

# Medical Device User Fee Amendments IV Independent Assessment of Food and Drug Administration's Device Review Process Management

DELIVERABLE 17 AND DELIVERABLE 20:  
FINAL REPORT  
AND RECOMMENDATIONS

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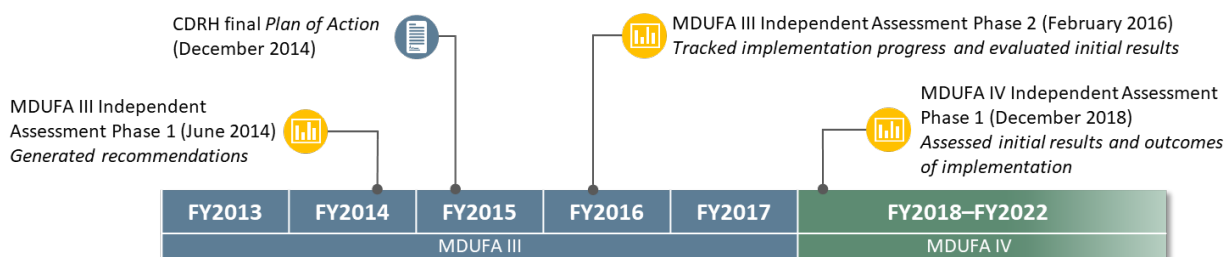
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# EXECUTIVE SUMMARY

Booz Allen evaluated the overall impact of the Food and Drug Administration’s actions to improve the medical device review process under the Medical Device User Fee Amendments of 2012.

The Medical Device User Fee Amendments of 2012 (MDUFA III) and 2017 (MDUFA IV) included provisions for the independent assessment of the Food and Drug Administration’s (FDA) medical device review process. The independent assessment conducted during MDUFA III was performed by Booz Allen and consisted of two phases. Phase 1 focused on identifying best practices and process improvements to promote predictable, efficient, and consistent premarket reviews that meet FDA’s regulatory standard. The Phase 1 final report was published in June 2014 and outlined 11 recommendations for improvements to the submission review process. In response, FDA’s Center for Devices and Radiological Health (CDRH) developed a *Plan of Action* to address these 11 recommendations. In Phase 2 of the MDUFA III Independent Assessment, Booz Allen assessed whether CDRH had completed each project in its *Plan of Action* to address the Phase 1 recommendations. At the completion of Phase 2, the assessment determined that CDRH had fully implemented the *Plan of Action*, but insufficient time had elapsed to allow Booz Allen to assess the overall impact of implementation on the medical device review process. In February 2016, Booz Allen published the final MDUFA III Phase 2 report outlining CDRH’s actions and proposing metrics to complete the assessment to determine the impact of those actions. This report, conducted as a MDUFA IV commitment, assesses the initial results and overall impact of CDRH’s actions and completes the MDUFA III Phase 2 evaluation. Figure ES-1 illustrates the timeline for the independent assessment of medical device review process and corresponding actions taken by CDRH.



**Figure ES-1. Timeline of MDUFA III/IV independent assessment of medical device review process**

In this assessment, Booz Allen utilized the previously established five-stage framework, which evaluated each implementation project based on its planned objectives, measurability, execution of project plans, initial results, and impact. This assessment focused on completing the evaluation of Stage 4 (Measure Initial Results) and Stage 5 (Assess Outcomes) for each recommendation. Booz Allen applied established assessment methodologies, including appropriate evaluation metrics, and determined whether the implementation projects achieved their intended outcomes. A summary of the completed evaluation framework for FDA’s implementation projects to address all recommendations is provided in Table ES-1.

**Table ES-1. Summary of recommendations for FDA implementation completed against Booz Allen evaluation framework**

| RECOMMENDATION   | DESCRIPTION  | EVALUATION FRAMEWORK |   |   |   |   |
|--|--|----------------------|---|---|---|---|
|  |  | 1                    | 2 | 3 | 4 | 5 |
| 1a. CAPA and CPI*  | Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas  | ●                    | ● | ● | ● | ● |
| 1b. Document Control Enhancements*   | Deploy planned document control system enhancements (e.g., CTS, DocMan, Image2000+, SharePoint, eCopy) using a quality-oriented focus to optimize the utility of system changes to all review staff    | ●                    | ● | ● | ● | ● |
| 1c. Review Process Metrics*  | Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement   | ●                    | ● | ● | ● | ● |
| 2. Decision-Making Consistency   | Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process  | ●                    | ● | ● | ● | ● |
| 3. RTA Process Improvement   | Optimize RTA process by improving awareness of and clarity around Administrative requirements for 510(k) submissions   | ●                    | ● | ● | ● | ● |
| 4. Withdrawn Submission Analysis   | Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence  | ●                    | ● | ● | ● | ● |
| 5. Sponsor Communications  | Implement a consistent practice for communicating early and frequently with Sponsors during the Substantive Review (SR) phase to address and resolve potential issues prior to Substantive Interaction | ●                    | ● | ● | ● | ● |
| 6. IT System Training*   | Provide mandatory training for the three primary IT systems that support MDUFA III reviews   | ●                    | ● | ● | ● | ● |
| 7. eCopy Guidance  | Provide increased clarity to applicants beyond existing eCopy Guidance to enhance organized submission structure   | ●                    | ● | ● | ● | ● |
| 8. Workload Management Tool Review   | Evaluate tools for providing a comprehensive view of staff workload  | ●                    | ● | ● | ● | ● |
| 9. Training Program Evaluation & Metrics*  | FDA should identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes  | ●                    | ● | ● | ● | ● |
| 10. Promote Informal Training  | Promote informal training and knowledge sharing by seasoned staff for review staff and management to share division or science-specific review processes, lessons learned, and best practices          | ●                    | ● | ● | ● | ● |
| 11. Staff Turnover & Transition Plans  | Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews   | ●                    | ● | ● | ● | ● |
| <b>Stage 1   Validate Implementation Plan Objectives - Confirm whether FDA developed plans to address the recommendations</b>                |  |                      |   |   |   |   |
| <b>Stage 2   Assess Measurability of Implementation Plans - Assess whether projects are sufficiently specific, measurable, and timebound</b> |  |                      |   |   |   |   |
| <b>Stage 3   Track Implementation Progress - Determine whether projects are executed to schedule</b>   |  |                      |   |   |   |   |
| <b>Stage 4   Measure Initial Results - Assess whether projects meet the recommendations intent and yield measurable results</b>              |  |                      |   |   |   |   |
| <b>Stage 5   Assess Outcomes - Evaluate whether projects help achieve desired outcomes</b>   |  |                      |   |   |   |   |

\*Priority recommendations

Based on the assessment of each implementation project against this framework, Booz Allen determined that CDRH staff are aware of and utilize the products and resources developed and implemented by CDRH for all recommendations. Further, most of CDRH’s implementation projects met the intent of the recommendations and several projects have progressed far beyond the original recommendations. A summary of CDRH’s implementation project outcomes against each recommendation is included in Table ES-2. Overall, CDRH’s efforts have been very effective at standardizing CDRH operations, increasing staff knowledge to perform submission reviews, increasing regulatory process clarity, and improving decision-making consistency.

**Table ES-2. Outcomes of FDA implementation plans**

| RECOMMENDATION                                | OUTCOMES   |
|---|--|
| 1a. CAPA and CPI*                             | CDRH implemented a system (FEEDBACK/CDRH) for documenting and communicating issues. Staff use the system to communicate CDRH specific issues and the system provides CDRH management a location to review and address the necessary changes.   |
| 1b. Document Control Enhancements*            | CDRH implemented an effective a Document Control System (DCS), putting in place a central repository where CDRH staff locate and obtain the documents required to perform their work. CDRH developed and implemented standardized processes for performing Information Technology enhancements and documenting Administrative Files.               |
| 1c. Review Process Metrics*                   | Attributes of submissions that missed the 90-day review goal highlight the potential benefit of review performance metrics to identify these submissions. CDRH leadership frequently reviews public and internal metrics, with the goal of continuous process improvement and effective monitoring of review performance during premarket review.  |
| 2. Decision-Making Consistency                | Staff are aware of and use CDRH-developed resources and mechanisms aimed at improving review consistency, including the SMART memo template, the biocompatibility Focal Point Program, and structured management oversight. Staff believe that these resources are improving decision-making consistency.  |
| 3. Refuse to Accept (RTA) Process Improvement | CDRH revised the RTA Checklist, which correlates with a decrease of first cycle non-acceptance rates for Traditional 510(k)s from 39% in Fiscal Year (FY) 2015 to 33% in FY2017. Reviewers appear to be using reviewer discretion to address missing elements interactively during review.   |
| 4. Withdrawn Submission Analysis              | CDRH outlined procedures for withdrawal documentation. The Traditional 510(k) withdrawal rate of accepted submissions remained constant at approximately 6% from FY2015 to FY2017. It appears that withdrawals continue to be associated with deficiencies described in Additional Information (AI) Letters and made close to the MDUFA goal date. |
| 5. Sponsor Communications                     | CDRH identified best practices and developed procedural documents to guide interactive communications with sponsors. Reviewers do not appear to be initiating communications earlier during review, although we observed a slight trend toward increased interaction, from 3.8 rounds per submission in FY2015 to 4.8 in FY2017.                   |
| 6. IT System Training*                        | CDRH staff responded positively to IT system training being incorporated into the Reviewer Certification Program.  |
| 7. eCopy Guidance                             | CDRH has made continuous enhancements to the eCopy Program, including fine-tuning error messages. Submissions undergoing eCopy holds decreased from 26% in Calendar Year (CY) 2013 to 8% in CY2017.  |
| 8. Workload Management Tool Review            | CDRH developed, implemented, and enhanced a workload tool that allows Branch Chiefs to assess team workload. This tool is used in combination with branch-specific resources to ensure work is appropriately distributed.  |
| 9. Training Program Evaluation & Metrics*     | CDRH implemented the Kirkpatrick Model in all CDRH premarket training programs. This resulted in changes to the Reviewer Certification Program. Users feel these changes enhanced their ability to perform review work and feel comfortable with 510(k)-specific elements.   |
| 10. Promote Informal Training                 | Informal training is embedded in the culture of CDRH, as demonstrated by the increase in the number of informal training events and training participants over the past three years.   |
| 11. Staff Turnover & Transition Plans         | Managers use Center-wide resources to prepare for staff turn-over as it occurs. CDRH has worked to enhance staff satisfaction and provide more resources for career growth, with the goal of increasing staff retention.   |

\*Priority recommendations

Overall, CDRH’s actions have positively impacted efforts to enhance and improve medical device submission review. We also identified additional opportunities, such as enhanced review performance metrics and analytics, better search capabilities within CDRH IT systems, and implementing resources to facilitate structured electronic submissions, which would build on the success of these efforts to increase efficiency and streamline the medical device submission review process.

# 1. ASSESSMENT BACKGROUND AND OBJECTIVES

In this assessment, Booz Allen evaluated the overall impact of changes made to the medical device review process in response to recommendations made in Phase 1 of the independent assessment.

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In 2002, Congress passed the Medical Device User Fee and Modernization Act (MDUFMA), granting the Food and Drug Administration (FDA) the authority to collect user fees from device manufacturers to help increase the efficiency of its regulatory processes and reduce the time to bring safe and effective medical devices to market. During each Medical Device User Fee Amendments (MDUFA) reauthorization, FDA and the medical device industry have agreed to user fees, performance goals, procedures, and certain studies and evaluations for a five-year period. During MDUFA III (Fiscal Years [FY] 2013-2017), Booz Allen completed a two-phased independent assessment to evaluate FDA's device review program and to identify recommendations for improving process efficiency and reducing review times.

The initial phase of the independent assessment focused on identifying best practices and process improvements to promote predictable, efficient, and consistent premarket reviews that meet FDA's regulatory standards. Booz Allen's Phase 1 final report<sup>1</sup> was published in June 2014 and detailed 11 recommendations for improving the submission review process, information technology (IT) infrastructure, training and retention policies and practices, and quality management (QM) systems. In December 2014, FDA's Center for Devices and Radiological Health (CDRH) published its final *Plan of Action*<sup>2</sup> to address each Phase 1 recommendation. The second phase of the assessment focused on evaluating FDA's implementation of the recommendations from Phase 1. The Phase 2 final report,<sup>3</sup> published in February 2016, demonstrated that FDA successfully completed each project in its *Plan of Action*, which satisfied the Agency's commitment in MDUFA III to fulfill the recommendations from Phase 1.

