Letter does not include requirements for reporting in dashboards or other accessible reporting formats on the FDA website. ISO 30414 recommends providing information that "transparently reports on an organization's people-related issues" in a manner that is both digestible and accurately reflects workforce challenges. This is an opportunity for maturity within MDUFA's current performance metrics and workforce data reporting framework. The Offices and Centers involved in the MDUFA program use advanced IT systems such as ITR and CAAPS, and the FDA has reporting process in place that could align the MDUFA program with these standards.

Accessible Reporting

The MDUFA program's workforce reporting can be expanded to include easy-to-understand definitions and easy-to-access platforms aligning with best practices and other use fee programs.

ISO 30414 also highlights the importance of providing reporting that is comparable to other organizations. The GSA agenda demonstrates how a dashboard with key areas such as executive summaries and interactive data visualizations can make data accessible to a wide audience. Separate web postings or interactive dashboards could be used to display MDUFA workforce data, making it easier for stakeholders to evaluate the MDUFA program's performance against other programs. Additionally, the HR systems within MDUFA can provide more detailed information than they currently do. For example, the first-time filled reporting methodology and varied FTE metric methodology limit the usability of these metrics beyond their exact intent. See ***Current MDUFA Workforce Measurement System*** for more information. ISO 30414 emphasizes the importance of HR reporting systems remaining functional and being able to supply reliable data. As such, the MDUFA program's current reporting approach can be updated to align with government-wide best practices and the recommendations of the CDO and GSA for leveraging dashboards to improve trends and transparency. This reporting approach, like many prior discussed features, is an element of the joint agreement reached by both the FDA and industry representatives and changes would require discussion during the next reauthorization cycle.

Metrics as a Reflection of Workforce Capacity

Another difference exists currently between standards and best practices and MDUFA for calculating and utilizing key metrics as a reflection of workforce capacity. ISO 30414 specifically discusses the importance of tracking workforce availability as a metric to examine capacity, highlighting that an FTE metric should be calculated based on average working time to reflect work done, rather than simply a formula of 2,080 hours.

Standards and Benchmarks

These standards stress that FTEs should represent the work actually completed and should be used to assess workforce capacity effectively. The current MDUFA workforce metrics, including the MDUFA Process FTEs and MDUFA Hires, are not intended to capture workforce capacity, as discussed in ***Current MDUFA Workforce Measurement System***. CDRH's informal workforce capacity planning measures are not reported publicly or made available for this assessment. The specific methodology and approach of those planning measures may align with these standards, but the publicly reported Process FTE does not.

Metrics as a Measure of Capacity

Introducing capacity measures like a productive FTE metric or attrition metrics could mature MDUFA workforce reporting and align with established standards and best practices.

Additionally, MDUFA's internal position tracking systems, such as CAAPS HR-PBM, capture regular attrition. MDUFA reporting does not track vacancies after a position is filled for the first time. The "first-time filled" approach to vacancy tracking – where once a MDUFA Hire employee occupies a designated position, the position maintains its "filled" status for MDUFA reporting purposes, independent of the position's current fill status – does not align with industry best practices or OPM workforce planning guidelines.[64] The best practices and guidelines emphasize the ongoing tracking of vacancies as a crucial component of effective workforce planning. ISO 30414 supports this, noting that tracking turnover rate and vacancies is key to understanding organizational health and forecasting capacity accurately. The current framework does not capture the true staffing needs and potential gaps within FDA's workforce supporting the MDUFA program.

There is a disconnect between the FDA's current reporting practices as seen in MDUFA and the best practices outlined in ISO 30414 and OPM guidelines. For example, while the user fee programs in FDA use the first-time filled methodology for reporting on hiring goals, the other programs also provide additional hiring data such as net headcount. This allows external partners to understand current and future workforce needs. The use of a turnover rate metric for example, as suggested by ISO 30414, could add more clarity to vacancies for certain position types and may provide additional insight into the hiring goals' effect on the workforce. It is worth noting that industry representatives have raised overall concerns about the clarity and transparency of the FTE and vacancy data shared by the FDA. In the future, capacity adjustment may contribute to increased visibility.

The analysis above highlights differences between MDUFA's workforce metrics system and established best practices, particularly in the areas of digestible reporting and metrics as a measure of workforce capacity. Addressing these gaps by providing additional metrics could improve the clarity, reliability, and effectiveness of the MDUFA program's workforce metrics, enhancing trust and aligning with industry expectations. The potential addition of these metrics and reporting functions requires collaboration and cooperation between the FDA and industry representatives during future reauthorization cycles.

Gap Analysis

This benchmark analysis concludes with a comprehensive gap analysis, designed to evaluate the MDUFA workforce metric system's structure and effectiveness against established benchmarks, standards, and best practices. A gap analysis is a strategic analysis method used to identify the differences between a program's current performance and the desired outcomes. Within the context of this assessment, the gap analysis focuses on the MDUFA workforce metrics system, using relevant government standards and industry benchmarks to define ideal structures, methodologies, and practices. This method is effective in uncovering areas where the system could be matured, revealing gaps that may hinder external understanding of the program or its alignment with best practices. By clearly outlining where improvements are needed, the gap

[64] This first-time filled methodology is currently in use within other centers such as CDER and CBER within the FDA; however, these Centers also report additional information regarding headcount and vacancies as a part of their CBER and CDER Net Hiring Data and PDUFA and BsUFA Quarterly Hiring Updates on the FDA website.

analysis provided a structured way to pinpoint actionable opportunities for optimizing the workforce metrics system.

The gap analysis is structured around a systematic approach to identifying, evaluating, and addressing gaps within the MDUFA workforce metrics system. The first step is defining the gap itself, which involves comparing the current state of the program to established standards and identifying where discrepancies exist. Once the gap is defined, the impact of the gap is assessed, considering how it affects the overall effectiveness of the MDUFA workforce metrics system and its alignment with industry benchmarks. Based on this assessment, the future considerations that address the identified gaps are noted. The findings from the gap analysis are organized into categories that align with overarching themes, making it easier to understand the key areas requiring attention. It is important to acknowledge again that many of the future considerations noted, such as suggested changes or implementation that would require changes to the existing statute or the MDUFA Commitment Letter, are not solely within CDRH's or the MDUFA program's control and would need additional collaboration with industry representatives.

Increasing Transparency and Enhancing Communication

The gap analysis identified an opportunity to increase the MDUFA program's workforce reporting effectiveness in promoting transparency and communication. When compared to like-sized standards and programs, the MDUFA program can more fully leverage its current reporting mechanisms to share metric-based information about the program's workforce in a clear and accessible manner. Additionally, the FDA and industry representatives can better align on metrics that more effectively convey the MDUFA program's performance against overall objectives. Addressing these gaps is crucial to enhancing both transparency and communication within the program.

Table 6: Gap Analysis Finding 1: Reporting Mechanisms

Gap Analysis Category	Description
Overview of Finding	The MDUFA program can more effectively utilize its reporting mechanisms to communicate metric-based information on the program's workforce to increase transparency.
Identified Gap	A clear, accessible, and digestible reporting structure for workforce data and performance metrics can align MDUFA with benchmark programs. Other FDA user fee programs such as PDUFA and BsUFA provide easily accessible and detailed updates on the FDA webpage. Specifically, providing regular external hiring updates or data on a productive FTE metric, could increase transparency and the ability of external partners to evaluate the MDUFA program's current workforce capacity at a given time. While the MDUFA program has made enhancements to date towards increased financial reporting, addressing this gap would further enhance transparency on workforce metrics and could foster additional collaboration with industry representatives.
Impact of Gap	This gap impacts MDUFA's ability to demonstrate effective progress toward meeting its workforce goals and respond to external concerns. Industry representatives face challenges in assessing the MDUFA program's performance data across several complex reports, and the program has opportunities to align with industry standards for transparency. Additionally, using benchmarking against other user fee programs offers the MDUFA program a resource for best practices and improvements in workforce management. The differences in the scope of the FDA user fee programs (e.g., product lifecycle approaches) underlines the need for transparent reporting metrics. In the absence of information, stakeholders may come to their own conclusions using information from other user fee programs and sources.
Future Considerations	To enhance transparency and align with best practices, the FDA should leverage existing time reporting and position tracking systems, such as ITR and CAAPS HR-PBM, to expand data collection and report key workforce metrics like productive FTEs and current vacancies. Additionally, the FDA established reporting structures, such as the FDA website, can provide regular, accessible updates on MDUFA hiring goals allowing external partners to easily monitor and assess the program's workforce development and performance.

Strengthening Workforce Capacity Planning

The analysis also revealed a critical finding to better represent the current workforce completing MDUFA activities using capacity planning measures**.** First, agreeing to a Resource Capacity Adjuster would directly link resources and workforce capacity to MDUFA performance goals. The FDA has sought to integrate RCP into its MDUFA program framework to improve resource and capacity management in the past; however, an agreement was not reached with industry representatives due to conflicting views on funding.[65] Adding RCP may improve industry representatives' visibility into the efforts being made to increase capacity within the MDUFA program.

Second, the program can use its systems and reporting mechanisms in a way that fully reflects or enhances future capacity. As a result of several IT modernization efforts, the FDA currently has the capability to use capacity measures to more clearly demonstrate the connection between MDUFA funds and MDUFA activities. Addressing these issues can improve workforce planning and help the MDUFA program meet operational goals.

Table 7: Gap Analysis Finding 2: Building Workforce Capacity

Gap Analysis Category	Description
Overview of Finding	The MDUFA program's systems and reporting mechanisms have the ability to use and expand upon workforce capacity measures.
Identified Gap	Unlike other FDA user fee programs such as PDUFA, BsUFA, and GDUFA, which incorporate detailed RCP capabilities to adjust user fee revenues based on forecasted resource needs, the MDUFA commitment letter does not include RCP. Adding a defined approach to integrate workload data with user fee adjustments offers opportunities to report more holistically on capacity and incorporate mechanisms to build capacity within the MDUFA program.
Impact of Gap	By including RCP, the FDA can optimize the use of MDUFA user fee funds and link workforce capacity with workload demands, such as premarket reviews, leading to greater efficiencies in staffing and resource allocation.
Future Considerations	To strengthen capacity planning, the MDUFA program should continue discussions with industry representatives to implement a formal RCP methodology, similar to those used by PDUFA, BsUFA, and GDUFA, to align user fees with resource needs. Additionally, program maturation and greater adoption of capacity planning tools, as outlined in other FDA user fee programs, would support this effort.

Expanding Metric Usage within MDUFA

Finally, the benchmark and gap analysis found that there are significant areas for improvement regarding metric use within the MDUFA program. Currently there is a misalignment between the methodology used to calculate key metrics, such as the MDUFA Process FTE, and the industry representative's desire to effectively see workforce capacity maturity demonstrated through workforce reporting. This key metric in use was not intended to measure workforce capacity; therefore, introducing a different metric into public reporting such as a productive FTE could prove more effective in bridging understanding of capacity between the FDA and industry stakeholders. Other metrics used currently within the program, such as hiring metrics, could also be expanded to include attrition to shed more light on capacity within the program. Including role- and people-based metrics, including attrition, can help to provide insightful information to industry representatives on current capacity and foster more collaborative future discussions.

[65] FDA. (2021, May 29). FDA – Industry MDUFA V reauthorization meeting, the FDA's proposal related to development of a capacity adjuster (p. 5)

Table 8: Gap Analysis Finding 3: Metric Expansion

Gap Analysis Category	Description
Overview of Finding	The MDUFA program can expand metrics and standardize methodologies to better represent workforce capacity.
Identified Gap	The use of the MDUFA Process FTE, based on a standard formula that includes unworked hours such as leave and PTO, was not intended to and does not reflect the complete capacity of the workforce completing MDUFA activities. Additionally, the current MDUFA position reporting methodology, which tracks positions for the first time filled does not align with standards and best practices and therefore may not reflect current staffing needs.
Impact of Gap	The current representation of workforce level of effort through the MDUFA Process FTE makes it difficult to assess staffing needs and forecast future resource requirements. Tracking vacancies beyond the first-time filled aligns the MDUFA program with best practices and better equipped partners to respond to staffing challenges. Accurate, comprehensive data increases external partners' confidence in the program's ability to meet its performance goals and address workforce gaps.
Future Considerations	To better align its metrics with workforce capacity goals, the MDUFA program should utilize its existing position tracking system to report vacancies, headcount, and roles in an ongoing manner. Additionally, reporting a productive FTE metric as a part of the MDUFA regular performance reporting would provide a more accurate and real-time reflection of workforce capacity.