Measurement of outcomes is the most critical and meaningful component of the overall assessment framework because it determines whether each project has achieved the intended impact of the original recommendations. In Phase 2, the time available to measure results and outcomes for each recommendation was insufficient. In the MDUFA IV Performance Goals and Procedures,<sup>4</sup> FDA and industry agreed that an independent contractor should complete the evaluation of FDA's implementation of the corrective action plan developed in response to the recommendations from the MDUFA III Independent Assessment and publish a final report of the evaluation.

The key objective for Booz Allen's MDUFA IV Independent Assessment was to evaluate the overall impact of the implementation of the recommendations identified in MDUFA III Phase 1. We applied established assessment methodologies, including appropriate evaluation metrics, and determined whether the implementation projects achieved their intended outcomes. CDRH is currently piloting a large organizational transformation to align premarket and postmarket review (Office of Product Evaluation and Quality (OPEQ) pilot). As this change did not begin under MDUFA III, Booz Allen did not evaluate this transformation. We did consider the future impact the transformation may have on select recommendations.

## 2. METHODOLOGY

Booz Allen used evaluation and strategic frameworks to develop metrics for the assessment of initial results and outcomes. We identified appropriate data sources for analysis of each recommendation, including CDRH data systems, training data, audits, internal/external communications, case studies, interviews, and surveys.

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### 2.1 Overall Approach

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<sup>1</sup> Independent Assessment of FDA Device Review Process Management – Phase 1

<sup>2</sup> Center for Devices and Radiological Health's Plan of Action Based on Booz Allen Hamilton MDUFA II/III Evaluation Deliverable 10: Final Report on Findings and Recommendations

<sup>3</sup> [Independent Assessment of FDA Device Review Process Management – Phase 2](#)

<sup>4</sup> [MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022](#)



## EVALUATION FRAMEWORK

Booz Allen defined a five-stage evaluation framework during Phase 1 of the MDUFA III Independent Assessment, depicted in Figure 2-1, and leveraged this framework to assess the implementation, results, and outcomes of CDRH’s *Plan of Action*. Each stage of the framework evaluates a distinct stage of maturity in implementation and is characterized by a set of key questions. Booz Allen completed an assessment of the preceding stage implementation projects before beginning the next stage of the framework (e.g., Stage 1 was completed before beginning Stage 2). The present assessment completes the Stage 4 evaluation for seven recommendations<sup>5</sup> and completes Stage 5 evaluation of all implementation activities.

|   |   |
|---|---|
| <b>1. Validate Implementation Plan Objectives</b>     | <ul style="list-style-type: none"> <li>• What are the issues and associated recommendations identified for further improvement?</li> <li>• Does FDA have a plan in place to address each recommended area for improvement?</li> </ul>   |
| <b>2. Assess Measurability of Implementation Plan</b> | <ul style="list-style-type: none"> <li>• Is the planned implementation of each recommendation sufficiently specific, measurable, and time-bound to be able to effectively assess?</li> <li>• If not, what changes would enable FDA’s plan to be assessed?</li> </ul>            |
| <b>3. Track Implementation Progress</b>               | <ul style="list-style-type: none"> <li>• Are activities being executed according to planned schedules?</li> <li>• If not, are there plans and points of contact in place for course correction, oversight, and activity completion?</li> </ul>                                  |
| <b>4. Measure Initial Results</b>                     | <ul style="list-style-type: none"> <li>• What metrics may be used to assess whether activities were performed as intended by the implementation plan?</li> <li>• What initial results are feasible to measure during the Phase 2 study timeframe?</li> </ul>                    |
| <b>5. Assess Outcomes</b>                             | <ul style="list-style-type: none"> <li>• What measures may be used to assess FDA achievement of desired outcomes?</li> <li>• What are the actual outcomes of FDA implementation?</li> <li>• What outcomes are feasible to assess during the Phase 2 study timeframe?</li> </ul> |

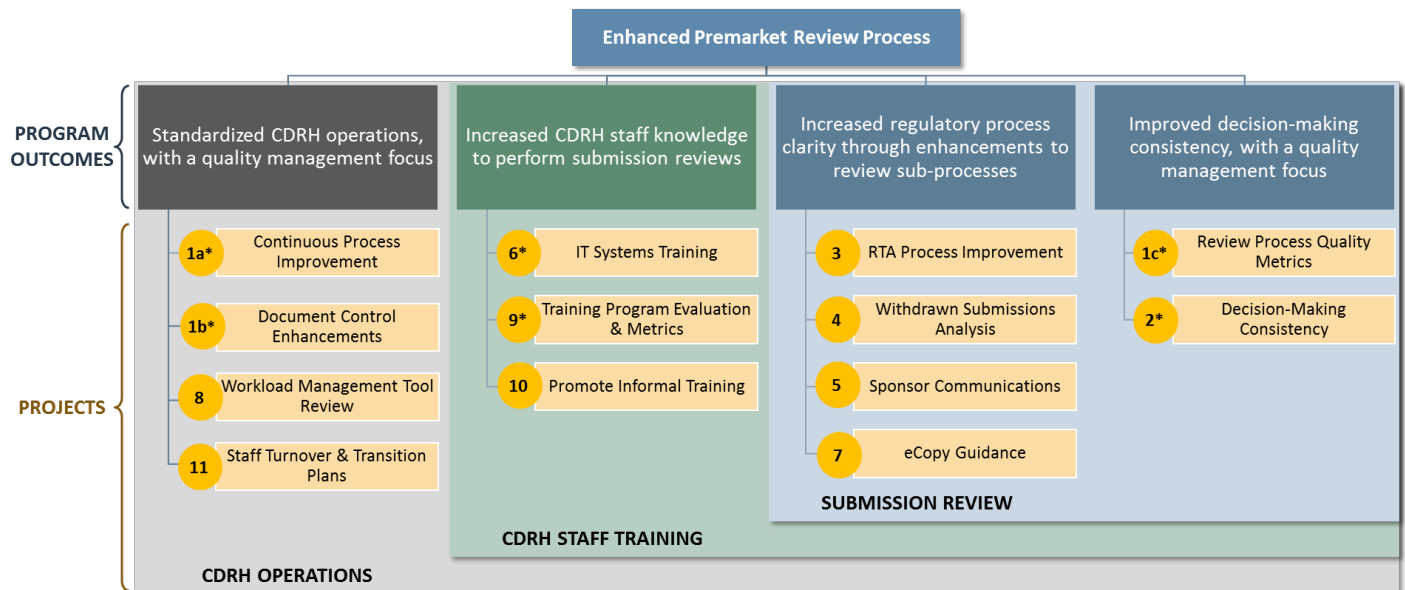
**Figure 2-1. Booz Allen’s evaluation framework**

Stage 4 (Measure Initial Results) of the evaluation framework ascertains whether CDRH initiatives are being implemented as intended. The purpose of Stage 5 evaluation (Assess Outcomes) is to assess whether the implementation projects from CDRH’s *Plan of Action* has fulfilled the ultimate intent of Booz Allen’s original recommendations.

## STRATEGIC FRAMEWORK

Booz Allen created a strategic framework to guide the outcome and impact analysis, and to better illustrate the objectives of, and the relationships between, the implementation projects. As outlined in Figure 2-2, we established the overall objective of an enhanced premarket review process that is accomplished by four program-level outcomes, which are in turn supported by the implementation projects. We generated metrics to evaluate how each project contributed to the program-level outcomes. The four program-level outcomes impacted three categories: CDRH operations, CDRH staff training, and submission review.

<sup>5</sup> During Phase 2, Booz Allen tracked implementation progress and completed Stage 1-3 evaluation of all recommendations. Initial results (i.e., Stage 4) were evaluated only for Recommendations 1a, 6, 9, and 10



\*Priority recommendations and corresponding implementation projects

**Figure 2-2. Booz Allen’s strategic framework**

This report is organized according to the strategic framework, and groups recommendations with similar outcomes associated with CDRH operations, CDRH staff training, and submission review.

## 2.2 Data Collection and Analysis

Using the information on the current state of each implementation project, Booz Allen identified metrics to assess the initial results (Stage 4) and outcomes (Stage 5) of FDA’s implementation projects. We selected a subset of the available data sources, represented by the dots in Figure 2-3, to evaluate each implementation project. We met and worked in conjunction with FDA stakeholders for each project to ensure that the metrics and analyses accurately assessed the impact of each project.

| DATA SOURCE                      | CDRH OPERATIONS |     |   |    | CDRH STAFF TRAINING |    |    | SUBMISSION REVIEW |   |   |   |     |    |
|----------------------------------|-----------------|-----|---|----|---------------------|----|----|-------------------|---|---|---|-----|----|
|                                  | 1a*             | 1b* | 8 | 11 | 6*                  | 9* | 10 | 3                 | 4 | 5 | 7 | 1c* | 2* |
| CDRH Data Systems                | ●               | ●   |   |    |                     |    |    | ●                 | ● |   | ● | ●   |    |
| Training Data                    |                 | ●   |   |    | ●                   | ●  | ●  | ●                 | ● | ● |   |     | ●  |
| Audits                           |                 | ●   |   |    |                     |    |    | ●                 | ● | ● |   |     | ●  |
| Internal/External Communications |                 | ●   |   |    |                     |    | ●  |                   |   |   | ● |     | ●  |
| Case Studies                     | ●               | ●   | ● | ●  | ●                   | ●  |    |                   |   |   | ● |     |    |
| Interviews                       | ●               | ●   | ● | ●  | ●                   | ●  | ●  |                   |   |   |   | ●   | ●  |
| Surveys                          |                 |     |   |    | ●                   | ●  |    |                   |   |   |   |     | ●  |

\*Priority recommendations and corresponding implementation projects

**Figure 2-3. Summary of data sources for the evaluation of FDA implementation projects**

## CDRH DATA SYSTEMS

Booz Allen queried multiple databases within CDRH’s data systems (Table 2-1) to analyze premarket review data and evaluate CDRH’s QM processes.

**Table 2-1. Description of data sources from CDRH data systems**

| TYPE                      | DATA SOURCE                         | DESCRIPTION   |
|---------------------------|-------------------------------------|---|
| Premarket Review Database | CDRH Ad Hoc Reporting System (CARS) | Database that supports queries and reporting of premarket review performance data, including MDUFA Quarterly Performance Reports  |
|                           | Center Tracking System (CTS)        | Workflow management and tracking system for CDRH’s premarket review activities  |
|                           | DocMan                              | Document management system that provides a single location to manage and store review staff’s premarket review records  |
|                           | Image2000+                          | Final repository of industry submissions  |
|                           | eCopy Submission Records            | Records kept on all original, supplement, and amendment eCopy submissions   |
| QM Infrastructure         | FEEDBACK/CDRH                       | Feedback system to collect staff feedback and to log, track, and prioritize continuous process improvement (CPI) issues   |
|                           | DCS                                 | Document control platform consisting of CDRH Docs (central repository for current document versions, accessible to all CDRH staff), SWIFT Docs (repository with all versions of documents), and databases of Transmittal Notices (notification of document changes) and Document Change Requests, to support CDRH operations and QM |

To analyze trends in premarket review, Booz Allen focused on Traditional 510(k)s because they represent the majority of 510(k) submissions and were the original focus of many implementation projects. We evaluated data from FY2015–FY2017, which spanned the period before and after FDA’s implementation of updated premarket review procedures. We performed a CARS query to obtain records for all Traditional non-third party 510(k)s received during FY2015–FY2017, creating a comprehensive data set of 9392 submissions for the Receipt Cohort.<sup>6</sup> At the time of our query (July 12, 2018), 100% of FY2015, 99.8% of FY2016, and 95.9% of FY2017 submissions from the Receipt Cohort were closed.<sup>7</sup>

To evaluate CDRH’s QM processes, we obtained and analyzed system data and logs generated by CDRH’s QM infrastructure, including FEEDBACK/CDRH and DCS. Booz Allen evaluated data from the systems’ launches in March 2015 and May 2017, respectively, to a cut-off date of April 2018.

## AUDITS

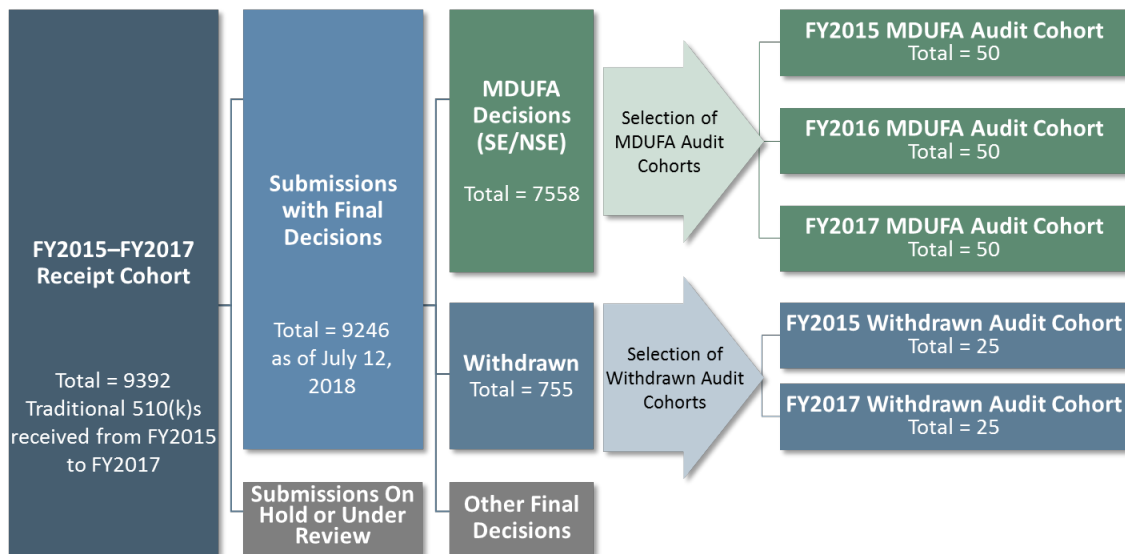
Booz Allen conducted in-depth audits of Traditional 510(k) submissions, with either Substantially Equivalent (SE)/Not Substantially Equivalent (NSE) or withdrawal decisions, and CDRH’s QM systems to evaluate specific aspects of the premarket review and QM processes.

### *Traditional 510(k) Audit*

As illustrated in Figure 2-4, we first filtered the FY2015–FY2017 Receipt Cohort for submissions with final decisions. We then separated the submissions based on decision status. The three MDUFA Audit Cohorts contained submissions with MDUFA decisions (i.e., SE or NSE decisions). The Withdrawn Audit Cohorts consisted of submissions that were withdrawn during any phase of the review process.

<sup>6</sup> Receipt dates were defined as the date by which FDA received validated eCopies and user fees for premarket submissions. The Receipt Cohort consisted of Traditional 510(k) submissions with receipt dates starting on October 1, 2014 and ending on September 30, 2017 (FY2015–FY2017), and excludes records of other types of 510(k)s (i.e., Special, Abbreviated, third party reviewed)

<sup>7</sup> Closed submissions are those that have received a final decision



**Figure 2-4. Generation of MDUFA and Withdrawn Audit Cohorts from FY2015–FY2017 Receipt Cohort**

Traditional 510(k) cohorts and the relevant analyses performed using each are summarized in Table 2-2.

**Table 2-2. Summary of Traditional 510(k) cohorts and associated analyses**

| COHORT                        | DESCRIPTION   | ANALYSES PERFORMED  |
|-------------------------------|---|---|
| Receipt Cohort                | All non-third party Traditional 510(k)s received during FY2015–FY2017 (9392 submissions)        | <ul style="list-style-type: none"> <li>• First-cycle Refuse to Accept – Decline Decision (RTA1) rates</li> <li>• RTA cycles</li> <li>• Rates and timing of withdrawals</li> <li>• Review attributes by performance goal status</li> </ul>   |
| FY2015 MDUFA Audit Cohort     | Sample of 50 FY2015 submissions with SE/NSE decisions randomly selected from the Receipt Cohort | <ul style="list-style-type: none"> <li>• Adherence to Administrative File procedures</li> <li>• Missing elements in first-cycle Refuse to Accept – Approval Decision (RTAA) and RTA1 Checklists and second-cycle RTA1 Checklists</li> <li>• Frequency and timing of interactive communications</li> <li>• Adoption of SMART memo template for 510(k) review</li> <li>• Documentation of consult recommendations</li> <li>• Attributes of Additional Information (AI) letters</li> </ul> |
| FY2016 MDUFA Audit Cohort     | Sample of 50 FY2016 submissions with SE/NSE decisions randomly selected from the Receipt Cohort | <ul style="list-style-type: none"> <li>• Missing elements in first-cycle RTAA and RTA1 Checklists and second-cycle RTA1 Checklists</li> <li>• Adoption of SMART memo template for 510(k) review</li> </ul>  |
| FY2017 MDUFA Audit Cohort     | Sample of 50 FY2017 submissions with SE/NSE decisions randomly selected from the Receipt Cohort | <ul style="list-style-type: none"> <li>• Adherence to Administrative File procedures</li> <li>• Missing elements in first-cycle RTAA and RTA1 Checklists and second-cycle RTA1 Checklists</li> <li>• Frequency and timing of interactive communications</li> <li>• Adoption of SMART memo template for 510(k) review</li> <li>• Documentation of consult recommendations</li> <li>• Attributes of AI letters</li> </ul>   |
| FY2015 Withdrawn Audit Cohort | Sample of 25 FY2015 withdrawn submissions randomly selected from the Receipt Cohort             | <ul style="list-style-type: none"> <li>• Adherence to withdrawal-related procedures</li> <li>• Reasons for withdrawal</li> </ul>  |
| FY2017 Withdrawn Audit Cohort | Sample of 25 FY2017 withdrawn submissions randomly selected from the Receipt Cohort             | <ul style="list-style-type: none"> <li>• Adherence to withdrawal-related procedures</li> <li>• Reasons for withdrawal</li> </ul>  |



To ensure that all CDRH review divisions were represented, Booz Allen constructed each MDUFA Audit Cohort to mirror the proportion of submissions received by each division, in Characteristics of FY2015–FY2017 Receipt Cohort and MDUFA Audit Cohorts see Figure 5-1. Each MDUFA Cohort also demonstrated similar percentages of SE and NSE decisions, RTA review outcomes, and Substantive Interaction (SI) decisions as the Receipt Cohort (in Characteristics of FY2015–FY2017 Receipt Cohort and MDUFA Audit Cohorts see Table 5-2).

Booz Allen designed evaluation criteria for the Traditional 510(k) audits based on relevant CDRH processes and procedures reviewable by workflow logs in CTS, contents of the Administrative Files in DocMan, and submission records in Image2000+.

### QM Audit

To assess adherence to the protocols related to the QM systems processes and procedures, we performed audits of DCS, a crucial component of CDRH’s QM infrastructure. Through DCS, CDRH notifies staff of updates to procedural documents via transmittal notices. We performed an in-depth audit of the content and timing of transmittal notices to understand CDRH’s adherence to the document-related QM policies and procedures put in place by the Center. Based on the full population size of 518 transmittal notices from May 2015 to September 2018, we generated a random sample for each transmittal notice type. The random selection mirrors the distribution of the full population as demonstrated in Table 2-3.

**Table 2-3. Distribution of transmittal notices in audit of CDRH’s QM systems**

| TRANSMITTAL NOTICE TYPE  | TOTAL POPULATION | AUDIT SAMPLE |
|--------------------------|------------------|--------------|
| Major Document Revisions | 58               | 6            |
| Minor Document Revisions | 223              | 96           |
| Newly Created Documents  | 135              | 35           |
| Withdrawn Documents      | 82               | 13           |

### TRAINING DATA

Booz Allen acquired training completion and evaluation data, as well as sample training materials, from CDRH’s Division of Employee Training and Development (DETD), to perform quantitative and qualitative assessments of the impact of training initiatives on the programs listed in Table 2-4. Booz Allen reviewed newly created or enhanced training modules and related documents and also evaluated staff’s training completion to determine exposure to new protocols and procedures.

**Table 2-4. Descriptions of formal training programs**

| FORMAL TRAINING PROGRAM                               | DESCRIPTION   |
|---|---|
| Reviewer Certification Program (RCP)                  | Mandatory new reviewer training program, which provides core reviewer skills and competencies   |
| Leadership Enhancement and Development Program (LEAD) | Mandatory and continuous training program for all supervisors, which provides core leadership skills  |
| Experiential Learning Program (ELP)                   | Voluntary training program in which reviewers visit industry sites to gain first-hand experience of new processes, procedures, and technologies |
| Leadership Readiness Program (LRP)                    | Voluntary, competitive training program for staff interested in gaining the skill sets necessary to transition into a supervisory position      |

Booz Allen also acquired available Kirkpatrick Model data to understand training impact. The Kirkpatrick Model is a training evaluation framework consisting of four levels which assess the extent to which training programs are meeting previously defined performance goals:

- Level 1: Reaction—Measures participant reaction to and satisfaction with received training
- Level 2: Learning—Evaluates changes in participants’ attitudes, knowledge, and/or skills as a result of participating in the training program

- Level 3: Behavior—Assesses transfer of knowledge, skills, an/or attitudes after completing training, based on performance in the participants’ work environment
- Level 4: Results—Determines training results based on pre-identified program metrics

Booz Allen used Kirkpatrick Level data collected by CDRH to determine how the Center leveraged the available metrics to improve the formal training programs.

## INTERNAL/EXTERNAL COMMUNICATIONS

Booz Allen obtained records of FDA’s internal and external communications to evaluate specific activities from the implementation projects. FDA and CDRH management use internal platforms (e.g., email) to alert staff of upcoming IT enhancements and promote various initiatives such as informal training, and use external channels (e.g., guidance development, eCopy submission messages, or Federal Register notices) to provide sponsors with instructions regarding specific review sub-processes. When applicable, we reviewed the communications for content and timing.

## CASE STUDIES

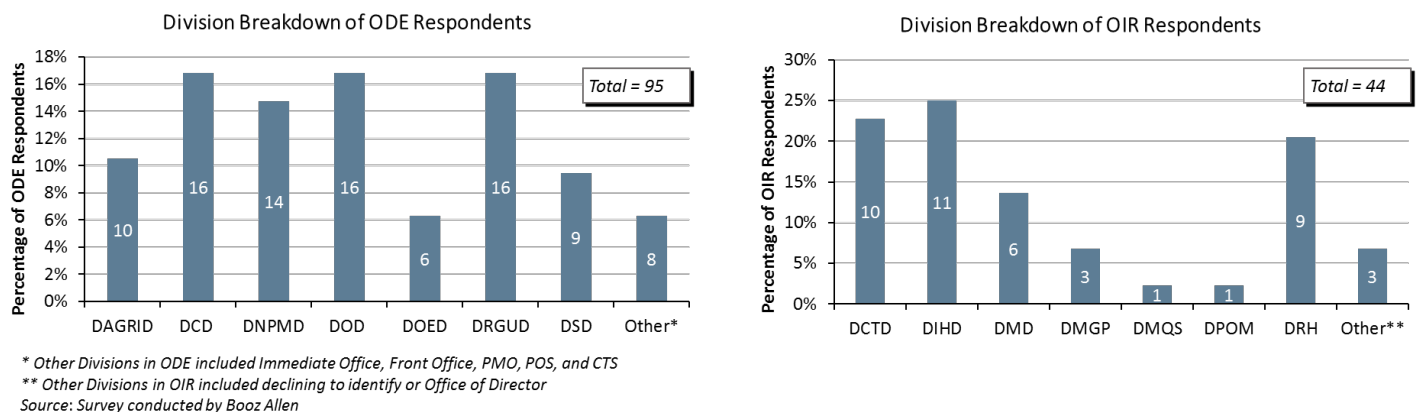
Booz Allen analyzed case studies to generate qualitative insights and gain a comprehensive perspective on the end-to-end lifecycle of selected processes. Upon request, CDRH provided case studies to highlight outcomes and demonstrate how CDRH’s recent modifications to their processes and procedures have impacted CDRH operations. Booz Allen supplemented case study findings with interviews to determine the broader applicability of themes and trends identified in the case studies.

## INTERVIEWS

Booz Allen generated targeted interview guides to collect feedback from a wide range of CDRH stakeholders, including Office and Division Directors, Branch Chiefs, and premarket Lead Reviewers. These interviews helped us to understand the impact of current initiatives and potential areas for improvement in CDRH’s implementation activities. These results informed the generation of survey questions.