Key Findings

The key findings, denoted in bold, align with the assessment's research questions and key considerations. The key findings highlight successes while identifying the primary areas for improvement uncovered during the analysis. These findings inform the recommendations that are designed to address the areas for improvement. Key findings included in this section summarize insights gathered from the assessment:

1. The current reporting framework meets reporting requirements. **The standards can be enhanced to provide more transparent and definitive insights into the workforce completing MDUFA activities.** For instance, while the FD&C Act requires reporting of the distribution of the MDUFA Process FTE by Center and Office, the conclusions from the MDUFA Process FTE can be bolstered with additional information for a more complete perspective of the workforce completing MDUFA activities.

2. **There is a misalignment of understanding between the FDA and industry representatives when interpreting the inputs and outcomes of the current workforce metrics due to the complex definitions used in reporting.** For example, the FDA provides hiring goal updates in four settings: quarterly verbal performance updates, annual written performance and financial reports to Congress, and annual written updates to the five-year financial plan. While the reports provide similar information, there are no clear definitions for "FTEs" and "hires" in all available sources.[66]

3. The workforce reporting focuses on the MDUFA Process FTEs and MDUFA positions. The metrics capture the level of effort supporting the MDUFA process and progress toward hiring goals as defined by the commitment letter and statute, but **additional metrics can offer further insights into the current state of the workforce.**

4. **The MDUFA Process FTE methodology is complex, difficult to describe, and challenging to communicate easily. The methodology relies on assumptions to estimate the total time spent on MDUFA activities.** These assumptions, detailed in this report, were previously unavailable publicly. The approach and assumptions differ in each Center and Office in the MDUFA program. These complexities increase confusion and reduce transparency to external partners.

5. **The available MDUFA hiring data is limited to a subset of the FDA workforce completing MDUFA activities, and current reporting provides a single data point based on a first-time filled methodology**.[67,68] Providing additional people-based insights into the workforce completing MDUFA activities, including activities and roles, would enhance transparency and foster collaboration between the FDA and industry.

6. **The FDA's human resources and time reporting systems, especially those of CDRH and CBER, are equipped to provide more insights into the workforce completing MDUFA activities.** Formal processes to use the systems to their full potential should be considered for greater clarity and transparency.

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[66] The definition for "hires" is included in the MDUFA V Commitment Letter; however, the definition does not appear in the Five-Year Financial Plan or the Annual Financial Report. Both reports reference hires and hiring goal data. The definition of Process FTE (or any FTE) does not appear in the Five-Year Financial Plan. FTEs are referenced in the document. Additionally, the Five-Year Financial Plan uses "FTE" to describe progress toward the Hiring goals. See pages 20 and 23 of FY 2023 - FY 2027 MDUFA Five-Year Financial Plan and page 67 of FY 2023 MDUFA Performance Report to Congress.

[67] The FDA uses the first-time filled approach for reporting against MDUFA hiring goals. Once a permanent employee occupies a designated position, that position is always considered filled in future reporting.

[68] The hiring data point encompasses number of hires made, number of hires made internally vs. externally, and the number of hires by office.

Key Findings

7. **The FDA's, specifically CDRH's, data system investments improved workforce data collection and analysis capabilities**. However, both MDUFA Process FTE processes, position tracking processes, and the CAAPS HR-PBM system lack consistent formal documentation (e.g., SOPs, data dictionaries).

8. **Other user fee programs within the FDA, such as PDUFA, BsUFA, and GDUFA, relate workforce capacity with program performance using RCP measures**. These programs adjust user fee revenues to forecast resource needs and use time reporting data to factor productive FTE counts into a Capacity Planning Adjustment (CPA). These capabilities are a function of the unique features of the programs and are negotiated with their respective industry representatives across reauthorization cycles. The FDA and industry representatives have not reached agreement on the use of a CPA. By prioritizing RCP and a CPA, the FDA and industry can better align workforce capacity with performance. Maturing the MDUFA program's capacity planning capabilities and incorporating existing RCP in the Centers and Offices within MDUFA as well as the ongoing development of RCP in OII into a formal Workforce Capacity Plan, in line with OPM guidelines[69] and other FDA user fee programs, can enhance workforce measurement.

Workforce Capacity Planning

FDA's human resources and time reporting systems (within CDRH and CBER) collect much of the information needed for resource capacity planning. Developing processes and methodologies, in partnership with industry, could enable a more mature workforce capacity planning approach.

9. **MDUFA consistently meets requirements for workforce reporting but has opportunities to improve data accessibility.** Additional workforce metrics provided in easy-to-access sources (e.g., dashboards, webpages) by benchmark programs PDUFA and BsUFA can serve as future goals for MDUFA as the program matures. PDUFA and BsUFA provide publicly available quarterly hiring progress updates and Center-wide workforce metrics, such as net headcount. These user fee programs use public dashboards to update partners about staffing levels, hiring progress, and capacity. The dedicated websites and dashboards enhance accountability and understanding of how user fees impact staffing and review timelines.

Hiring Metrics

Other FDA user fee programs provide Center-wide workforce metrics (e.g., net headcount, hiring) in publicly available sources, offering a more comprehensive understanding of the programs' workforces.

[69] OPM, Workforce Planning Guide OPM-2025-01, 2022

Recommendations

The FDA has made notable strides in enhancing workforce reporting by investing in time reporting, position tracking, and other processes. This demonstrates a commitment to improving operational efficiency and transparency across all Centers and Offices. The following recommendations build upon these existing efforts. Implementing any changes will require close collaboration with the FDA and industry representatives, which is essential for successful implementation and long-term sustainability.

This report provides three key recommendations to improve the effectiveness and transparency of MDUFA workforce reporting. The assessment identified recurring pain points from MDUFA SME and industry representative discussions, document review findings, quantitative analysis, and gap analysis. The following recommendations aim to address the root causes of those recurring pain points to improve workforce reporting. When developing these recommendations, feasibility was prioritized and the recommendations consider the current constraints of the MDUFA environment. Each recommendation highlights the pain points it intends to address, outlining practical, discrete activities to mitigate challenges. Implementation considerations for each recommendation are noted. While these recommendations reflect feasible and realistic FDA capabilities, it is worth noting that implementation requires collaboration and concurrence between the FDA and industry representatives.

Recommendation 1: Implement a Comprehensive Framework for Workforce Metric Reporting

The current MDUFA program's workforce reporting, while fully compliant with the requirements set with industry in the MDUFA V Commitment Letter, provides a limited view into the workforce completing MDUFA activities. To make the MDUFA program more transparent and easier to understand, the FDA and industry representatives should create a clear framework for reporting workforce metrics that connect MDUFA workforce information to performance goals.

This framework should delineate the roles necessary to complete MDUFA activities and the specific MDUFA activities required for each role. By focusing on MDUFA-related roles and activities, this framework would improve transparency about the workforce capacity of the CDRH, CBER, OII, and HQ staff supporting MDUFA activities. More transparency into capacity would enable greater accountability and stewardship of MDUFA user fees. The FDA can generate these metrics using much of its existing data, systems, and processes. Finally, in adhering to the OPM and the OMB best practices, the framework should include a continuous improvement process to realize the transparency and utility of the framework.

A more thorough framework capable of providing more precise insights into how workforce dynamics affect the overall program performance would help the FDA and industry make more informed decisions during program reauthorizations.

Table 9*:* Recommendation 1: Implement a Comprehensive Framework for Workforce Metric Reporting

Recommendation Category	Description
Identified Benefit	The FDA and MDUFA stakeholders operate from the same level of understanding of the capacity of the workforce completing MDUFA activities and requirements to meet the MDUFA program's objectives.
Pain Points Addressed	• Existing workforce metrics lack alignment to MDUFA performance goals, making it difficult to quantify capacity increases and program performance and compare against commitments. • There is misalignment between what the FDA communicates about its workforce and what industry representatives want to understand about the program. • The methodology and intent of current workforce metrics align with agreed upon metrics, but appear misaligned with the information external partners request and best practices.

Recommendations

Recommendation Category	Description
Recommended Activities	1. The FDA and industry collaborate to identify priority workforce-related questions and objectives for workforce reporting, including the connection between workforce capacity and MDUFA goals. Incorporate reporting at the Center and Office level, as MDUFA work requires a broad network of support services. 2. Align priority objectives with existing data sources, identifying areas where existing data can be used, proxy data may be required, and/or data capabilities need to be expanded. Align on additional resource requirements and approach to meet those needs. 3. Design a comprehensive reporting framework to address identified questions, including detailing the workforce capacity needed for key MDUFA activities and volume of work across the organization. 4. Incorporate data considerations and limitations, including routine cadence and reporting format. 5. Implement a continuous improvement process (i.e., gather feedback, develop implementation plan, implement changes, revise plans with new information) to identify strengths and areas for improvement. 6. Add tags to positions to allow for tabulation by functional roles or duties (e.g., Team Lead, MDUFA Reviewer, etc.)
Implementation Considerations	• Building and implementing a framework may require additional and sustained collaboration from all stakeholders. • Additional resources may be required to expand data collection and reporting (e.g., technology infrastructure, dashboards). • Comprehensive and shared activity- and role-based capacity reporting and planning (e.g., resource capacity planning) requires investment by the MDUFA program and can enhance the current negotiation plans and practices with more specific and granular insights.
Related Key Findings	• The current reporting framework meets statutory requirements. The standards can be enhanced to provide more transparent and definitive insights into the workforce completing MDUFA activities. • Additional metrics can offer further insights into the current state of the workforce. • There is misalignment on understanding between the FDA and industry representatives when interpreting the inputs and outcomes of the current workforce metrics due to complex definitions used in reporting. • The MDUFA Process FTE methodology is complex, difficult to describe, and challenging to communicate easily. The methodology relies on assumptions to estimate the total time spent on MDUFA activities. • The available MDUFA hiring data is limited to a subset of the FDA workforce completing MDUFA activities, and current reporting provides a single data point on hiring, which encompasses number of hires made, number of hires made internally vs. externally, and the number of hires by office. • The FDA's human resources and time reporting systems, especially those of CDRH and CBER, are equipped to provide more insights into the workforce completing MDUFA activities.

Recommendation 2: Centralize Workforce Reporting for Improved Communication and Transparency

Currently, the MDUFA program's workforce-related reporting occurs in multiple reports issued at different times throughout the year. To improve communication and visibility across the MDUFA program, the FDA and industry should agree to centralize the MDUFA program's workforce-related reporting into a single comprehensive report or dashboard. The dashboard should include current reporting requirements (i.e., MDUFA Process FTEs and MDUFA Hires) and can be expanded to include metrics determined by the framework in *Recommendation 1*. The FDA and industry should consider including total employee headcount for CDRH (e.g., beyond hires) and net increases, headcount by functional role, and distribution of functional roles to align with comparable FDA user fee programs and best practices from OMB and OPM. These documents should include clear definitions of terms used, intended uses, methodological notes that outline any

limitations or considerations, and an easy-to-understand summary of key points related to the MDUFA commitments.