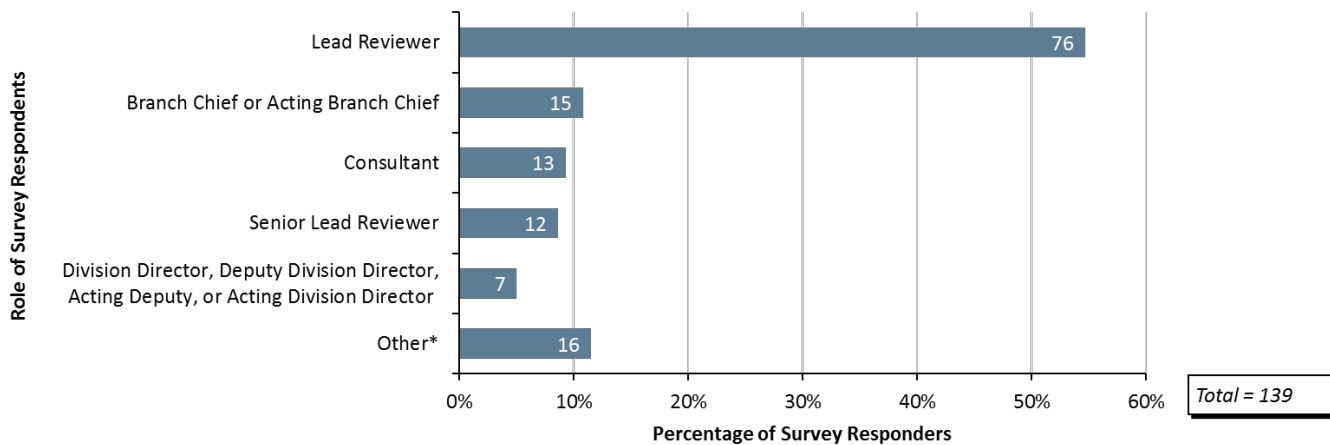
## SURVEYS

Booz Allen administered an online survey to Office of Device Evaluation (ODE) and Office of In Vitro Diagnostics and Radiological Health (OIR) review staff involved in premarket submission review from 2013 to 2017 to collect feedback on training programs and review process consistency. The majority of the survey questions gauged staff’s perspectives regarding CDRH’s current implementation activities, and a subset of questions probed for potential areas for improvement. A total of 139 respondents from ODE and OIR provided feedback through the survey. Figure 2-5 depicts the division breakdown of ODE and OIR respondents.



**Figure 2-5. Division breakdown of ODE and OIR respondents**

The majority of the survey responders were Lead Reviewers, as demonstrated by Figure 2-6.



\*Other Roles included Policy Analysts, Deputy Office Directors, Medical Officers, 510(k) Program Staff, and Regulatory Advisor  
Source: Survey conducted by Booz Allen

Figure 2-6. Role of survey respondents

Booz Allen also reviewed survey data provided by FDA, where applicable.

### 3. ASSESSMENT FINDINGS

Booz Allen evaluated initial results and outcomes for each recommendation and organized the assessment findings following the structure of the strategic framework, grouping the assessment of each program outcome. For each recommendation, we describe the recommendation and findings from the previous phases, followed by Stage 4 (where applicable) and 5 assessments, and conclusions.

#### 3.1 CDRH Operations

The implementation projects outlined under the Program Outcome of “Enhanced CDRH Operations, with a Quality Management Focus” aim to provide reviewers and CDRH staff with the tools and resources necessary to perform their work in an environment of continuous improvement.

#### RECOMMENDATION 1A\*: CONTINUOUS PROCESS IMPROVEMENT (CPI)

In Phase 1 of the MDUFA III Independent Assessment, Booz Allen found that, while ODE had a mechanism to resolve Corrective and Preventive Action (CAPA) issues that impacted multiple divisions, it had no formal and uniform mechanism to resolve division-specific issues (also referred to as non-CAPA issues). Additionally, CDRH did not have a method to formally document feedback cycles for non-CAPA issues from the Branch-level to the Center-level. These findings led to Recommendation 1a: Develop a more formal method for logging, prioritizing, tracking, communicating, and providing feedback on non-CAPA issues and improvement ideas.

#### PHASE 2 FINDINGS – INITIAL RESULTS

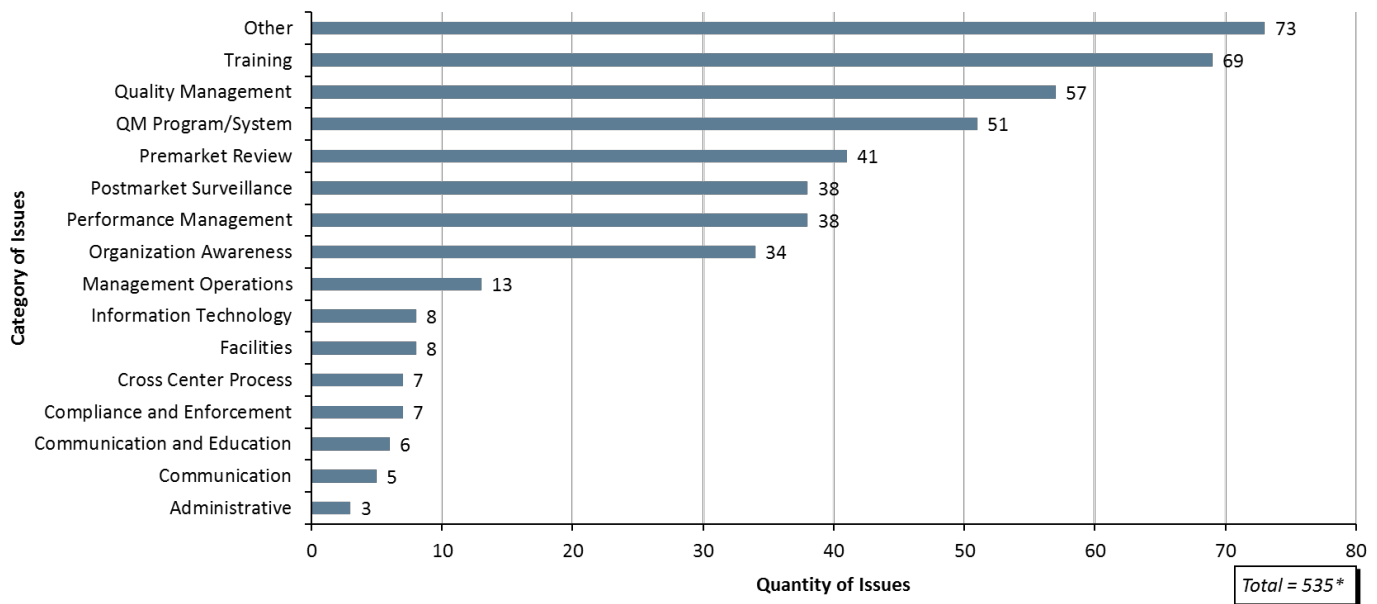
During Phase 2, Booz Allen found that CDRH developed and deployed a Center-wide system called FEEDBACK√CDRH to capture, prioritize, and address quality issues and feedback, including process improvement and management oversight processes. The FEEDBACK√CDRH Standard Operating Procedure (SOP) accompanied the implementation of the system; it described, and outlined new processes associated with, the system. CDRH also developed a *Management Review* SOP to establish how CDRH senior management should review and resolve issues to improve QM oversight and ensure CPI.

Based on this progress, by the end of Phase 2, Booz Allen was able to measure the initial results of the implemented mechanisms. From the implementation of FEEDBACK/CDRH in March 2015 to December of that year, 187 cases were reported and 44% of these cases were closed. The number of reported cases demonstrated that staff were utilizing the new system. The number of closed cases illustrated that CDRH completed the entire feedback process of collecting, triaging, addressing, and resolving issues, as outlined in both the FEEDBACK/CDRH SOP and the Management Review SOP.

## OUTCOMES

After receiving 187 cases before the Phase 2 analysis, FEEDBACK/CDRH received an additional 348 cases through April 2018, totaling 535 cases. The volume of cases submitted to FEEDBACK/CDRH indicates staff were aware of and utilized the system.

The nature and classification of these issues are outlined in Figure 3-1. The most frequent categories for issues submitted to FEEDBACK/CDRH were Training, QM, and the QM Program/System. The Other category also ranked highly and included suggestions about social events, human resources (e.g., diversity awareness), and topics related to CDRH activities that did not align with any other category.

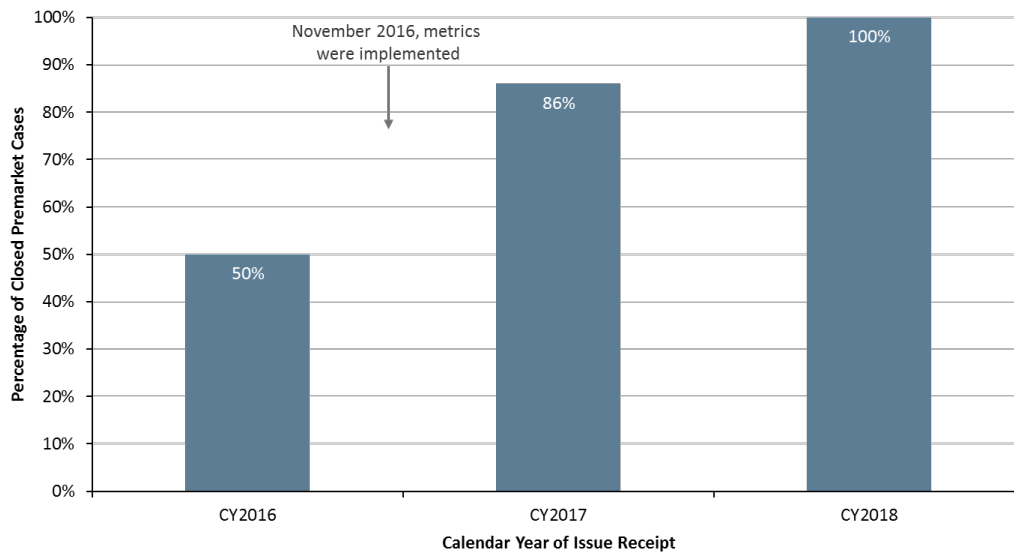


\*Excluding 77 issues considered out of scope for FEEDBACK/CDRH  
Source: FEEDBACK/CDRH

**Figure 3-1. Number of issues per issue category collected by FEEDBACK/CDRH (March 2015 to April 2018)**

The Center aims to address submitted issues and close them promptly. To facilitate continuous improvement of CDRH's management of FEEDBACK/CDRH, the Center implemented metrics in November 2016 to promote resolution of 80% of all cases (closed or closed with pending action) within 90 days of assignment to the corresponding Office. As of April 2018, CDRH resolved 86% of the 535 submitted issues and closed 1% with pending action. The remaining 13% of issues were still open and awaiting resolution. Creation of the new metrics increased the percentage of closed issues. Figure 3-2 illustrates the impact of the metrics on premarket review related issue resolution over the past three years.





Source: FEEDBACK/CDRH

**Figure 3-2. Percentage of closed premarket review issues from November 2016 to April 2018**

At the Center level, to keep management up-to-date with submitted issues and feedback, CDRH holds review meetings between Office directors and the CDRH Associate Director of Quality Management on a regular basis. At the Office level, QM Office Representatives work with subject matter experts and management to produce and execute a strategy to address selected issues. Office management reviews and prioritizes issues based on its direct impact to staff and on their ability to perform work.

Booz Allen analyzed two examples with different outcomes, illustrating CDRH management’s approach to reviewing, prioritizing, and resolving premarket issues. In one, a staff member submitted a suggestion to FEEDBACK/CDRH proposing the implementation of specific standardized topics to be included in pre-submission (Q-Submission) review. These standardized topics would enhance the structure and consistency when requesting and providing information to industry. Management reviewed and prioritized the issue as high due to its influence on the quality of Q-submissions. In response, management directly resolved the issue by incorporating the suggested questions and classifications into the Q-Submission Program Draft Guidance,<sup>8</sup> and included corresponding examples to address the core concerns of the staff member’s initial feedback.

The second example demonstrates that management sometimes resolves issues by redirecting them towards appropriate personnel within CDRH. In this case, a staff member suggested creating a program within the SMART memo template to promote consistent language during review. The suggested program would build out pre-defined statements and sentences via Boolean logic. Management reviewed the issue and transferred the case to the appropriate subcommittee responsible for the SMART memo templates, as this suggestion was under the purview of that subcommittee. Taken together, the two examples demonstrate that management follows a timely procedure to either resolve or appropriately redirect all issues depending on the case, its degree of impact on workload, and the allocation of resources.

The Center expanded upon the original recommendation and created other systems, including CDRH Docs, which is a part of the DCS, to further improve processes and procedures relating to quality management. DCS provides a document control process to promote version control, provide a central document repository, and ensure staff have access to the most up-to-date documents. According to interviewees, the addition of these systems significantly decreased discrepancies and increased effectiveness of the Center’s established processes and procedures. Interviews demonstrated that topics currently discussed at the management review meetings expand beyond FEEDBACK/CDRH and now include topics focused on all of the quality management systems. The Center has progressed beyond the establishment of FEEDBACK/CDRH and begun to stand up a comprehensive quality management program.

<sup>8</sup> [The Q-Submission Program Draft Guidance](#)

## CONCLUSIONS

The implementation of FEEDBACK/CDRH created a formal method for logging, prioritizing, tracking, communicating, and providing feedback on issues. FEEDBACK/CDRH is a very mature system utilized by both CDRH staff and senior leadership as initially intended. This system provides senior leadership with a central repository for case collection and enables CDRH to generate a systematic approach to resolving issues and improving QM. Since the development of FEEDBACK/CDRH, the Center has established other QM systems such as DCS. Current management review meetings focus on issues captured by the QM systems. The Center operates in a CPI environment, enhancing and growing the QM program beyond the initial recommendation for a method to monitor and track non-CAPA issues (FEEDBACK/CDRH).

## RECOMMENDATION 1B\*: DOCUMENT CONTROL ENHANCEMENTS

In the Phase I Independent Assessment, Booz Allen identified a lack of senior management oversight and a formalized process for improving document control and IT data systems, resulting in inconsistencies within document control elements that ultimately detracted from review performance. These findings led to Recommendation 1b: Deploy planned document control system enhancements using a quality-oriented focus to optimize the utility of system changes to all review staff.

## PHASE 2 FINDINGS

During Phase 2, Booz Allen found that CDRH took several steps to incorporate QM components into its management of document control and IT system enhancements. CDRH promoted a revised QM Program site that houses quality-related documents and SOPs. Additionally, CDRH completed an analysis of premarket administrative records to identify needed revisions to the Administrative File process and ensure that inconsistencies in submission document control were addressed. CDRH subsequently revised the Administrative File SOPs and Work Instructions (WI) to provide additional accuracy, clarity, and thoroughness. CDRH also incorporated Administrative File training into RCP (see Recommendations 6\* and 9\*: Enhancements of Formal Training) for new reviewer training.

CDRH analyzed the effectiveness of the IT system enhancement process, identified gaps in the process, and assessed whether the enhancement process maintained QM components. The Center tasked the Premarket IT Steering Committee (PITSC) to provide IT support and oversight of the IT enhancement process. CDRH also created the *CDRH IT System Requests SOP* and *CDRH IT Request WI* to outline how IT enhancement requests should be submitted, planned, analyzed, prioritized, and implemented for continuous improvement of CDRH IT systems. Together, these actions established mechanisms for improving the document control and system enhancement process.

## INITIAL RESULTS

To assess initial results of CDRH's document control system (DCS) enhancements, Booz Allen evaluated CDRH actions for implementing a QM process, including enhancing document control, improving the quality of Administrative Files, and ensuring a consistent IT enhancement process.

### *CDRH Docs and Document Control System*

To improve the document control process, CDRH implemented a Center-wide central repository for documents and SOPs using QM policies and processes to maintain version control and minimize discrepancies. The Center-wide repository comprises multiple parts: SWIFT (SOPs, Work Instructions, Forms, and Templates) Docs is the internal facing platform that house documents in their original form (archive); CDRH Docs is the external-facing platform that staff utilize to acquire documents and SOPs, DCR (Document Change Requests) is the external facing platform used to request document changes and Transmittal Notices is the external facing platform to announce document changes. Taken together they comprise CDRH DCS, the all-encompassing internal system used by authorized personnel to oversee and manage the document control process. To assess the use of CDRH Docs and DCS, Booz Allen determined the number of CDRH Docs page views and unique users at the initial stand-up of the system. Within the first month of the system's roll-out in May 2017, there were 16,483 page views and 1,986 unique visitors, indicating that staff began using the system immediately.

### Administrative File Procedural Documents

To clarify what constitutes an accurate and complete Administrative File for its staff, CDRH revised the Administrative File SOPs and WI, and the Administrative File training. Booz Allen reviewed training completion data and conducted management interviews to understand staff's awareness of these updated Administrative File procedural documents. Training data demonstrated that as of December 2017, 93% of CDRH staff from ODE, OIR, Office of Surveillance and Biometrics (OSB), and Office of Science and Engineering Laboratories (OSEL) completed the Administrative File training. Interviews with Branch Chiefs revealed that due to the incorporation of the Administrative File training into RCP in September 2015, new reviewers are more aware of the revised Administrative File procedural documents than seasoned reviewers resulting from the incorporation of the Administrative File training into RCP in September 2015. Previously, reviewers relied on more experienced reviewers for guidance. According to interviewees, with the implementation of CDRH Docs, it is now easier for reviewers to rely on a combination of resources including SOPs, WIs, and division-specific materials, in addition to insights gained from experienced reviewers. We found that although reviewers may not specifically reference the Administrative File procedural documents during their reviews, they are knowledgeable in the general concepts and adhere to principles outlined in the SOPs and WI. Overall, managers feel that their staff are aware of and able to access the resources they need to complete compliant Administrative Files during their review.

### CDRH's IT System Enhancement Processes

CDRH created the *CDRH IT System Requests SOP* to facilitate improvement of the IT systems used by reviewers. Booz Allen interviewed members of the PITSC to understand the current procedure for IT enhancements. PITSC is responsible for planning, prioritizing, and working with contractors to implement requested IT changes to premarket systems. Before 2013, PITSC predominantly consisted of IT subject matter experts and focused heavily on technical challenges related to system enhancements. Since 2013, PITSC focuses more on submission review business challenges and only addresses IT challenges once the committee has validated the business process requirements. As outlined in Figure 3-3, PITSC follows a three-step process to identify, assess and perform IT system enhancements.

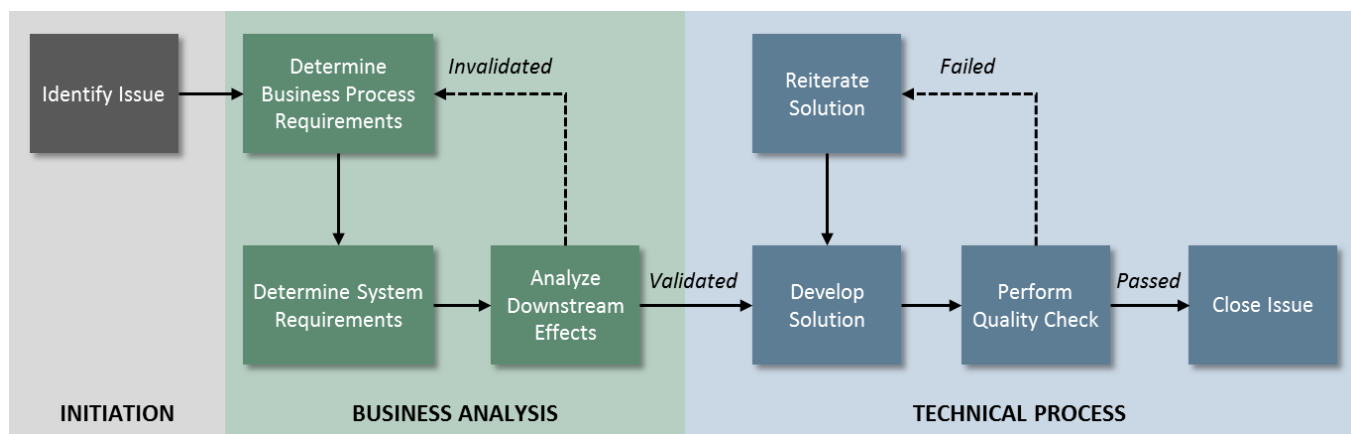


Figure 3-3. Booz Allen's high-level overview of the IT system enhancement process

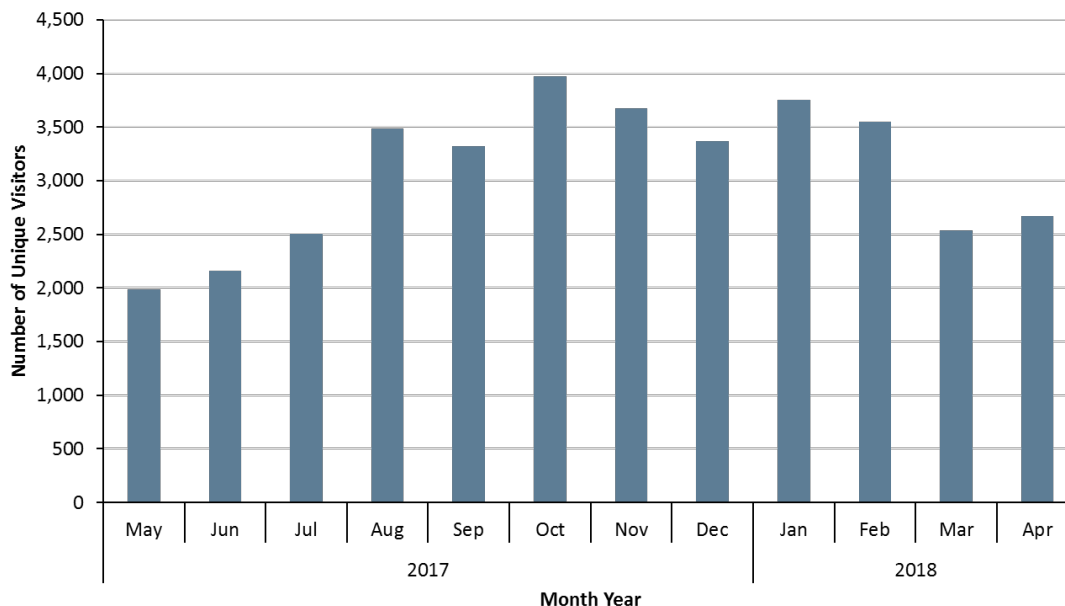
CDRH staff initiate the CDRH IT system enhancement process when they submit an IT change request for an identified issue or suggested improvement. This occurs through a number of platforms, including FEEDBACK/CDRH, the IT systems help desk, or direct communication with members of PITSC. PITSC holds regular meetings to evaluate how each proposed IT enhancement will affect business processes, if it is compatible with the Center's priorities, and how it impacts relevant staff, before deciding on whether to proceed with the requested IT enhancement. Selected IT enhancements are put into the Center's JIRA system and management leverage the system to plan, monitor, and track the workflow. Once a solution to an issue is developed or addressed, the solution undergoes User Acceptance Testing (UAT) to ensure that it fits the users' need and business process. During UAT, selected staff provide feedback on the IT enhancement through an internal document, which is monitored and reviewed. All input from UAT is collected and significant findings are discussed at the PITSC meetings. Post-deployment, there are Center-wide mechanisms (e.g., FEEDBACK/CDRH) for staff to submit suggestions to encourage CPI. Staff actively participate in the IT system enhancement process in a number of ways, including issue identification, UAT, and providing closed-issue feedback. CDRH has several deployments every year, illustrating ongoing use of the current process.

## OUTCOMES

Booz Allen evaluated the use of CDRH QM resources to assess outcomes related to CDRH’s DCS enhancements and adherence to updated procedures and guidelines associated with document control and IT system enhancements.

### *CDRH Docs and Document Control System*

To assess the effectiveness of CDRH Docs and DCS, Booz Allen analyzed use of the system by CDRH staff. From the initial launch in May 2017 to April 2018, Offices including ODE, OIR, and Office of Compliance (OC) published 1,218 documents to CDRH Docs. Use data based on unique visitors to the DCS, as illustrated in Figure 3-4, shows increased uptake from staff shortly after site launch and continued use over time. The most commonly visited sites, which accounted for 37% of all site pages accessed from May 2017 to April 2018, included the CDRH Docs homepage, the Correspondence Generator template, and the CDRH QM homepage. In addition, there were 42,795 referrals to the DCS through various CDRH groups’ SharePoint sites. The Investigational Device Exemption (IDE), 510(k), and Premarket Approval (PMA) groups were the top three referrers.