Table 10: Recommendation 2: Centralize Workforce Reporting for Improved Communication and Transparency

Recommendation Category	Description
Identified Benefit	The FDA and stakeholders reference an accessible, single source of MDUFA workforce information. Standard data fields and terminology streamline reporting, information exchanges, and historical tracking.
Pain Points Addressed	• There is misalignment between how the FDA communicates about its workforce and what industry representatives want to understand about the program's performance. • The methodology and purpose of current workforce metrics does not capture the full scope of the work done in MDUFA program. • Lack of cohesion in workforce reporting limits accessibility, usability, and understanding of vital program information.
Recommended Activities	1. Develop a unified dashboard or report that collects CDRH staffing information, and provides supplemental CBER, OII, and HQ information. 2. Integrate historical data, such as process FTE counts, CDRH staffing levels, and hiring statistics, to enable accurate and direct comparisons. 3. Provide visible summaries of progress toward goals and changes across time. 4. Create a data dictionary using specific and clear language to describe each metric and remain consistent across reporting. 5. Create documents that clearly define all terms in the reporting or dashboard and provide methodological notes outlining limitations or considerations. 6. Develop continuous improvement frameworks to incorporate stakeholder feedback and facilitate technological enhancements and requirements (e.g., application programming interfaces (APIs)), per government best practices.
Implementation Considerations	• Additional resources may be required to expand, maintain, and update data reporting (e.g., building dashboards), requiring organization-wide support. • May necessitate revisions to current reporting requirements to streamline, update, or modify processes. • Clear and intentional language must be used to limit confusion and misinterpretation of data.
Related Key Findings	• The current reporting framework meets statutory requirements. The standards can be enhanced to provide more transparent and definitive insights into the workforce completing MDUFA activities. • There is misalignment on understanding between the FDA and industry representatives when interpreting the inputs and outcomes of the current workforce metrics due to complex definitions used in reporting. • Other user fee programs within the FDA such as PDUFA, BsUFA, and GDUFA, relate workforce capacity with program performance using RCP measures. • MDUFA consistently meets requirements for workforce reporting but has opportunities to improve data accessibility.

Recommendation 3: Expand the Existing Governance Framework

Currently, the processes and procedures for calculating the MDUFA workforce metrics are inconsistently documented. To make workforce reporting more consistent, comprehensive, and efficient, the FDA should build on current governance frameworks[70] to create a roadmap for the MDUFA program's workforce reporting. The FDA should continue to formalize and document internal processes, standardize data collection, enhance transparency, and improve real-time reporting across and within the Centers and Offices, all while streamlining the reporting workflow. Where possible, the FDA should continue to standardize MDUFA reporting processes

[70] The FDA has established a user fee governance board that can be used as a model for a MDUFA governance framework.

(e.g., methodology for calculating MDUFA Process FTEs, time reporting requirements[71]), and examine general activities for inclusion in the MDUFA workforce metrics. By building on current governance frameworks, the FDA can create a robust roadmap for the MDUFA program's workforce reporting that preserves process know-how and enables straightforward communication.

Table 11: Recommendation 3: Expand the Existing Governance Framework

Recommendation Category	Description
Identified Benefit	Documenting MDUFA reporting processes and procedures reinforces sustained and consistent operations across the FDA. Developing clear processes and procedures increases transparency, promotes consistency across Centers and Offices, and reduces programmatic risk (e.g., reliance on institutional knowledge). Reviewing the full scope of MDUFA work increases an organization-wide understanding and alignment with MDUFA goals.
Pain Points Addressed	• MDUFA lacks formal workforce metrics governance policy and procedures as it relates to tracking and reporting position data. • The MDUFA workforce measurement system lacks standardization across offices in how workforce data is collected and calculated (e.g., use of different FTE calculations, inconsistent time reporting).
Recommended Activities	1. Expand upon existing documentation of methodologies and processes for calculating and reporting workforce metrics across each Center and Office. 2. Clearly define the processes for calculating workforce metrics, including detailing different applications of similar methodologies. 3. Continue regular reviews of general activity codes to identify those most necessary for supporting organizational goals. 4. Continue to standardize methods for collecting and calculating workforce data, including practices for cleaning and validating data.
Implementation Considerations	• Coordination with the existing User Fee Financial Management Council (UFFMC) to align changes with current governance standards. • Current activities are in progress and may need time to formalize methodology. • Existing differences and reporting requirements across Centers and Offices may limit capability to standardize. • FDA IT systems are decentralized and do not have the same capabilities across the agency.
Related Key Findings	• The MDUFA Process FTE methodology is complex, difficult to describe, and challenging to communicate easily. The methodology relies on assumptions to estimate the total time spent on MDUFA activities. • The FDA's, specifically CDRH's, data system investments improved workforce data collection and analysis capabilities. • The FDA's human resources and time reporting systems, especially those of CDRH and CBER, are equipped to provide more insights into the workforce completing MDUFA activities.

[71] Each Center and Office that contributes to MDUFA activities has different processes and requirements for determining the MDUFA Process FTE. For example, HQ, which accounts for about 6% of the MDUFA program, does not have the same time reporting standards as the other Centers and Office.

Appendix I: Assessment Methodology

This assessment validated understanding of the MDUFA program and workforce measurement requirements while developing recommendations for improvement. The assessment began in July 2024 with a review of publicly available documentation to establish a foundational understanding of the MDUFA program and the scope of its workforce reporting. Based on document review findings, the assessment involved developing focused questions and engaging internal SMEs and industry representatives. Additional internal documentation and benchmarking research identified measurement best practices within the FDA and other organizations. These activities were organized into four phases – Describe, Identify, Assess, and Report, illustrated below – as a structured approach to the assessment.

Table 12: Assessment Methodology Phases and Objectives

Describe the purpose of workforce measurement broadly and in the FDA Medical Device User Fee Amendments (MDUFA) program and describe the current MDUFA workforce measurement system
Identify benchmarks, standards, and assessment criteria for comparable workforce measurement systems to assess fit with MDUFA program reporting
Assess the current MDUFA workforce measurement system against the evaluation criteria, recommend improvements
Report recommendations for improvement to represent MDUFA workforce resources

Methodology

The methodology for creating the assessment criteria involved a multi-step approach to validate an understanding of the MDUFA workforce metrics system. This process began with the development of internal tools to evaluate the system's inputs and outcomes. Internal SMEs and external partners participated through qualitative sessions to gather diverse insights into the system's operations and limitations, while also evaluating initial data sources and benchmarks. This led to the identification of additional data sources and key considerations, helping to shape research questions for a focused, evidence-based assessment. The resulting criteria, grounded in both qualitative and quantitative analysis, were designed to be relevant, measurable, and aligned with the program's objectives, ultimately offering meaningful insights into its impact and areas for improvement.

Data Sources

The assessment criteria rely on a variety of reliable data sources to enhance the evaluation's credibility, including the MDUFA V Commitment Letter, MDUFA Annual Performance and Financial Reports, and industry benchmarks. These sources were chosen for their ability to provide insights into key performance goals, workforce capacity, and industry standards, ensuring that the criteria are grounded in measurable, up-to-date information. This selection process strengthens the criteria's applicability to the assessment's analysis.

The quantitative analysis of MDUFA workforce metrics examines data exports from ITR and CAAPS, provided by CDRH. The ITR data set is comprised of employee time logs from FY 2023 and FY 2024 and contains records that tie the time to a 100% MDUFA time or general activities classification, center or office, tour of duty hours, funding source, and various work classification categories. The CAAPS data set contains position data from MDUFA IV and V that tie employee records to a tagged position that in turn is assigned to a center or office, fill status, funding source, and commitment area. This analysis also incorporated internal FDA reports, provided by HQ. These reports include PC01, 113-G, and WCF Split by Program reports from 2018 to 2024.

Document Review and Initial Research

The assessment began with a review of key public documents, including the MDUFA V Commitment Letter, the FDA's Annual and Performance Reports, MDUFA Five Year Plan, and OMB Circular A-11, establishing a

foundational understanding of the MDUFA program, workforce metrics, and reporting obligations. This was followed by an examination of internal FDA documentation, offering insights into workforce measurement practices across CDRH, CBER, OII, and HQ, as well as how MDUFA Process FTEs and MDUFA positions are tracked and reported. To summarize, this document review established three key findings:

- The MDUFA program has specific statutory reporting requirements under the FD&C Act, requiring detailed data on hires, vacancies, and FTEs funded by both user fees and BA.
- Workforce metrics serve compliance and support strategic resource allocation purposes.
- The MDUFA program implements various tracking mechanisms across CDRH, CBER, OII, and HQ to account for hiring commitments and efforts toward MDUFA activities across the organization.

SME and Partner Engagement & Methodology Discussions

Discussions with internal SMEs and external partners were guided by question sets developed using insights from the document review. These discussions garnered further insights into the MDUFA program's workforce tracking and reporting methodologies. Internal SME discussions began with CDRH executives to understand their priorities and led to the formation of a Core Assessment Team (CAT) with members from CDRH, CBER, HQ, and OII. The CAT met regularly to guide the assessment, validate findings, and provide necessary documentation. Targeted discussions with CAT members focused on how MDUFA Process FTEs are calculated and how CDRH and CBER manage position allocation. Additionally, the analysis includes findings from discussions with industry stakeholders, including representatives from Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA) and American Clinical Laboratory Association (ACLA), to gather their perspectives on the MDUFA workforce metrics system. To provide historical context, the analysis also examines publicly available notes from MDUFA IV and V Reauthorization Meetings.

Analysis Procedures

Before delivering the data sets for analysis, CDRH cleaned both the ITR and CAAPS exports to remove personally identifiable information (PII) from employee records. CDRH provided an amended ITR export that included the total MDUFA time by employee. As discussed above, the MDUFA process percentage is calculated by combining employee time at the cost center level. To determine the number of total MDUFA hours each employee spent, CDRH determined the total amount of general time attributed to the MDUFA process at the cost center. Then, they divided those hours proportionally to individual employees based on their records. Once received, the data sets were joined on the Enterprise Administrative Support Environment (EASE) data field, which would serve as an anonymized unique identifier for all employee records. With the combined data set, the analysis included reviewing data for 2,365 unique positions and the records of 2,565 distinct employees, of which 2,332 were in FY 2023 and 2,398 were in FY 2024. The analysis used the combined data file to review employee level of effort as related to the activities they performed. Additionally, the analysis utilized reports provided by HQ to analyze MDUFA Process FTE data. Data from the PC01, 113-G, and WCF Split by Program reports provided context and background information for determining the WCF spilt.

This analysis includes findings from a sentiment analysis of industry discussions and meeting minutes from MDUFA IV and V user fee negotiation meetings. Sentiment analysis is a technique used to determine the tone and themes found in a body of text. The analysis involved two reviewers who read and tagged the notes and transcripts. The reviewers also categorized opinions as positive, negative, or neutral. This method allowed for nuanced understanding of the text. The sentiment analysis relied on context and individual perceptions of the reviewers which varied. To minimize any variation, this assessment cites findings with reviewer consensus and themes that appeared more than once.

Research Questions

The assessment developed seven overarching research questions and 28 sub-questions (i.e., key considerations) aligned with the goals of the assessment. These questions were intentionally designed to address critical areas that would inform the assessment process, providing deeper insights into the MDUFA workforce measurement system's effectiveness. For a structured and focused approach, the research

questions were organized into four distinct themes: program scope, program performance, program benchmarks, and program tools. This thematic grouping not only directed the analysis in a coherent manner but also ensured that the questions remain relevant to the core objectives of the assessment and drove the analysis toward actionable conclusions and more informed recommendations.

Program Scope

A major objective of this assessment is to provide a comprehensive understanding of how workforce metrics are used within the federal government and specifically within the MDUFA program. To explore these areas, the following two research questions and eight considerations were designed to examine how the data is structured, how methodologies are applied, and whether roles and outputs align with the program's goals. The questions assessed whether the metrics provide the insights necessary for informed decision-making.

Table 13: Program Scope Research Questions

Research Questions	Key Considerations
1. **What is the purpose / key features of workforce measurement in the federal government in general and specifically in context of the FDA's MDUFA program?**	• How are workforce metrics used in the federal government in general? • How is the MDUFA program defined? What implications does this have for workforce metrics? • How do workforce metrics support the broader MDUFA program? • What goals or objectives are workforce metrics supposed to achieve? • What are the requirements for reporting on these metrics?
2. **What are the current MDUFA workforce metrics?**	• What is the level of detail and cadence required for reporting on these metrics? • How do these metrics connect to the execution of MDUFA user fees? • What are the specific data sets used for reporting on these metrics and reconciliation steps (if any) performed to clean and quality check data prior to reporting? • What are the current MDUFA workforce metrics measuring? • What information is captured and reported with the current MDUFA workforce metrics? • What are the MDUFA workforce metrics procedures and methodologies? How do these approaches impact what is reported with the metrics?

Program Performance

Another key goal of the assessment was to evaluate the performance of the MDUFA workforce metrics system, with a particular focus on the effectiveness of its workforce metrics, in accurately measuring the current workforce. Additionally, the assessment sought to understand how these metrics are reported and analyzed in comparison to similar programs, highlighting any discrepancies or best practices. Two research questions and eight considerations were developed to assess how well these metrics align with the program's goals, how they compare to those used by similar user fee programs, and to identify potential gaps or areas for improvement.

Appendix I: Assessment Methodology

Table 14: Program Performance Research Questions

Research Questions	Key Considerations
1. How effective are the current MDUFA workforce metrics at measuring what they are intended to measure?	• How well do the workforce metrics meet those goals? How are they effective and what are the gaps (if any)? Are there other metrics that would be better suited? • How well does the current MDUFA workforce measurement system holistically capture the FDA workforce completing MDUFA activities and its capacity? • Are there other aspects of workforce capacity that can be reported to provide greater clarity and understanding of the FDA workforce completing MDUFA activities? • How well are industry representatives able to understand the MDUFA workforce metrics? • How can the MDUFA workforce metrics system be matured to better inform stakeholders (e.g., industry, Congress) on the FDA workforce completing MDUFA activities?
2. How effective is the MDUFA workforce measurement system's reporting to stakeholders (e.g., industry, Congress)?	• How does the current MDUFA workforce measurement system's reporting compare to industry standards or best practices in terms of meeting and communicating objectives? • How effective is MDUFA workforce metrics system's reporting compared to other user fee programs? • How can CDRH improve how it reports its MDUFA workforce metrics, based on best practices/lessons learned from other user fee programs?

Program Benchmarks

Another important goal of the assessment was to explore and identify relevant benchmarks, standards, and best practices from other workforce metric systems to inform the assessment. This theme focuses on gaining a deeper understanding of how other comparable organizations – both within the U.S. federal government and internationally – measure and track workforce data. One research question and five key considerations were created to identify specific benchmarks and standards used by these organizations, the workforce metrics they rely on, and the strengths of their approaches to workforce measurement compared to MDUFA's current system.

Table 15: Program Benchmarks Research Questions

Research Question	Key Considerations
1. What are appropriate benchmarks, applicable standards, and assessment criteria from comparable workforce measurement systems?	• What are workforce metrics systems from comparable organizations, including those that operate under a similar user fee structure and leverage similar time reporting systems? • What standards and best practices from comparable organizations can serve as relevant and useful comparisons to measure MDUFA workforce metrics against? • Are there any exemplary uses of workforce metrics in the federal government that MDUFA can use as a benchmark? • What is similar and different between what MDUFA metrics measures and what other user free programs measure? What are the reasons for these differences? • What are the strengths and areas for maturity for the MDUFA workforce metrics system when compared to relevant internal benchmarks, other user fee programs, and/or relevant industry standards?

Program Tools

The final goal of the assessment was to evaluate the effectiveness of the MDUFA program's IT tools in supporting its overall objectives. To guide this analysis, one research question and five key considerations were developed to assess the functionality and performance of the IT tools in terms of data accuracy, efficiency, and reporting capabilities.

Table 16: Program Tools Research Questions

Research Question	Key Considerations
1. **How well do IT systems and processes support the goals of the MDUFA workforce measurement system?**	• How well do the IT systems support workforce data collection, analysis, and reporting? • How well do the workforce metrics processes support workforce data collection, analysis, and reporting? • How accurate and reliable is the data used to calculate the workforce metrics? • Are there existing opportunities to mature MDUFA workforce metrics reporting? • How are CDRH's technical systems (e.g., human resource systems, time reporting systems), processes, and outputs structured to respond to reporting requirements? How have they evolved in response to changes in requirements (e.g., reporting FTEs, tagging positions)?

Evaluation Framework and Benchmarks

Following the stakeholder discussions, research questions were developed to further guide the evaluation of the MDUFA program. The research questions led to additional rounds of document review, requesting additional internal documentation to answer these questions further. The documents include:

- Standard operating procedures, work instructions, and desk guides detailing the end-to-end process for calculating MDUFA workforce metrics
- Technical documentation for ITR and CAAPS platforms, such as data dictionaries and user guides
- Historical data extracts from ITR and CAAPS covering FY 2018-2024, including time reporting activity levels and position details
- MDUFA-related reports from FY 2018-2024, including SF-113G reports, PCO1 reports, process cost summaries, and monthly reports from the Division of Budget Execution
- Supporting materials on the share of device program workload attributable to MDUFA activities

In addition to reviewing available documents to answer the assessment's research questions, the analysis includes benchmarking research to identify best practices and evaluation criteria for workforce metrics tracking and reporting within the FDA, across the federal government, and outside the federal government. Findings from the benchmark analysis are detailed in the ***Standards and Benchmarks*** section.

The assessment's findings were developed through careful analysis of all collected information against the research question. Following this, a comprehensive analysis to identify key pain points and improvement opportunities in MDUFA's workforce tracking and reporting approach was completed. Pain points represent current challenges and limitations in the workforce tracking and reporting processes; improvement opportunities lead to the recommended activities that could strengthen the program's effectiveness. Draft findings were validated with internal stakeholders to ensure accuracy and completeness before being incorporated into the final report.

The following data sources referenced in the analysis are also found in the ***Standards and Benchmarks*** section.

- **CDRH**
  - MDUFA V Commitment Letter
  - MDUFA Annual Performance Report to Congress
  - MDUFA Annual Financial Report to Congress
  - MDUFA Quarterly Performance Reports
  - MDUFA Program 5-Year Financial Plan
  - ITR system
  - CAAPS system

  - PC01 Report
  - WCF Split by Program Report
  - Sf-113G Report
- **FDA**
  - Federal Food, Drug, and Cosmetic Act (FD&C Act)
  - Prescription Drug User Fee Act (PDUFA)
  - Generic Drug User Fee Act (GDUFA)
  - Biosimilar User Fee Act (BsUFA)
  - Animal Drug User Fee Act (ADUFA)
  - Animal Generic Drug User Fee Act (AGDUFA)
  - Nuclear Regulatory Commission (NRC) License Fee Program
- **External Standards and Benchmarks**
  - Nuclear Regulatory Commission (NRC) License Fee Program
  - Animal and Plant Health Inspection Service (APHIS) Agricultural Quarantine and Inspection Program
  - Environmental Protection Agency (EPA) Hazardous Waste Electronic Manifest Establishment Act
  - Federal Energy Regulation Commission (FERC) Electric Assessment Fees
  - Health Canada Medical Devices Directorate (MDD) Medical Device License Fees
  - Australian Therapeutic Goods Administration (TGA) Medical Device Application Fees
  - European Union European Medicines Agency (EMA) Medical Device Registration Fees

Limitations and Considerations

Limitations are factors related to real world resource and time constraints of an assessment. Limitations were carefully considered in the development of the assessment criteria to establish their alignment with the overall goals of the MDUFA program. These considerations help identify potential risks that could affect the scope, performance, or outcomes of the assessment.

- **Performance Enhancement Goals and Commitments and Reporting Methodologies:** The assessment is limited by the commitments and reporting methodologies outlined in the MDUFA V Commitment Letter, which limits data collection to the specific metrics it mandates. As a result, the assessment can only focus on these prescribed metrics and may not capture the full range of factors influencing program performance, potentially missing deeper insight into its effectiveness. Additionally, variations in reporting methodologies across FDA Centers and Offices interacting with the MDUFA program create challenges in establishing consistent comparisons. For instance, differences in how MDUFA Process FTEs are calculated complicate efforts to communicate results in a standardized way.
- **Stakeholder Engagement:** A significant limitation is the differing expectations and perspectives of internal and external stakeholders, which can influence the framing of assessment criteria, data collection, and interpretation of findings. For example, FDA stakeholders may prioritize operational performance and efficiency, focusing on meeting regulatory requirements and timelines; conversely, external stakeholders may emphasize long-term outcomes, such as the effectiveness and capacity of the MDUFA workforce metrics system.
- **Data Availability**: Data availability, due to incomplete records (e.g., lack of pre-MDUFA IV position data), inconsistent reporting, or gaps in data infrastructure hinders some aspects of the assessment. For example, analysis of the time reporting data is limited to FY 2023 and FY 2024 due to significant changes in activity code structures. Additionally, the need for manual data entry and validation of the time reporting data introduces the risk of human error, which could affect the accuracy of the analysis. Limited data on workforce metrics, such as net new positions, further complicates the evaluation of

MDUFA program outcomes, particularly regarding workforce growth and recruitment efforts. These challenges highlight the complexities in program evaluation and shaped the assessment criteria.

While the analysis draws robust insights from the data and reports provided, it is important to note that time limitations prevented more comprehensive analysis of historical time reporting data, historical personnel records and positions, and review performance data. Additionally, the analysis includes perspectives from a limited number of internal and external MDUFA program partners, and thus the considerations provided by these groups may not be representative of the entire population of stakeholders. Given these limitations, and the fact that CDRH's work represents the vast majority of MDUFA activity volume, the analysis focuses on CDRH. This, along with inconsistencies among MDUFA centers and offices in data collection practices and methodology in calculating metrics, meant that a more comprehensive analysis that included CBER and OII would not be feasible.

Appendix II: Workforce Measurement in the Federal Government and the FDA

Workforce metrics within the MDUFA program and across the federal government provide essential information about staffing levels, budget allocations, and resource use. These metrics enhance transparency and make complex work more understandable and accountable. This section aims to provide foundational knowledge and background information for assessing workforce measurement in the federal government, with a specific focus on the MDUFA program. It includes definitions of user fee programs, explanations of the purpose of workforce measurement systems, and key comparisons of workforce measurement terms used in the federal government and the MDUFA program.

User Fee Program Definition

Agencies across the federal government collect fees or charges from individuals, businesses, or other organizations that use or benefit from a government service. Agencies collect these fees, referred to as user fees or user charges, on voluntary services, such as attending a national park, applying for a passport, issuing securities, or registering a regulated establishment.

- **Government Accountability Office (GAO):** A fee assessed to users for goods or services provided by the federal government. GAO also notes these fees "generally apply to federal programs or activities that provide special benefits to identifiable recipients beyond what is normally available to the public."[72]
- **Office of Management and Budget (OMB):** A "fee, charge, or assessment the government levies on a class of the public directly benefiting from, or subject to regulation by, a government program or activity."[73]

A significant subset of user fee programs includes regulatory user fees. Agencies charge regulated businesses or individuals regulatory user fees to undertake certain activities subject to federal government regulation.[74] This category of user fees includes medical product application and tobacco manufacturing and importing fees assessed by the FDA, registration and application fees assessed by the Nuclear Regulatory Commission (NRC) and pesticide registration service fees assessed by the Environmental Protection Agency (EPA), among others. Other user fees, such as entrance fees or fees paid for purchasing a government good or product, do not involve regulatory activity.

User Fees in Practice

While establishing user fees, Congress provides agencies with varying authorities and abilities to set, collect, use, and report on collected fees. Variations across and between user fee programs highlight the unique applications of these programs while providing considerations for comparison.

Congress often determines how fee amounts are set and collected in statute. Fee amounts may be determined through direct legislation (e.g., EPA pesticide registration fees), prescribed methodologies (e.g., Securities and Exchange Commission (SEC) transaction fees), or broad authority to determine and spend fees (e.g., National Credit Union Administration (NCUA) examination fees). Additionally, fees may be collected on a per transaction basis or at regular intervals. The FDA's user fee programs have both application fees, required when applying for FDA review, and annual charges, required for registering establishments (e.g., manufacturers, importers, re-labelers).