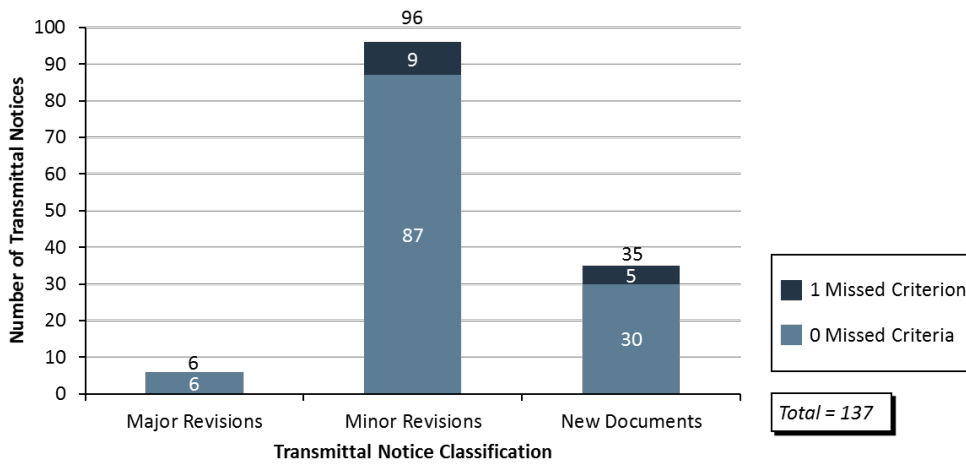
Source: CDRH Document Control System

**Figure 3-4. Number of unique visitors to CDRH DCS from May 2017 to April 2018**

The processes to create, revise, or withdraw documents and SOPs in the DCS are outlined in the *Document Control System (DCS) SOP*. To ensure that QM practices are being followed during the document control process, Booz Allen assessed staff adherence to the transmittal notices protocol outlined in the *DCS SOP* since this aspect impacts the end-user. Transmittal notices is the platform maintained by CDRH QM to notify staff of changes made to documents and SOPs, which can potentially impact their daily responsibilities and ultimately affect CDRH’s operations.

For transmittal notices related to major revisions, minor revisions, and new documents, Booz Allen looked for proper recording of a document number, version number, effective date, description of changes, and hyperlink to the document. We also determined whether the transmittal notice went out before or on the effective date. For transmittal notices notifying the withdrawal of documents, we only evaluated the presence of the document number, withdrawal date, and a compliant transmittal notice announcement date, as these are the only criteria required for withdrawal notices. The audit showed compliance for 100% of audited transmittal notices consisting of major changes, 91% of the transmittal notices with minor changes, and 86% of transmittal notices for new documents, as demonstrated in Figure 3-5.





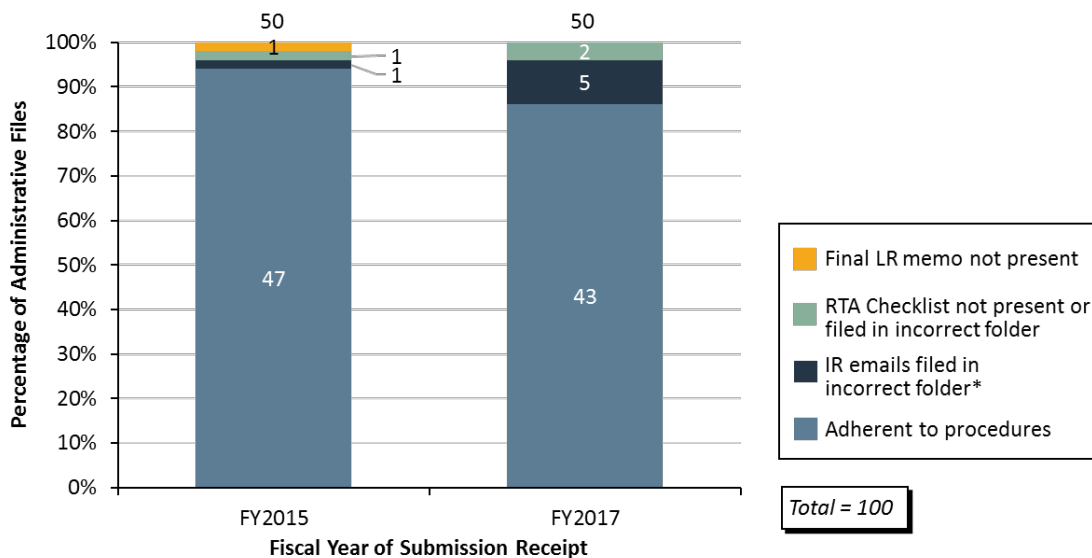
Source: CDRH Document Control System

Figure 3-5. Summary results of the audit of SOP criteria in major, minor, and new transmittal notices

Booz Allen found all 13 transmittal notices related to the withdrawal of SOPs and documents contained a document number and withdrawn date. Similar to the other transmittal notice categories, three withdrawal-related non-compliant notices did not have a valid transmittal notice date, meaning that the date of the withdrawal announcement was after the date of withdrawal. These data demonstrate that management is generally adhering to the criteria outlined in the DCS SOP and effectively communicating document changes to staff, thereby ensuring a successful QM program.

*Administrative File Procedural Documents*

Booz Allen evaluated the effectiveness of the revised Administrative File procedural documents and related training by assessing the quality of sample Administrative Files. We reviewed data provided by CDRH on their internal quality assessment of Administrative Files and also performed an independent audit using a similar approach. We conducted an audit of Administrative Files in the FY2015 and FY2017 MDUFA Audit Cohorts to determine file quality in relation to changes to the Administrative File procedural documents and related training. Booz Allen assessed each submission for the presence and correct location of the following required documents: Lead Reviewer (LR) memo, RTA checklist, official decision communications, and applicable Interactive Review (IR) emails. The results, illustrated in Figure 3-6, show that there was a high level of adherence to the Administrative File procedures in both FY2015 and FY2017. The slight decrease in adherence to procedures from FY2015 to FY2017 was due to incorrect placement of IR emails. Overall, the majority of 510(k) Administrative Files were compliant before and after the procedural document revisions, suggesting that the procedural documents formalized already-existing practices.



\*In all cases, IR emails were documented elsewhere in the Administrative File  
 Source: Booz Allen Traditional 510(k) audit

Figure 3-6. Results of Booz Allen’s 510(k) audit for adherence to Administrative File procedures by fiscal year

When assessing the presence of the documentation outlined above, CDRH saw similar results in their audit of 20 randomized 510(k) submissions from Calendar Year (CY) 2013 and 20 submissions from 2016 and 2017. CDRH found that 90% of the 510(k) submissions from CY2016 and CY2017 had compliant Administrative Files. CDRH found that in 2013, when DocMan was initially deployed, only 50% of the 510(k) submissions were compliant with the protocols outlined in the Administrative File documents. CDRH's audit demonstrated that Administrative Files for recent submissions are of higher quality than when staff initially began using DocMan.

Booz Allen conducted interviews with Branch Chiefs to gain insights on the effectiveness of the Administrative File procedural documents and related training. Branch Chiefs believe a reviewer's workload may impact the quality of the Administrative Files. In addition, Branch Chiefs shared that the quality of the Administrative File memos is impacted by the reviewers' technical writing skills and their judgment on the appropriate level of details to include. The creation of more device- and division-specific templates could help to produce more consistent outcomes. Branch Chiefs also suggested that increased automations of processes (e.g., automatically copying the DocMan email address on communications) and better search functionalities within CDRH IT systems could help staff maximize time efficiency and allocate more efforts toward content generation.

### *IT Enhancements*

To determine the impact of the revised *CDRH IT System Requests SOP* on the IT system enhancement process, Booz Allen analyzed case studies and deployment-related trainings and communications. First, we evaluated the effectiveness of the SOP procedures for issue submission and resolution by analyzing CDRH's approach to managing the technical considerations from the framework outlined in Figure 3-3. Then, we reviewed and analyzed sample roll-out plans, consisting of communication and training activities, for adherence to the *CDRH IT System Requests SOP*.

CDRH provided two case studies to represent the end-to-end IT enhancement process, from issue identification to issue resolution. Both cases demonstrated how PITSC identifies, prioritizes, and addresses issues within CDRH's review-related IT systems. In one case, after becoming aware of the issue from a Division Director, PITSC ensured that CTS, the workflow management system, only generated automated emails at the correct review milestone. For the second, PITSC resolved inconsistencies in the concurrence process in CTS after confirming the requirements of the De Novo concurrence process. Once issues were identified, PITSC prioritized them based on downstream impact and volume of affected submissions/personnel. Significant issues that impacted all or multiple submission types were prioritized at the highest level, whereas less significant issues that only impacted one submission type, impacted a smaller user group, or had little impact to the review process were prioritized lower. Ultimately, the technical staff developed solutions in lower development environments, performed UAT to ensure the solution fit the needs of review staff, and deployed the enhancement to the Production environment. In both cases, Booz Allen found that PITSC utilized the mechanisms outlined in the *CDRH IT System Requests SOP* to implement requested IT changes, demonstrating an effective enhancement process from the initial issue identification to issue resolution.

For each deployment, PITSC develops a roll-out plan which includes a communication plan and a determination of training requirements. These plans ensure that affected personnel are aware of and trained on the upcoming IT changes. PITSC makes training determinations based on the impact each deployment will have on the users. Any enhancement that has no impact to the user or the user's actions in the system will not require training, whereas any enhancement that adjusts or changes the user business process or visualization in the system will require training to ensure the user is comfortable with the changes and can continue to perform their review work in the system.

Booz Allen analyzed 18 CDRH system deployments, from June 2015 to November 2017, to determine adherence to the procedure for roll-out plan generation. Each deployment encompassed enhancements to multiple premarket review systems (e.g., CTS, Image2000+, and DocMan). We found that CDRH communicated all deployments with staff via email before implementation of system changes impacting user experience. For all releases, the level of communication was tailored to the impact of the release. Major releases, which require training and have larger impact to reviewers, were communicated a few weeks ahead of the deployment to ensure staff take the associated training. For minor releases with no required training and little impact, communications generally occurred within the week leading up to the release. We found that CDRH provided training for all IT enhancements that resulted in a user-facing SOP, WI, or reference update. The Center provided multiple training sessions for higher impact changes, such as PMA migrations and changes related to MDUFA IV. Our analysis of the deployments and associated roll-out plans demonstrates that

CDRH follows a consistent approach to ensure staff awareness of enhancements and to avoid interruptions to the premarket review process.

## CONCLUSIONS

CDRH initiatives improved the document control and IT system enhancement processes. The Center implemented DCS to formalize a document control process and increase QM oversight. System data demonstrate that staff are aware of and use these systems. In addition, audit data show that staff working on the QM systems generally adhere to the guidelines outlined in the *DCS SOP*, demonstrating a robust document control process. The Administrative File audit confirms that staff are generally compliant with procedures for compiling the Administrative File. Finally, CDRH has implemented a mechanism to consider both business and technical aspects when IT enhancements are necessary. As outlined in the *CDRH IT Systems Request SOP*, management has communication and assessment roll-out plans to notify staff of the IT changes and determine if follow-up IT support is required through trainings.

While CDRH management has put in place the systems and mechanisms needed to improve QM and enhance the document control and IT system enhancement processes, interviewees identified several opportunities for improvement. Suggestions included: increased automation within DocMan to help reviewers use their time more efficiently, and enhanced search functionalities within CDRH Docs to help staff more seamlessly locate documents and SOPs to help support their daily workload activities. Creating central repositories, a formalized document control process, and an IT enhancement process were crucial steps toward building an effective QM program; however, the program is still relatively early in its development stages. With the ongoing implementation of the quality management program, opportunities remain for increased management oversight and technological enhancements to better support staff needs. While the future landscape may change due to CDRH's Office of Product Evaluation and Quality (OPEQ) pilot to align premarket and postmarket review, it will be important to adopt current best practices into CDRH's operations and continue maturing the QM program.

## RECOMMENDATION 8: WORKLOAD MANAGEMENT TOOL REVIEW

In Phase 1 of the Independent Assessment, Booz Allen found that managers lacked a resource to provide a comprehensive view of staff workload. Managers created their own approaches and utilized a combination of resources, including CTS and CARS, to obtain the necessary information for workload assignment. These findings led to Recommendation 8: Evaluate tools for providing a comprehensive view of staff workload.