Congress may also determine a threshold for beginning to collect user fee funds. In the FDA, user fee programs rely on funding "triggers," meaning the FDA uses a specific amount of appropriations supporting product review in proportion to user fee dollars. Like the FDA's user fee programs, the EPA pesticide

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[72] GAO, A Glossary of Terms Used in the Federal Budget Process, GAO-05-734SP, September 1, 2005
[73] OMB, Circular A-11 (2018), Section 20.7(g),
[74] GAO, Federal User Fees: Key Considerations for Designing and Implementing Regulatory Fees, GAO-15-718, September 1, 2015

registration user fee program stipulates Congress must provide a determined level of appropriations before user fees may be spent.

Across user fee programs, an agency's authority to manage and spend user fee funds also differs significantly. Collected user fees may be deposited in the U.S. Treasury General Fund or special accounts and may be accessed for regular spending or specific projects. For example, the FDA user fee programs support premarket review activities, including hiring additional staff for premarket application review to reduce review time. Other programs, like national park entrance fees fund maintenance projects, while passport application fees support passport adjudicators and advanced printing technology.[75]

User fee programs also differ in reporting requirements and review methods. OMB budget documents and U.S. Treasury financial reports contain summaries of the user fees collected and spent by agency. Beyond that, the transparency and accountability provided by reporting differs across each program. For instance, the FDA must provide detailed annual reports to Congress on the performance of its user fee programs, including how the fees are spent and whether performance goals are met. Additionally, the FDA negotiates the terms (e.g., fee amounts, performance goals) of the user fee agreements with industry representatives every five years, introducing frequent changes and variability within a program. In contrast, other agencies may have less stringent reporting requirements, focusing more on financial audits and general oversight. This variability can impact the effectiveness and public perception of user fee programs, highlighting the need for tailored reporting standards that reflect each agency's unique operations and goals.

Workforce Measurement in the Federal Government

Across the federal government, agencies use workforce metrics to effectively and efficiently allocate their employees. Agencies rely on quantifiable metrics, indicators, or measures to track and assess the status of specific processes, activities, or outcomes.[76] Generally, workforce measurement and metrics serve one or more of the following four purposes:

- Budget and resource allocation
- Workforce planning and management
- Performance measurement
- Accountability and transparency

Budget and Resource Allocation

One of the primary purposes of workforce measurement is budget and resource allocation. As a part of annual budget preparation and execution, agencies must estimate and report the expected employment levels necessary to accomplish their mission. Once Congress appropriates funding for the agency, the agency must monitor their total workforce and manage it within the funding level. OMB Circular A-11 provides guidance for determining staffing levels, including considerations for program requirements (e.g., establishing new programs aligned with strategic goals), productivity gains, and technology enhancements. These workforce estimates must also consider a realistic workload for an employee, including adjustments for training, leave (e.g., annual leave, sick leave), location, activity, and organization. Agencies use and monitor FTEs, employee counts, average compensation, and other workforce statistics to conduct and maintain regular operations. By assessing past, current, and anticipated workforce needs and aligning them with budgetary constraints, agencies can allocate funds to support critical tasks adequately.

[75] U.S. Department of the Interior, National Park Service, "Your Fee Dollars at Work," October 11, 2024; U.S. Department of State, Schedule of Fees for Consular Services-Passport Security Surcharge, 86 FR 59613

[76] OMB, Circular A-11 (2018), Section 200.24

Appendix II: Workforce Measurement in the Federal Government and the FDA

Workforce Planning and Management

Workforce planning and management are other key aspects of workforce measurement. OPM defines workforce planning as a collaborative process for systematically identifying the size and composition of a workforce. Workforce planning serves as the foundation for managing agencies' workforce capacity and meeting current and future mission needs. To engage in workforce planning effectively, an agency should outline the specific activities required to reach each strategic objective, set benchmarks, gather quantifiable data, and continuously monitor performance.[77] Agencies engaging in comprehensive and detailed workforce planning can more accurately determine the number of employees with the appropriate skills to accomplish an agency's mission. GAO notes in a report discussing the FDA's workforce planning that "strategic workforce planning is particularly important for agencies with science and technology missions such as the FDA, which must compete for talent with the private sector, universities, and non-profit research centers, and keep up with scientific advancements".[78]

Performance Management

Understanding how agencies use resources to meet their goals is vital for performance management. Across the government, agencies develop, prioritize, and execute workforce related goals so that they can meet their missions. Agencies monitor hiring targets, including those with the right skills and experience, employee engagement, and tenure information. Beyond workforce goals, employee-focused metrics, such as time-to-hire for high impact roles and retention rates, serve as indicators toward larger government and agency goals.[79] Tracking progress against established benchmarks and adjusting is needed to improve efficiency and effectiveness.

Accountability and Transparency

Finally, workforce measurement is a crucial component of government accountability and transparency. By providing clear and accessible information on how agencies use resources, government organizations can build trust with the public, Congress, and other stakeholders. Detailed reports allow for oversight and monitoring of agencies' performance toward meeting the public interest. Additionally, more information available provides decision-makers with greater understanding of the strengths and growth opportunities for an organization or program. Agencies benefit from providing information beyond government-wide employee counts and salary distributions, such as training metrics (e.g., completion rates, cost per employee).

Key Terms

This section provides key definitions and comparisons of workforce measurement terms used in the federal government and the MDUFA program. The section focuses on key terms used to capture and distinguish elements of the workforce: *FTEs*, *on-board employees*, and *positions*. Additionally, a discussion of *hires* and *vacancies* is provided in the initial overview. For a more complete list of terms, see ***Appendix IV: Glossary of Key Acronyms and Terms*****.** The table below provides key terms, a simplified and MDUFA-specific definition, and notes for consideration.

Table 17: Definitions of Key Workforce Measurement Terms

Term	Simplified definition	Notes
On-board employees (employee)	The total number of people currently employed, performing work, and supervised	Includes individual employee headcount as of a particular date and may consist of full-time, part-time, and seasonal employees

[77]OPM, The Work Planning Guide (2022)
[78] GAO, FDA WORKFORCE: Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs (2022)
[79] OPM, Federal Workforce Priorities Report (2022)

Appendix II: Workforce Measurement in the Federal Government and the FDA

Term	Simplified definition	Notes
	by another employee of the federal government[80]	
Full-time equivalent (FTE)	A calculation of the number of hours worked by employees divided by the number of work hours in a year (e.g., 2,080)[81]	For a budget-based FTE, work hours include annual leave, sick leave, and other approved leave categories. Productive FTEs only include the hours an employee is actively working, excluding paid time off
Positions	The slot or roles allocated and created in order to accommodate and track MDUFA Hires	A position may also refer to the specific duties and responsibilities assigned to an employee
Hires	In the MDUFA context, a hire is an employee confirmed as on board by the date indicated in a full-time position	Hires may be new employees recruited from outside the FDA, or, in some cases, a hire can be a current FDA employee who is changing positions within the agency
Vacancies	The established positions unoccupied by employees	Complete employee counts and comprehensive position information is required to determine the number of vacancies and open positions

FTEs, employees, and positions provide different information. For example, in budgeting, FTEs provide valuable information on the total workload and how it is covered within the budget constraints. Employee information is more definite and provides greater insights into specific payroll and benefits calculations. Long-term workforce planning relies on position information (e.g., vacancies) to meet organizational needs. The table below illustrates the differences between employees, positions, and budget-based FTEs (e.g., including leave).

Table 18: Comparisons of Employees, Positions, and FTEs

Employees	Positions	Schedule	Total Work Hours	FTEs
1	1 position (e.g., biologist)	Full-time (i.e., working 40 hours per week for 52 weeks)	2,080	1
2	2 positions (e.g., statisticians)	Half-time (i.e., working 20 hours per week for 52 weeks)	2,080	1
20	20 positions (e.g., chemists)	Full-time	41,600	20
30	30 positions (e.g., engineers)	Half-time	31,200	15
1	1 position (e.g., orthopedic surgeon)	Full-time vacant position filled six months into the year (i.e., working 40 hours per week for 26 weeks)	1,040	0.5

The final row in this example assumes an employee filled a vacant position six months into a year. This position was unfilled for half of the year, impacting the employee's total work hours and the calculated FTE.

Workforce measurement is vital for effective governance and accountability within the federal government. The FDA maintains transparency and demonstrates the efficient use of MDUFA resources by systematically tracking and reporting on workforce metrics such as FTEs, employee counts, and budget allocations. Understanding and utilizing these metrics is crucial for achieving strategic objectives and maintaining public trust in government operations.

[80] U.S. House of Representatives, Section 2105 of Title 5
[81] GAO, A Glossary of Terms Used in the Federal Budget Process, GAO-05-734SP, September 1, 2005

Appendix III: Technical Supplement

This technical supplement provides a comprehensive description of detailed technical analysis completed to support the findings and recommendations of the MDUFA Workforce Metrics Assessment. The analysis presented in this appendix delves into the details of the core calculations. This analysis provides further insight into the calculation mechanics of the methodologies used to represent the level of effort supporting the MDUFA program as well as empirical rationale for how associated metrics can be reasonably interpreted. This information enhances transparency and reproducibility of the assessment's results.

MDUFA Process FTE Methodology Summary

The MDUFA Process FTE metric offers a data-driven way to measure the level of effort involved in the MDUFA process. To compute this metric, CDRH carries out detailed calculations for all MDUFA process-related activities.[82] These calculations, applied across all CDRH cost centers, incorporate simplifying assumptions for cost accounting purposes and have limitations due to statutory requirements. This appendix includes a technical description of how these assumptions and limitations impact the results and their ultimate interpretation, using CDRH activity-based time reporting data for context. It serves as supporting content for better understanding the MDUFA Process FTE metric. For a comprehensive review of metric inputs and opportunities for improvement, see the ***MDUFA Process FTE Overview***. Lastly, the following key terms are used throughout the remainder of this appendix:

Key Methodology Terms

General Time: Time recorded in general activity codes that support both MDUFA and non-MDUFA activities.

100% MDUFA Time: Time recorded in 100% MDUFA activity codes.

MDUFA Non-Allowable Time: Time recorded to MDUFA non-allowable activity codes.

General MDUFA Time: Time supporting the MDUFA process that is estimated from general time.

Total MDUFA Time: The total of 100% MDUFA time and general MDUFA time.

Total Non-MDUFA Time: Time not attributable to the MDUFA process which consists of MDUFA non-allowable time and non-MDUFA time estimated from general time.

Regular Straight-Line Hours: The total compensable hours applicable for each fiscal year, excluding overtime or holiday hours worked (typically 2,080 hours). Also generally referred to as the tour of duty for an employee.

Productive Hours: The available hours for productive work after all non-MDUFA process deductions (i.e., the time available for core tasks).

Prior to analyzing the mechanics of the MDUFA Process FTE methodology, it is first important to briefly review its main components as well as applicable assumptions and limitations. Figure 5 provides a high-level overview of the calculations used in CDRH's Process FTE methodology. As outlined in ***Process FTE Calculations***, the methodology consists of two main components: the MDUFA process percentage and reporting activities used to produce the final Process FTE output. The reporting activities component is determined by statutory requirements, meaning it remains a fixed element throughout the analysis in this section.[83] In contrast, the MDUFA process percentage incorporates the assumptions and limitations that are examined in detail.

[82] This appendix focuses primarily on CDRH's methodology for calculating the Process FTE metric in alignment with rest of the report.
[83] In practice, the values for both the FTE and Total Costs terms change depending on the cost center; however, given that the assumptions and limitations evaluated in this section primarily relate to the process percentage, these terms are treated as fixed to simplify communication and interpretation of analytical results.

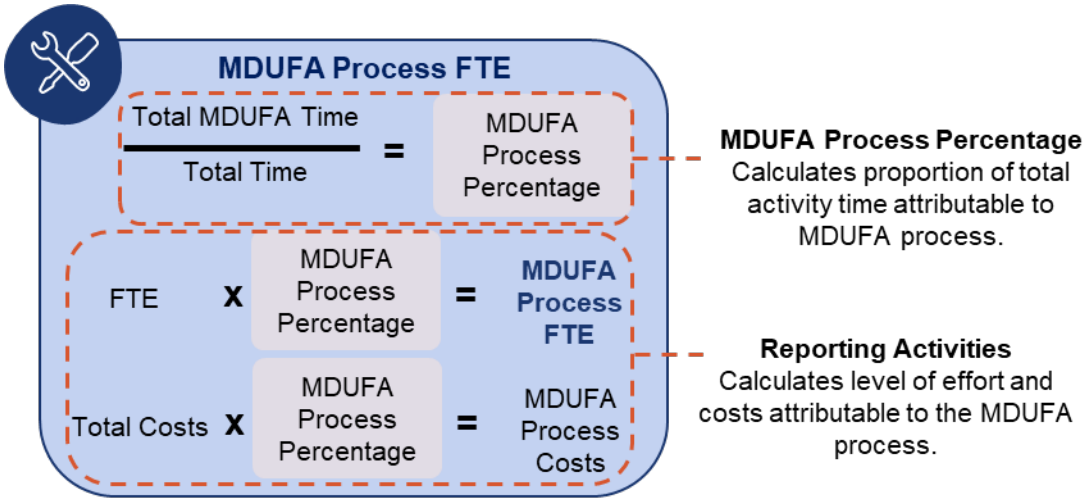

Figure 5: High-level description of MDUFA Process FTE calculations. Calculations are broken up into two distinct components: the MDUFA Process Percentage and Reporting Activities.

The assumptions and limitations of the Process FTE metric are summarized as follows:

Assumptions:

- *Labor Distribution Assumption*: General time attributed to MDUFA activities is distributed proportionally based on total non-general time reported in each individual cost center (i.e., it does not vary by functional role).[84]
- *General Activities Assumption*: All general activity codes are included when calculating the proportion of general time associated with MDUFA activities.

Limitations:

- *Overtime Limitation*: Overtime hours can only be included in the Process FTE metric through the MDUFA Process Percentage.

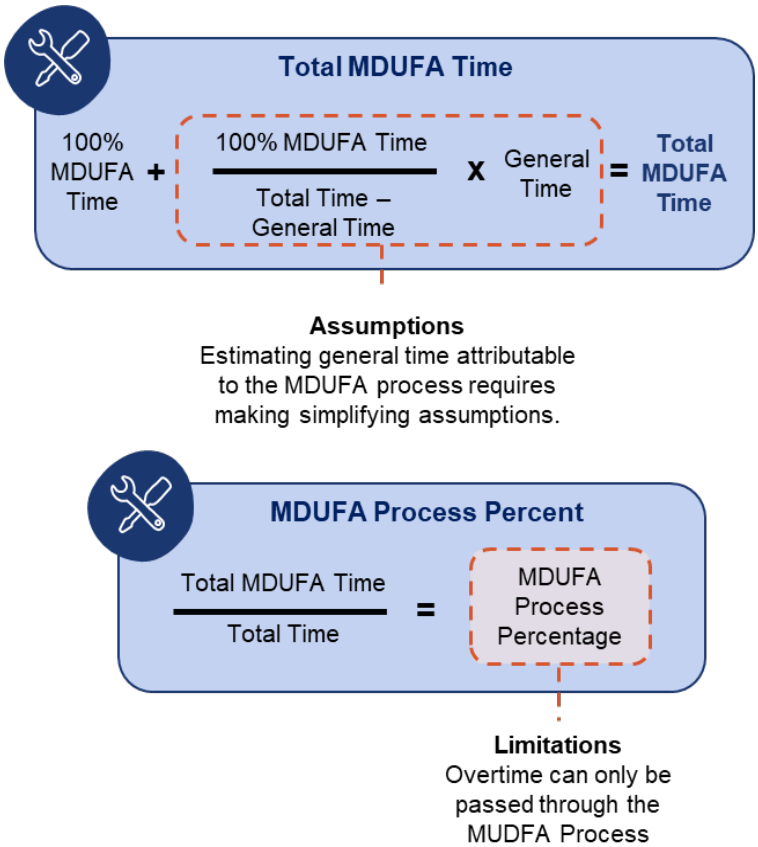

Figure 6: High-level description of Total MDUFA Time and MDUFA Process Percent calculations as well as associated assumptions and limitations.

These assumptions and limitations are crucial for understanding the methodology associated with MDUFA Process FTE calculations and for interpreting the reported metric accurately. As the MDUFA Process FTE metric is intended for cost accounting (i.e., reporting paid level of effort), the following analysis focuses primarily on distinguishing Process FTEs from standard capacity metrics by highlighting areas in which

[84] An important regarding the interpretation/mechanics of this assumption vary depending on the type of cost center (e.g., support organization cost centers use a center-wide average for general time spreading).

the outlined assumptions and limitations may impact a capacity-oriented interpretation. Impacts on level of effort measurement are also discussed; however, these are largely confined to methodological limitations.

Analysis

Labor Distribution Assumption

CDRH calculates the MDUFA Process FTE metric using time reporting data from Insight Time Reporting (ITR), focusing on three activity code categories: 100% MDUFA, general, and MDUFA non-allowable. Time reported under 100% MDUFA codes is fully attributable to the MDUFA process, while CDRH estimates the time reported in general codes that pertains to MDUFA activities. MDUFA non-allowable activity code time is used in general time spreading.[85] Reported time from all three categories is leveraged via the Process FTE methodology to calculate total MDUFA time and ultimately the Process FTE metric for each individual cost center. This approach of estimating total MDUFA time at the cost center level supports effective cost accounting but involves smoothing employee level time reporting variation within cost centers.[86] This smoothing effect, referred to as the labor distribution assumption, means that general time attributed to the MDUFA process is distributed proportionally based on total non-general time reported in each individual cost center. Although this assumption is aligned with the methodology's intent, it also means that the Process FTE metric may not fully capture role-related differences within CDRH cost centers.

As discussed in ***Discussion and Opportunities for Improvement***, external stakeholders tend to interpret the MDUFA Process FTE as a capacity metric; therefore, it is important to explore the implications of this assumption for capacity measurement. While role-related differences in time reporting are more likely to have minimal impact on level of effort interpretations for most cost centers, they could lead to systematic underestimation or overestimation of general MDUFA time when focusing instead on capacity. This makes sense intuitively as paid level of effort is less likely to vary significantly by role versus process attributable workload. Lastly, systematic error under a capacity interpretation is further compounded by the fact that Process FTEs are aggregated across all CDRH cost centers when the metric is reported to external stakeholders. Even a relatively small degree of estimation error could have a significant impact on reported outputs when magnified across the entire organization (i.e., accumulated across many cost centers). As a simple example, if general MDUFA time is underestimated in one cost center and then overestimated in another, the estimation error associated with the ultimate process FTE output will be largely offset once aggregated. However, if there is either systematic underestimation or overestimation (e.g., both cost centers are underestimated), then aggregate FTE metrics will reflect cumulative estimation error.

To empirically evaluate whether the assumption aligns with actual time charging patterns in the MDUFA program and its impact on the Process FTE metric under a capacity interpretation, it is essential to analyze how MDUFA process time is distributed across cost centers and throughout the Center. Due to the time reporting structure and the nature of work at CDRH, employees can log time across multiple categories, meaning *no employee is expected to devote all their working hours to MDUFA-related tasks*. Additionally, MDUFA and non-MDUFA activity code labels are incorporated as part of the CDRH's activity code structure. This means employees select activity codes based on relevance of their completed work – such as premarket review – rather than on the fee category under which the work falls.

CDRH time reporting data indicates that among staff who reported any 100% MDUFA time in FY 2023 and FY 2024, approximately 50% reported the majority of their total time to 100% MDUFA codes. Conversely, nearly a quarter of staff recorded no hours to 100% MDUFA codes across these two years (see Figure 7). This bimodal time distribution[87] is expected as not all organizational roles directly complete 100% MDUFA code activities. However, employees in roles such as IT staff and legal counsel, who typically do not conduct 100% MDUFA

[85] See Process Costs and MDUFA Activities for an illustrative example of general time spreading.
[86] "Smoothing" in this context means reducing variation in time charging behavior.
[87] A bimodal distribution is a statistical distribution with two distinct peaks, or modes. The shape of the distribution presented in Figure 7 displays this type of shape.

code activities like premarket review, still play a significant role in supporting the MDUFA process. Cost center level calculations in the Process FTE methodology do not directly account for this, as total MDUFA time is estimated using the labor distribution assumption instead of differentiating by functional roles or specific activities.

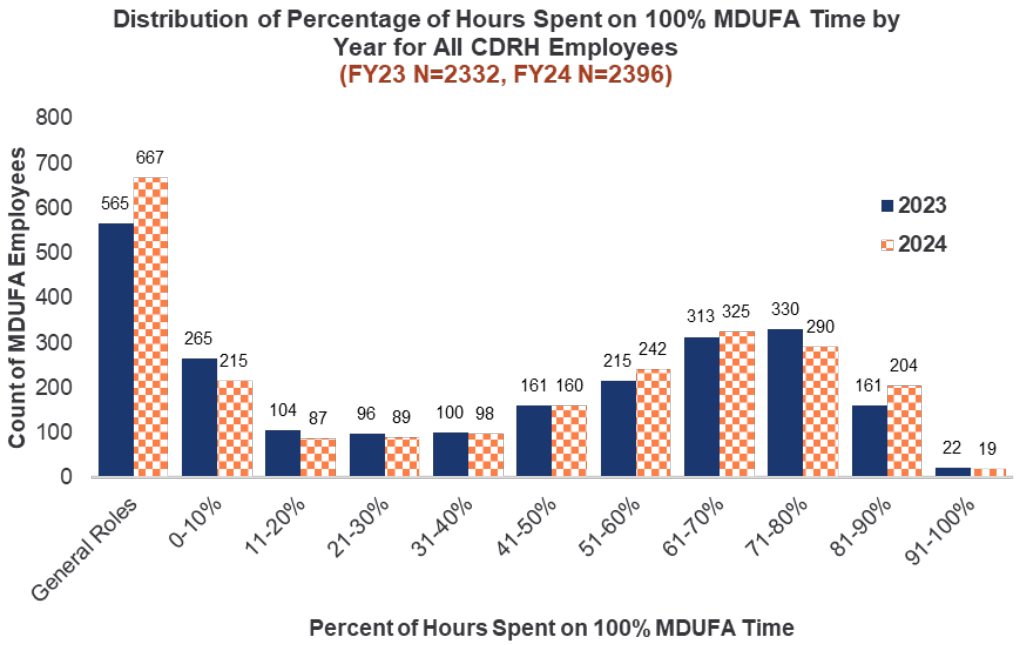

Figure 7: Distribution of 100% MDUFA time as a percentage of total time across 10 different time buckets and "General Roles". The 0-10% bucket is not inclusive of 0% as the "General Roles" bars in the plot represent staff members who did not log time to 100% MDUFA activity codes.

After incorporating estimated general time attributed to the MDUFA process at the cost center level, a noticeable change occurs in the shape of the proportional time charging distribution (see Figure 8). When considering total MDUFA time – which includes both 100% MDUFA time and general MDUFA time – nearly half of CDRH employees report 91% or more of their hours to the MDUFA process. The transition from the 100% MDUFA time distribution to the total MDUFA time distribution highlights how the proportional allocation of general time, influenced by the labor distribution assumption, can complicate the assessment of overall capacity among employees supporting the MDUFA program. Although this smoothing effect can help mitigate extreme cases of individual staff-level variation, it may 3mask potential role-related differences in time reporting behavior that are important when considering productive capacity. Moreover, the distribution of total MDUFA time post-spreading offers little insight if assessing workload, resources, or impact on employees, particularly for those who log most of their time under general activity codes, such as recruiters and IT technicians.