## PHASE 2 FINDINGS

During the Phase 2 Independent Assessment, we found that, in response to the Phase 1 recommendation, CDRH collected information on the use of existing workload tools and staff needs. CDRH used this data to create an IT Requirements document to support the development of a prototype of a new workload reporting tool. The Center also implemented the *Best Practices for Workload Management* guide in November 2015 to further standardize the process of workload assignment.

## INITIAL RESULTS

After CDRH collected feedback from focus groups regarding use of the prototype, the Center further refined the requirements and functionality of the tool. After finalizing the IT requirements—and consequently, the prototype—CDRH deployed the initial production version of the workload tool to accompany the previously implemented *Best Practices* guide.

## OUTCOMES

To assess the outcomes and impact of CDRH's actions, Booz Allen evaluated the implementation of the workload management tool and staff's adherence to the principles outlined in the best practices guide for workload management. Although the tool does not collect data on usage, CDRH estimates that approximately half of the branches across ODE, OIR, and OC use the workload tool on a monthly basis. Beyond initial roll-out, CDRH also enhanced the workload management tool based on user feedback. An example is improvement to the workload tool's visualizations. Early

versions of the workload tool organized submission due dates into a visualization that was similar to a Gantt chart. Managers provided feedback that they were transferring the information from the tool into their calendars to provide them with a traditional calendar visual output. In response, CDRH enhanced the workload tool to change the visualization of submission due dates from a Gantt-like chart to a calendar display. Another example of the user-driven enhancement process is adding features to provide historical context of reviewer performance. As a result of this enhancement, managers spend less time establishing a baseline workload for each reviewer.

Similar to the workload report tool, the *Best Practices* guide is a resource to help Branch Chiefs assign workload to staff. The *Best Practices* guide outlines factors to consider when assigning workload to staff such as the type of device, the nature of the submission, and the expertise of the reviewer. Booz Allen evaluated manager adherence to the *Best Practices* guide when assigning workload. Interviews with Branch Chiefs from ODE and OIR confirmed that staff adhere to the principles presented in the guide. Any differences in how workload is assigned are due to the unique considerations of each Branch. A common theme throughout the interviews was that while Branch Chiefs assign submissions as outlined in the guide, they also take into consideration other factors, such as providing learning opportunities to team members. Finally, Branch Chiefs rely on staff feedback to validate whether workload is being properly assigned.

Staff interviews also revealed possible improvements to aid Branch Chiefs in assigning workload for their staff. Specifically, interviewees noted that they would like better information regarding each submission's level of effort. For example, the tool and related Office workload estimates do not take into consideration the variable level of effort required for a submission that has been bundled or includes clinical data. Branch Chiefs believe this would enable them to assign workload better and use their time more efficiently.

## CONCLUSIONS

CDRH's actions exceeded those originally outlined in the recommendation. Not only did the Center evaluate possible options for providing a comprehensive view of workload to staff, CDRH also developed and put into practice various resources to help managers assign and manage workload. The implementation and enhancements of the workload report give managers a tool to more comprehensively view staff workload and make assignments. To optimize this process, staff would like to see better accounting of the level of effort required for individual submissions. This would enable effective resource allocation and ensure that staff have the necessary bandwidth to conduct submission reviews. As outlined by the MDUFA IV Commitment Letter, CDRH will implement complete time reporting by the end of FY2022, which should provide the more detailed view of staff workload to help address this concern.<sup>9</sup> Additionally, if managers have the necessary tools and information to more efficiently assign workload, they will have more time to dedicate to review related tasks.

Modifications to the workload management tool will be necessary if/when CDRH reorganizes to create OPEQ and when enhanced time reporting, mandated by MDUFA IV, will be implemented. CDRH can leverage the lessons learned from the development process of the current tool and *Best Practices* guide moving forward to further enhance the workload management process.

## RECOMMENDATION 11: STAFF TURNOVER AND TRANSITION PLANS

In Phase 1 of the Independent Assessment, Booz Allen found that while there were some informal practices at the division level, there were no formal mechanisms for transitions and successions at either the Center or Office levels. Since seamless transitions and successions are vital to minimize disruptions to workload and related processes, these findings led to Recommendation 11: Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews.

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<sup>9</sup> MDUFA IV Commitment Letter (August 2016)

## PHASE 2 FINDINGS

In response to Booz Allen's recommendation, the Center reviewed existing transition and succession planning activities and related resources to understand current processes and identify areas for improvement. The Center documented these processes through the creation of the *Transition Planning SOP* and the revision of the *Succession Planning SOP*. In addition, CDRH created the *Transition Planning Template* and the *Succession Planning Template* to be used to facilitate adherence to best practices related to transitions and successions.

## INITIAL RESULTS

To assess initial results of CDRH's implementation activities, Booz Allen evaluated staff awareness of transition and succession planning processes by performing interviews with different levels of CDRH management, from Office Directors to Branch Chiefs. The interviews demonstrated that managers utilize the *Transition Planning SOP*, *Succession Planning SOP*, *Transition Planning Template*, and the *Succession Planning Template* when preparing for and responding to transitions and successions within the Center. They also address and incorporate nuances that are specific to their branch or division, to minimize the impact on remaining staff.

## OUTCOMES

First, Booz Allen evaluated the use and effectiveness of the transition planning process to assess the impact of CDRH's changes. The *Transition Planning Template* comprises four sections, including the departing employee's information, responsibilities/duties, workload/assignments, and committee and working group participation. The different sections are designed to capture and guarantee continuity of in-progress submission review work, despite the change in personnel. In the examples provided, all sections were filled out (when applicable) with sufficient details for the next staff member to understand the work required to complete the submission review. The case studies demonstrate that when approaching an upcoming transition, managers utilize the *Transition Planning SOP* and the *Transition Planning Template* to efficiently transfer workload from the exiting team member to remaining team members, ensuring minimal impact on in-progress submission reviews.

Second, Booz Allen evaluated the use and effectiveness of the succession planning process to assess the impact of CDRH's changes. Within CDRH, succession planning is an ongoing, annual process performed at the Office level to ensure CDRH continues to staff, enrich, and retain required leadership and expertise. The *Succession Planning SOP* and *Succession Planning Template* are used together in a four-step process. In Part 1, managers use strategic directions and priorities to understand the future leadership needs of the Center. Determining leadership needs encompasses assessing CDRH's mission, vision, and Strategic Priorities; determining the current workforce profile; and performing environmental scans for any additional factors. In Part 2, managers use the *CDRH Succession Planning Template* to identify succession targets and assess bench strength. The template documents 11 different key characteristics, including organizational component, duties and responsibilities, and anticipated timeframe for replacement. Once these characteristics are identified, Office leadership assesses the bench strength, or readiness of current employees to fill the target position. This identifies the talent pools, which leadership measures against the succession targets to determine if there is "low bench strength" or "high bench strength," based on the readiness of staff to immediately fill a target position. The bench strength for staff is also recorded in the *CDRH Succession Planning Template*. In Part 3, Offices develop and implement succession management strategies, which ensure qualified successors are prepared and in place to fill each position. This part of the process encompasses strategies for recruitment, retention, and development of current staff. Finally, in Part 4, management monitors the implemented strategies to ensure that they are adequately addressing all of the outlined requirements. This process demonstrates CDRH's efforts to plan for short- and long-term continuity of leadership, expertise, and knowledge throughout the Center.

While the *Succession Planning SOP* and the *Succession Planning Template* are useful references, CDRH also relies on a number of programs to prepare for successions. Through the detail program, staff are temporarily assigned to a certain position or statement of duties. CDRH's use of detail assignments is one of the on-the-job training strategies that prepare staff with the necessary knowledge and skills to succeed in a different role when the opportunity arises. Details help individuals gain full or part-time experience in a new position for a designated period of time. Not only does this enable staff to bring that experience and understanding back to their original team once the detail has been completed,



but it also creates a workforce that can succeed in various roles throughout CDRH and FDA. For example, when a management position became vacant, Office leadership was able to fill the position with a staff member that had previously detailed in the position and had firsthand experience and exposure to the management team. Another strategy to provide hands-on experience to staff is CDRH's LRP (see Recommendations 6\* and 9\*: Enhancements of Formal Training) which is a one-year learning opportunity for employees considering a supervisory career path. The program immerses the participants into a multiple component learning environment including classroom training, projects, and a mentorship to help them develop hands-on knowledge and the skill sets critical for a leadership position.

## CONCLUSIONS

CDRH has several methods and programs for supporting transition and succession planning processes. For transitions, staff adhere to the *Transition Planning SOP* and use the *Transition Planning Template* as a guide to ensure continuity and minimize the impact to review work. Current resources are beneficial to staff supporting transitions and successions and work to minimize the impact of these events when they occur. For successions, management uses the *Succession Planning SOP* and the *Succession Planning Template* annually to determine current staff readiness for possible staff successions. In addition, CDRH leadership promote and utilize these initiatives and programs to support professional growth of managers and review staff. These initiatives ensure managers and review staff are prepared for potential future opportunities.

Beyond the work done to address this recommendation, CDRH is also currently implementing several initiatives aimed at retaining CDRH staff by improving employee satisfaction and culture, providing an environment where staff can expand their professional development, ensuring staff succeed when moving to a new role, and providing CDRH leadership with information on the skills required to best fill vacant roles. CDRH's OPEQ pilot will facilitate more employee professional development opportunities by changing the structure of medical device review to an end-to-end total product review, thereby developing a more integrated, holistic review process. This will enable staff to develop knowledge and expertise in review areas beyond their current exposure. The pilot will also provide additional roles, such as the Associate Director for Professional Development, which will be responsible for coordinating activities related to hiring, mentoring, coaching, and training division staff to optimize their professional development and performance.

In addition, CDRH has identified "Employee Engagement, Opportunity, and Success," as a 2018–2020 Strategic Priority, aiming to make CDRH a place where staff feel they are provided growth opportunities, and the culture is one of open communication. The Center has introduced CDRH Engage, which is comprised of a two-year cross-Center working group that provides recommendations for improving employee engagement and manager-employee interactions. These efforts intend to help prevent transitions and reduce the impact of successions.

The Center also focuses on recruitment by working to develop competency models to aid in filling CDRH's Mission-Critical Occupations. Management interviews demonstrated that it often takes extended periods of time to fill positions with external candidates. CDRH has implemented recruitment and engagement strategies aimed at mitigating issues encountered in the recruitment of external candidates, including contracting with headhunters and attending job fairs to target highly qualified candidates.

These initiatives and programs ensure that staff are being provided the opportunities to grow into and succeed at their positions. In the case that a management position becomes vacant, CDRH's efforts aim to equip candidates, through strategies such as the LRP and detail assignments, with the necessary skills to seamlessly succeed in the new roles and responsibilities, ultimately reducing the impact of staff changes on CDRH's operations.

## 3.2 CDRH Staff Training

The implementation projects outlined under the Program Outcome of "Increase CDRH Staff Knowledge to Perform Submission Reviews" aim to provide CDRH staff, through formal and informal training events, the knowledge and skills necessary to successfully perform medical device submission reviews.

## RECOMMENDATIONS 6\* AND 9\*: ENHANCEMENTS OF FORMAL TRAINING

In Phase 1 of the Independent Assessment, Booz Allen found that after MDUFA III IT infrastructure and system upgrades, staff had varied levels of awareness and retention of IT knowledge from the educational resources, such as optional training and independent reviews of IT training documents. Data obtained from focus groups, interviews, and surveys indicated the need for consistent training of review staff on the three primary IT systems (CTS, DocMan, and Image2000+). More broadly, we found that FDA had gaps in the ability to determine staff needs, objectively evaluate improvements in knowledge, and understand the extent to which participants' behaviors changed as a result of training. These findings led to Recommendation 6: Provide mandatory training for the three primary IT systems that support MDUFA III reviews and Recommendation 9: Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes.