The labor distribution assumption highlights why the Process FTE metric should not be interpreted as a measure of capacity. The distribution of total MDUFA time after general time spreading provides little insight into the productive workload of employees, particularly those who log most of their time under general

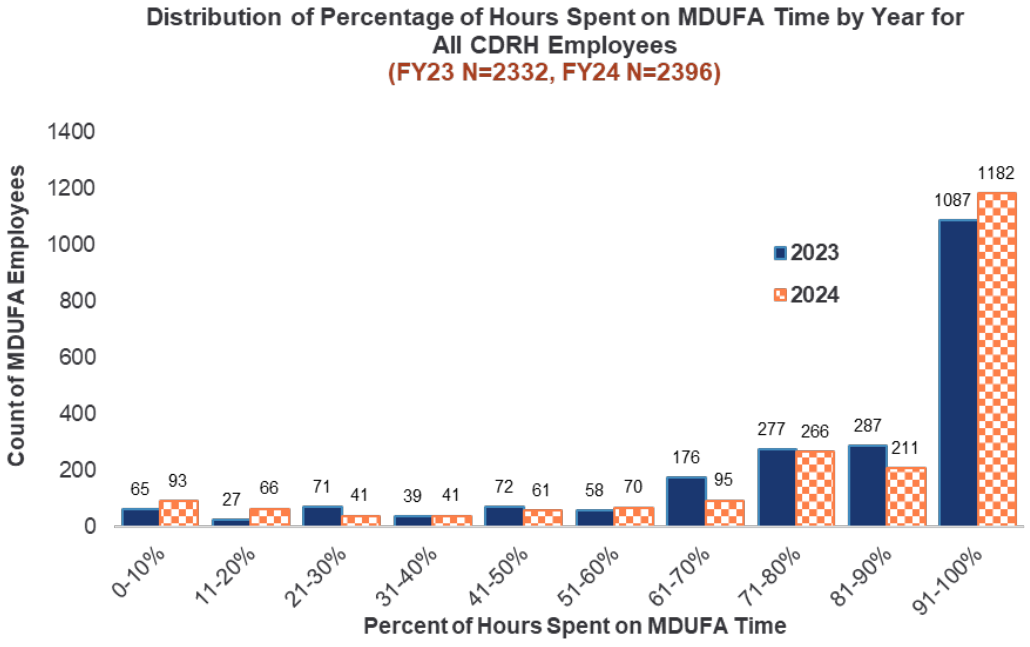

Figure 8: Distribution of Total MDUFA time as a percent of total time across 10 different time buckets. The 0-10% time bucket is not inclusive of 0% meaning that staff who recorded no time to MDUFA process are not included in the counts of employees in the plot.

time activity codes, such as recruiters and IT technicians. Additionally, workforce dynamics in certain offices, like OPEQ, highlight this issue. For example, 10% of staff in OPEQ accounted for 19% of all logged 100% MDUFA time in both FY 2023 and FY 2024, making potential capacity strains less visible in the final Process FTE outputs. Furthermore, general time spreading is executed at the cost-center level in practice. However, as shown in this analysis, the composition of individual employee time charging behavior can differ significantly. The *Employee Behavioral Case Study* provided below further illustrates how varying time charging behaviors impact the spreading of MDUFA process hours on an individual level.

Employee Behavioral Case Study

To further illustrate the mechanics of the general time spreading within cost centers, this assessment assembled the following notional case study of two hypothetical CDRH employees (see Figure 9 below). These hypothetical employees are treated as members of a cost center with N employees.

Assumptions:

Each employee's work year is 2,080 hours and includes a proportional spread of general hours at 75%. MDUFA non-allowable time is excluded for simplicity.

Results:

Employee A spends majority of their time on 100% MDUFA activity codes (e.g., conducts premarket application review) while Employee B spends the majority of their time on general activity codes (e.g., recruiting, IT, policy development, legal, etc.). Viewing their respective post-allocation time compositions underlines the core issue of MDUFA's Process FTE as a labor distribution when viewed through a capacity lens.

Despite Employee B charging less than 5% of their time to 100% MDUFA time activity codes, their total MDUFA time ends up being 76.2% of all the time they logged. This occurs because general time is spread using a cost center level allocation proportion per the labor distribution assumption. Based on this paradigm, the resulting distribution of total MDUFA time may not fully reflect time dedicated to process workload. Employees A and B exhibit distinct time charging behavior however the same allocation proportion is used to calculate their total MDUFA time.

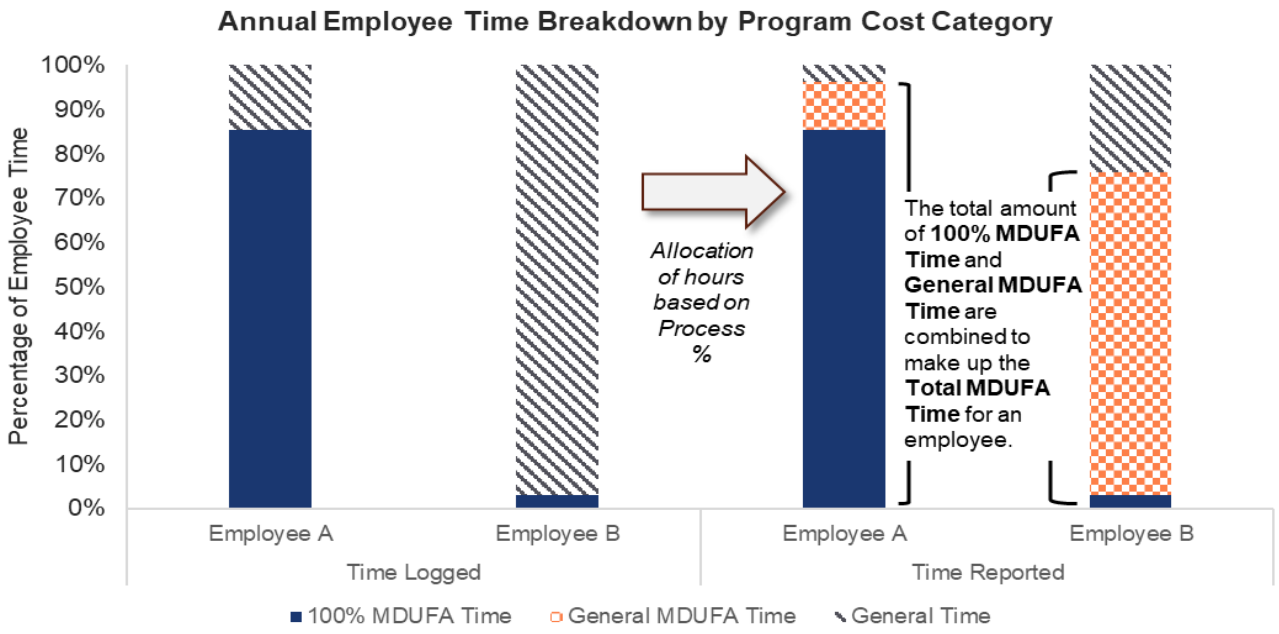

Figure 9: *Breakdown of annual time for hypothetical Employees A and B based on Employee Behavioral Case Study. Time recorded shows how general time is spread for individual employees using a cost center level process percentage. Employee A and B hours are based on the FY 2023 - FY 2024 average of 100% MDUFA time spent by staff in the top 10% of annual 100% MDUFA time charging and bottom 20% of 100% MDUFA time charging, respectively.*

General Activities Assumption

As mentioned above, general activities such as recruiting, IT support, and policy development are essential for the MDUFA program to function. The proportion of MDUFA process time attributable to general codes associated with these activities is estimated based on the labor distribution assumption. The general activities assumption is related but instead focuses on how general activity codes are used in the calculation of general MDUFA time. Similar to the labor distribution assumption, it supports effective cost accounting but also means that capacity interpretations of the Process FTE metric are unlikely to correctly reflect how time and effort was actually spent. Under this assumption, all general activity codes are included during general time spreading. While this approach provides a reasonably accurate estimate of FTE-associated *costs* to the MDUFA program, it differs from methodologies used in other Centers (e.g., CBER does not include leave) and is not intended to convey capacity.

Table 19: Top Six General Activity Codes by Percentage of Total General MDUFA Time

Activity	FY 2023	FY 2024
Leave	33.3%	33.1%
Operations	25.3%	34.1%
General & Administrative[88]	8.6%	0.0%
Education and Training	8.6%	10.7%
Organizational Excellence and Strategic Programs	4.9%	6.4%
IT Products, Data, and Analytics Systems	4.8%	5.6%

In FY 2023 and FY 2024, general MDUFA time accounted for approximately 60% of the total MDUFA time used to compute CDRH's MDUFA Process FTEs. Table 21 provides a breakdown of the six general activity codes that made up the largest share of general MDUFA time in these years.[89] The codes in Table 21 all represent paid employee time; however, some encompass activities that may not be dedicated to MDUFA

[88] The General & Administrative activity code along with associated recorded time was consolidated under other general activity codes in FY 2024 due to ITR code structure changes.
[89] It is important to note that the general activity codes listed only provide a high-level view of general activities reported. Each code generally has multiple additional levels of sub-codes that provide more granular activity level detail.

process workload (e.g., leave, education and training). This makes it challenging to equate MDUFA Process FTEs with capacity metrics that focus solely on productive hours, as those metrics often exclude non-workload-related activities Although estimating capacity is not the purpose of the Process FTE metric, this analysis highlights the challenges associated with interpreting it in that context.

Overtime Limitation

In addition to the labor distribution and general activities assumptions, the MDUFA Process FTE includes an overtime limitation. This limitation means that overtime can only be included in the final Process FTE metric through the process percentage. The implication of this limitation is that significant hours worked above the standard tour of duty may not be fully reflected in the Process FTE. This could lead to Process FTEs potentially not capturing all level of effort contributing to the MDUFA Program. Also, similar to the assumptions detailed above, this limitation impacts the viability of the Process FTE metric as a measure of capacity given that time dedicated to process workload would not be fully captured as well. Lastly, the current time reporting does not indicate which hours are a part of the normal tour of duty and which activities required time above the normal tour of duty.

Unlike the other assumptions, which simplify calculations at the cost center level for cost accounting purposes, the overtime limitation is dictated by statutory requirements. As explained in ***Process FTE Calculations***, overtime is not directly included in the FTE term used in the reporting activities component of the MDUFA Process FTE methodology. This is because the FTE term is based on OMB's definition of "FTE Employment," which excludes overtime and holiday hours worked. In contrast, the MDUFA process percentage does account for overtime, making it the sole method for incorporating overtime into the Process FTE metric. To understand the impact of the overtime limitation, one must analyze how different time inputs like 100% MDUFA time passthrough to the main intermediate/final outputs of the Process FTE methodology.

Overtime passthrough is analyzed empirically by measuring the rate at which a given Process FTE methodological output changes with respect to variation in 100% MDUFA, general, and MDUFA non-allowable time.[90] For context, the analysis uses the FY 2023/FY 2024 average time across all cost centers in OPEQ as the baseline for each input.[91] Table 22 illustrates how total MDUFA time, a key output, changes with each additional hour of overtime. The values provided are estimates of the rate of change in total MDUFA time based on a numerical approximation approach.[92] They indicate the additional hours contributed to total MDUFA time for every one-hour change in the associated input field.

Table 20: Overtime Passthrough to Total MDUFA Time

	100% MDUFA Time	General Time	MDUFA Non-Allowable Time
Change in Total MDUFA Time	1.16	0.79	-0.58

A few key points emerge from this analysis. First, the difference in rate signs for 100% MDUFA and general versus MDUFA non-allowable time suggests that additional overtime in MDUFA activities increases total MDUFA time, whereas overtime in MDUFA non-allowable activities reduces it. This aligns with CDRH's methodology for estimating general MDUFA time.[93] Second, the magnitude of pass-through varies for each

[90] Remaining non-MDUFA time estimated from general time spreading calculations is only included in the total time denominator of the process percentage component therefore it is impacted primarily by changes in general time.
[91] These averages are only hypothetical and meant to support estimation of applicable rate of change terms. Actual time in each OPEQ cost center may differ from what is used in this section's calculations.
[92] The numerical approximation method leveraged involved permuting each input variable separately and computing the resulting total MDUFA time. The change in total MDUFA time per unit change in input (i.e., slope) gives an approximate estimate of rate of change. Reported values were also assessed for robustness by taking the partial derivative of the total MDUFA time formula with respect to each input parameter. Derivative estimates were found to be generally in-line with reported numerical approximation results however were not completely identical given their higher dimensionality/precision (i.e., the numerical approximation involves estimating rate of change in 2 dimensions while partial derivatives were computed in 3 dimensions for each input parameter).
[93] MDUFA non-allowable time is captured in the denominator of the proportion used to calculate general MDUFA time as a part of the MDUFA process percentage component (see Figure 6 in MDUFA Process FTE Methodology Summary). This denominator (i.e., total time minus general time) can be equivalently formulated as the sum of 100% MDUFA time and MDUFA non-allowable time.

input. Notably, general time passes to total MDUFA time at a rate roughly equivalent to the percentage used in general time spreading, while 100% MDUFA passes through at rate greater than one, meaning each hour of 100% MDUFA overtime translates to 1.16 hours of total MDUFA time. Lastly, it is important to note that each rate of change value is calculated with other inputs held constant.[94] However, since the values are estimated for additional hours of overtime only, this assumption is reasonable.

Estimating the impact of additional overtime on the remaining Process FTE methodology outputs, namely the process percentage and Process FTE metric, offers further insight into how the overtime limitation functions. The impact is calculated using the same numerical approximation approach as Table 22, but here, estimated rate of change values are applied directly to hypothetical overtime hours. This evaluates how the process percentage and Process FTEs change with added overtime hours allocated to 100% MDUFA, general, and MDUFA non-allowable time.

Table 21: Overtime Passthrough to MDUFA Process FTE Methodology Outputs

Output[95]	100% MDUFA Overtime (50 hrs)	100% MDUFA Overtime (100 hrs)	100% MDUFA Overtime (1000 hrs)	General Overtime (50 hrs)	General Overtime (100 hrs)	General Overtime (1000 hrs)	MDUFA Non-Allowable Overtime (50 hrs)	MDUFA Non-Allowable Overtime (100 hrs)	MDUFA Non-Allowable Overtime (1000 hrs)
Total MDUFA Time	57.7530	115.5060	1155.0598	39.4847	78.9693	789.6934	-29.1122	-58.2244	-582.2439
Process Percentage	0.0002	0.0004	0.0042	0.0000	0.0000	0.0000	-0.0008	-0.0016	-0.0158
Process FTEs	0.0088	0.0177	0.1767	0.0000	0.0000	0.0000	-0.0332	-0.0663	-0.6633

Table 23 illustrates how the MDUFA process percentage and Process FTE outputs vary with increases in overtime of 50, 100, and 1,000 hours. The magnitude of these overtime inputs is generally in-line with the significant amount of hours above tour of duty typically worked across CDRH cost centers. Total MDUFA time changes are also presented to provide a complete understanding of all intermediate and final outputs. The changes resulting from 100% MDUFA and MDUFA non-allowable overtime generally align with the rate of change values shown in Table 22 when larger amounts of additional overtime are considered. However, while the increase in total MDUFA time for general overtime mirrors Table 22 results as well, the process percentage and Process FTE metrics show almost no pass-through effect.[96] This outcome suggests that additional general overtime has minimal to no impact on the process percentage and Process FTE outputs, which could lead to an underestimation of level of effort related to general MDUFA activities. In support organizations, where a significant amount of recorded time is associated with general activity codes, this underestimation could have a particularly notable impact.

Overall, these results indicate that the calculations used to estimate the MDUFA Process FTE can lead to unexpected dynamics in how overtime is accounted for, particularly regarding interactions between different methodological components. These complexities may hinder effective communication about the Process FTE metric and its intended purpose. Additionally, due to these apparent technical limitations, there is a need to consider supplemental metrics for stakeholders seeking a more comprehensive understanding of the CDRH workforce completing MDUFA activities.

[94] The impact of simultaneous changes in input associated overtime hours on total MDUFA time can be conceptualized as a weighted average of input rates of change values. The technical term for this joint rate of change is called the total derivative.
[95] Outputs are in hours, percents, and full-time equivalents for total MDUFA time, process percentage, and Process FTE, respectively.
[96] Zero values in Table 24 cells associated with these outputs are in reality very small values. Reported output values are limited to four decimal places of precision for interpretability.

Appendix IV: Glossary of Key Acronyms and Terms

Acronyms and specific terms are used throughout this report. The table below provides definitions and descriptions.

Term	Definition
ADUFA	Animal Drug User Fee Act
AGDUFA	Animal Generic Drug User Fee Act
APHIS	Animal and Plant Health Inspection Service
ATR	Activity Time Reporting. Time reporting system in the Center for Veterinary Medicine.
BsUFA	Biosimilar User Fee Act
Budget Authority (BA)	The limit on new financial obligations federal agencies may incur.
CAAPS	CDRH Acquisition and Administrative Planning System. Center for Devices and Radiological Health IT system used for tracking position status.
Capacity	Workforce capacity evaluates an organization's ability to meet workload demands within a specified timeframe. It encompasses the supply and demand of the workforce by considering factors such as the number of employees, their skills, and their availability. Workforce capacity is measured through different forms, including design capacity, which represents potential maximum output, and operational capacity, which reflects actual, feasible output under typical conditions. To accurately assess organizational performance, it is crucial to measure output alongside capacity, allowing for alignment with strategic objectives and market needs.
CBER	Center for Biologics Evaluation and Research
CDO	Chief Data Officer
CDRH	Center for Devices and Radiological Health
Cost Center	A business unit that is assigned a portion of an organization’s expenses based on role and function.
CPA	Capacity Planning Adjustment. A process used to manage and allocate resources effectively based on projected needs
DOT	Department of Transportation
DRR	Departmental Results Report. Reports that provide an account of actual performance against planned results for Canadian government departments.
EASE	Enterprise Administrative Support Environment. Food and Drug Administration (FDA) IT system used for personnel record management
EMA	European Medicines Agency. European Union agency responsible for the evaluation and supervision of medicinal products.
EPA	Environmental Protection Agency
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FERC	Federal Energy Regulatory Commission
Full-time equivalents (FTE)	A calculation of the number of hours worked by employees divided by the number of work hours in a year (e.g., 2,080). “Work hours” include annual leave, sick leave, and other approved leave categories for purposes of defining FTEs
GAO	Government Accountability Office
GDUFA	Generic Drug User Fee Act. FDA User Fee Program
GSA	General Services Administration
Hires	In the MDUFA context, a hire is an employee confirmed as on board by the date indicated in a full-time position. Hires may be new employees recruited from outside the FDA, or, in some cases, a hire can be a current FDA employee who is changing positions within the agency

Appendix IV: Glossary of Key Acronyms and Terms

Term	Definition
HQ	FDA Headquarters. HQ includes the Office of the Commissioner (OC), and OC components including the Office of Operations (OO), Office of Policy, Legislation, & International Affairs (OPLIA), and certain other central offices.
IBAPS	Integrated Budget and Acquisition Planning System. FDA IT system used for planning and managing budgets and acquisitions.
ISO	International Organization for Standardization
ITR	Insight Time Reporting system. FDA IT system used for time reporting.
MA	Mass Allocation
MDD	Medical Devices Directorate. Health Canada directorate overseeing Medical Device License Fee program.
MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
NCUA	National Credit Union Administration
NPS	National Park Service
NRC	Nuclear Regulatory Commission
OII	Office of Inspections and Investigations
OM	Office of Management. Component of CDRH.
OMB	Office of Management and Budget
On-board employee (employee)	The total number of people currently employed, performing work, and supervised by another employee of the federal government. Includes individual employee headcount as of a particular date and may consist of full-time, part-time, and seasonal employees.
OPM	Office of Personnel Management
PC01 Report	Report aggregating MDUFA program costs at the cost center level
PDUFA	Prescription Drug User Fee Act
Positions	The authorized slots or roles within an organization that can be filled by employees. A position may also refer to the specific duties and responsibilities assigned to an employee.
RCP	Resource Capacity Planning. The process of determining and allocating resources effectively to meet organizational demands.
SEC	Securities and Exchange Commission
SF-113G	Report filed with OPM providing the number of FTEs reporting time monthly. Includes the FDA's program-level WCF Split.
SME	Subject Matter Expert
TAP	Total Product Life Cycle Advisory Program
TGA	Therapeutic Goods Administration. Australian administration overseeing the Therapeutic Goods Administration (TGA) Medical Device Application Fee Program
TPLC	Total Product Life Cycle
Trigger Amount	Legal conditions that must be satisfied each year for FDA to collect and spend MDUFA user fees
User Fee	Fees collected from companies that produce certain products (such as drugs, medical devices, etc.) and from some other entities. User fees supplement the annual funding that Congress provides for the agency, helping the FDA fulfill its mission.
User Fee Agreement	Outlines the commitments made by the FDA and industry as part of a related agreement they develop, which is implemented when Congress authorizes the user fees. Often called "Commitment Letters" or "goals letters," user fee agreements include goals such as timelines to evaluate applications to bring products to market or commitments for the FDA to publish guidance on topics of interest to industry.
USPTO	United States Patent and Trademark Office
Vacancies	The established positions unoccupied by employees. Complete employee counts and comprehensive position information is required to determine the number of vacancies and open positions.
WCF	Working Capital Fund. WCF is a financial mechanism authorized by Congress to support the FDA's centralized services. This fund helps manage the financial resources collected from user fees.

Appendix V: Figures and Tables

Figures

Figure 1: Process map outlining the key activities of CDRH's MDUFA FTE & Position Tracking process. 13
Figure 2: High-level description of MDUFA Process FTE calculations. Calculations are broken up into two distinct components: the MDUFA Process Percentage and Reporting Activities. 17
Figure 3: High-level description of Total MDUFA Time and MDUFA Process Percent calculations as well as associated assumptions and limitations. 18
Figure 4: MDUFA tagged positions account for less than 20% of all positions in CDRH. 21
Figure 5: High-level description of MDUFA Process FTE calculations. Calculations are broken up into two distinct components: the MDUFA Process Percentage and Reporting Activities. 56
Figure 6: High-level description of Total MDUFA Time and MDUFA Process Percent calculations as well as associated assumptions and limitations. 56
Figure 7: Distribution of 100% MDUFA time as a percentage of total time across 10 different time buckets and "General Roles". The 0-10% bucket is not inclusive of 0% as the "General Roles" bars in the plot represent staff members who did not log time to 100% MDUFA activity codes. 58
Figure 8: Distribution of Total MDUFA time as a percent of total time across 10 different time buckets. The 0-10% time bucket is not inclusive of 0% meaning that staff who recorded no time to MDUFA process are not included in the counts of employees in the plot. 58
Figure 9: Breakdown of annual time for hypothetical Employees A and B based on Employee Behavioral Case Study. Time recorded shows how general time is spread for individual employees using a cost center level process percentage. Employee A and B hours are based on the FY 2023 - FY 2024 average of 100% MDUFA time spent by staff in the top 10% of annual 100% MDUFA time charging and bottom 20% of 100% MDUFA time charging, respectively. 60

Tables

Table 1: MDUFA Workforce Reporting Requirements 12
Table 2: FDA IT Systems Supporting MDUFA Workforce Metric Development 14
Table 3: Illustrative Example of MDUFA Process Percentage Calculation 16
Table 4: MDUFA V Minimum Hiring Goals 20
Table 5: Comparison of Count of MDUFA-Tagged Positions, Employee Count, and MDUFA Process FTEs 22
Table 7: Gap Analysis Finding 1: Reporting Mechanisms 35
Table 8: Gap Analysis Finding 2: Building Workforce Capacity 36
Table 9: Gap Analysis Finding 3: Metric Expansion 37
Table 10: Recommendation 1: Implement a Comprehensive Framework for Workforce Metric Reporting 40
Table 11: Recommendation 2: Centralize Workforce Reporting for Improved Communication and Transparency 42
Table 12: Recommendation 3: Expand the Existing Governance Framework 43
Table 13: Assessment Methodology Phases and Objectives 44
Table 14: Program Scope Research Questions 46
Table 15: Program Performance Research Questions 47
Table 16: Program Benchmarks Research Questions 47
Table 17: Program Tools Research Questions 48
Table 19: Definitions of Key Workforce Measurement Terms 53
Table 20: Comparisons of Employees, Positions, and FTEs 54
Table 21: Top Six General Activity Codes by Percentage of Total General MDUFA Time 60
Table 22: Overtime Passthrough to Total MDUFA Time 61
Table 23: Overtime Passthrough to MDUFA Process FTE Methodology Outputs 62