### PHASE 2 FINDINGS – INITIAL RESULTS

During Phase 2 of the Independent Assessment, Booz Allen tracked CDRH's implementation progress and was able to evaluate initial results for these two recommendations. CDRH determined the training evaluation requirements for all formal training programs, including RCP, ELP, LRP, and LEAD. The Center developed an approach for designing and evaluating Kirkpatrick Levels 1–4 metrics, including a survey tool for collecting Level 1 metrics and capturing Level 2 questions for pre- and post-tests. CDRH intended to collect Level 4 metrics 6–9 months after the completion of training. To assess initial results from CDRH's incorporation of metrics, we reviewed the data on Level 1 and Level 2 metrics collected from the RCP training cohorts. Through December 9, 2015, DETD collected Level 1 and 2 data for 12 cohorts consisting of 329 trainees who completed RCP training. Booz Allen found that CDRH was effectively using the new training metrics tools.

In response to the IT training recommendation, CDRH identified gaps and best practices from preexisting IT training materials to develop new training modules. The Center identified existing staff requiring training, incorporated enhanced IT training into RCP curriculum, and tracked participation rates. Since the incorporation of the IT Systems Training into RCP curriculum, CDRH began collecting Level 1 and 2 metrics in January 2015. Booz Allen found that the Center also established, and staff utilized the Cadre of Experts for assistance in the use of CDRH's IT systems.

### OUTCOMES

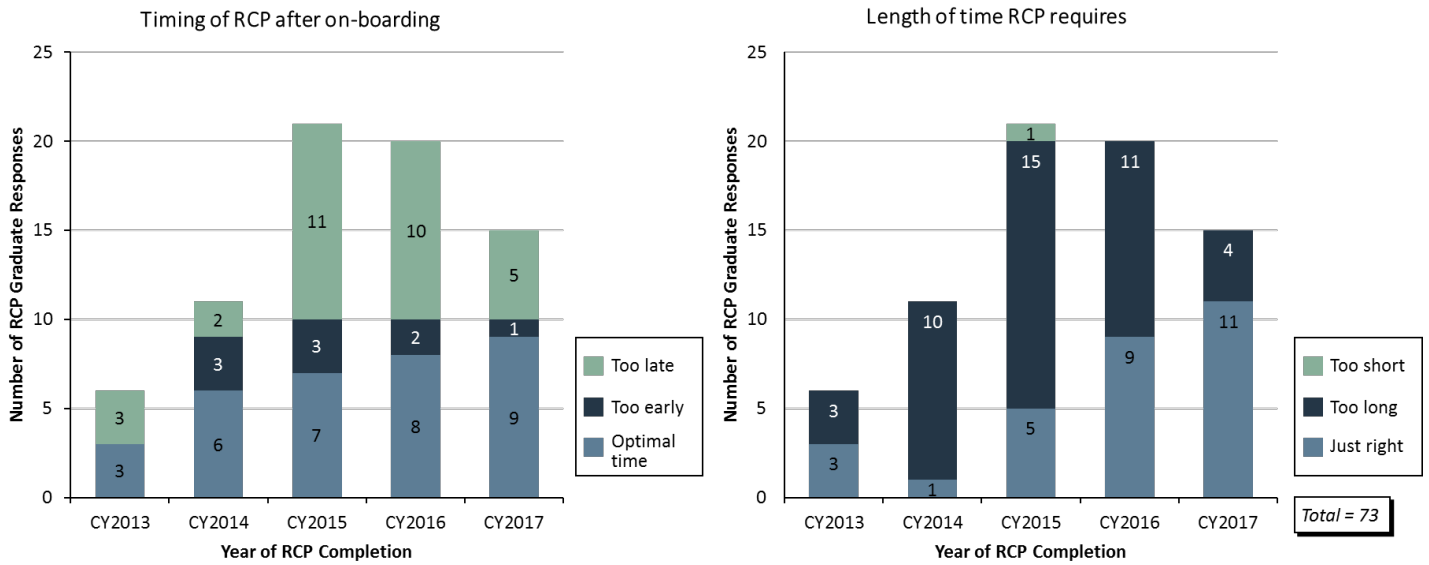
To assess the effectiveness of CDRH's metric implementation efforts on RCP, ELP, LRP, and LEAD formal training programs, Booz Allen analyzed available Kirkpatrick Levels data, evaluated a case study to assess management's response to the data and training feedback, conducted management interviews on improved formal training, and surveyed staff on the impact training has had on the review experience.

#### *Reviewer Certification Program*

Booz Allen reviewed all available Kirkpatrick Levels data and confirmed that CDRH continued to collect Level 1 and 2 metrics after January 2015. Example Kirkpatrick Level 1 data indicated that 97% (or 38 staff) who attended RCP's Basics of Four-Part Harmony in Lead and Consult Reviews course from June to December of 2016 understood the course learning objectives. Kirkpatrick Level 2 data showed that RCP's Fall of 2016 cohort, which trained 53 staff, improved on average by 36.2% from the pre- and post-tests, indicating a transfer of knowledge. DETD collected Level 3 metrics from the 2016 RCP cohort 6–12 months post-completion of the program to assess staff behavior changes resulting from knowledge gained during training courses. The metrics were obtained through in-person briefings with the participants' supervisors and online through informal discussions and surveys. Management also conducted an informal discussion at the Town Hall meeting with RCP graduates to gain insight to improve the program further. CDRH is first targeting RCP Least Burdensome training content to evaluate Level 4 metrics related to performance results. CDRH intends to utilize the Least Burdensome training Level 1 survey data, Level 2 pre- and post-test scores, and Level 3 qualitative discussions and feedback as a baseline for their Level 4 evaluation. Afterward, CDRH aims to implement Level 4 metrics for the entire RCP curriculum. The full Kirkpatrick Model is also being implemented for the other formal training programs

including ELP, LRP and LEAD. Based on the MDUFA IV Commitment Letter, CDRH will achieve implementation of the Level 4 evaluation for the RCP by FY2020.<sup>10</sup>

To assess CDRH use of Kirkpatrick metrics for program improvement, Booz Allen reviewed a case study provided by the Center. To address staff’s concerns regarding training content, timing of training delivery, length of the RCP program, and the inclusion of practical applications, management initiated a “Refresh” of RCP in 2016 by modifying the curriculum from 130+ hours taken over a 10-month period to 26 hours taken over two months. CDRH also changed the curriculum’s content to better accommodate the staff’s needs and concerns. Booz Allen conducted a survey to determine staff views regarding the formal training programs. We organized the responses by the RCP year of completion to understand how attitudes toward the program evolved over the last five years. As illustrated in Figure 3-7, survey responses indicate that the length of time required for RCP and the timing of administering RCP improved, but interviews demonstrate that there is still the opportunity for improvement on the timing of administering RCP after on-boarding.



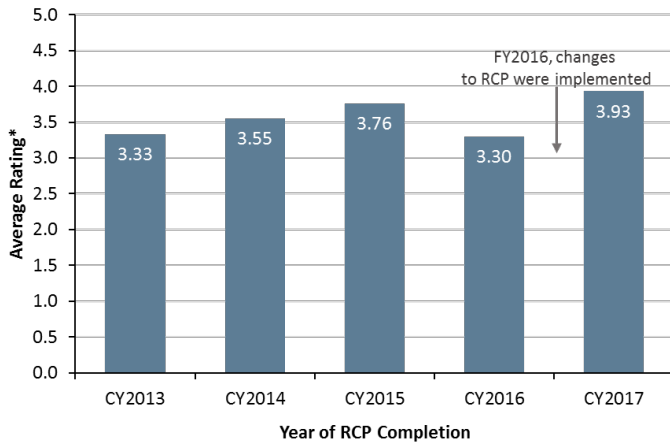
Source: Survey conducted by Booz Allen

**Figure 3-7. Staff survey responses on timing and length of RCP**

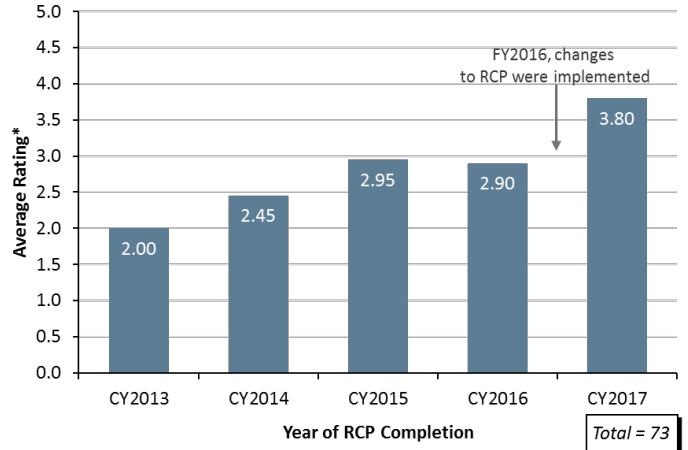
After the “Refresh” in 2016, survey responses from staff demonstrate that content of RCP improved, as shown in Figure 3-8. After the curriculum’s modifications in 2016, staff felt more confident in RCP’s ability to provide the basic foundations and training to become a successful 510(k) reviewer.

<sup>10</sup> MDUFA IV Commitment Letter (August 2016)

RCP provided the basic foundations (including an understanding of MDUFA goals, how to write a deficiency, etc.) necessary for me to become a successful 510(k) reviewer



RCP provided appropriate training on the 510(k) specific elements (including SMART template for 510(k)s, Interactive Review principles, and RTA processes) necessary for me to become a successful 510(k) reviewer



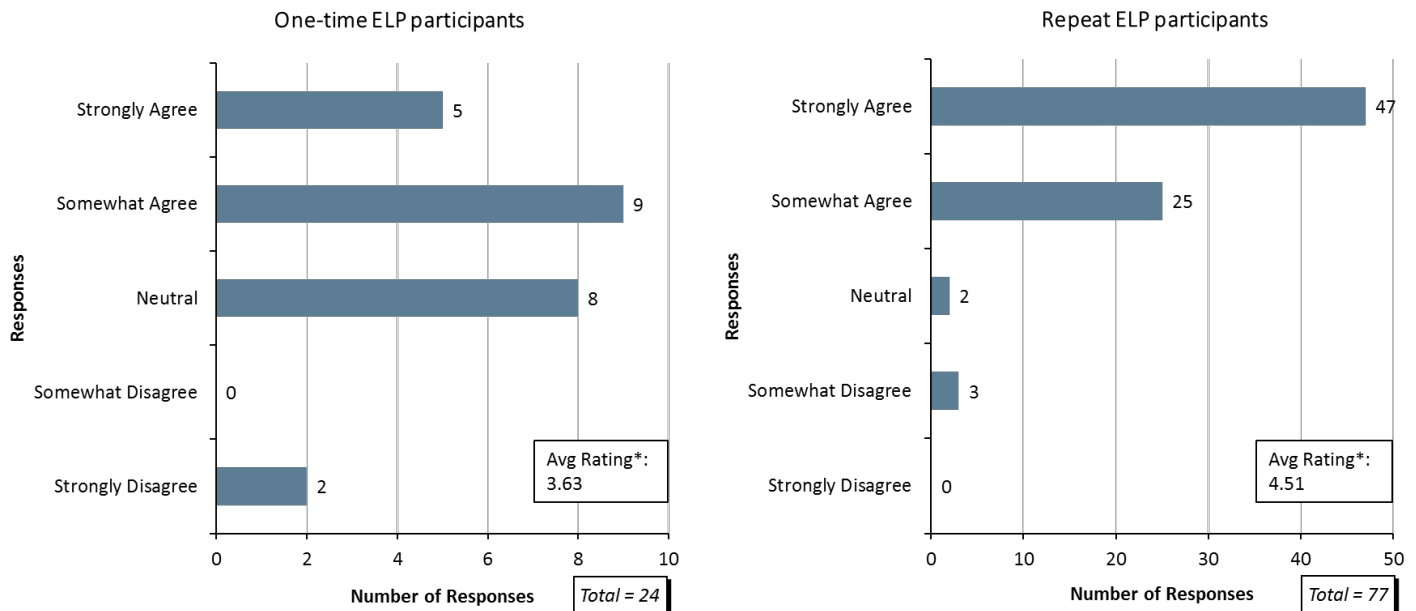
\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
Source: Survey conducted by Booz Allen

**Figure 3-8. Staff survey responses on RCP’s training content**

Interviewed Branch Chiefs shared that further opportunities to condense training remain. In addition, Branch Chiefs strongly expressed that while it may be more difficult to implement division-specific or device-specific content, such a focus could provide greater benefits from the training. Interviewees stressed that while RCP equips staff with the tools and foundational knowledge necessary to be able to conduct submission reviews, hands-on training provides the insights and experiences vital to becoming a successful reviewer.

*Experiential Learning Program*

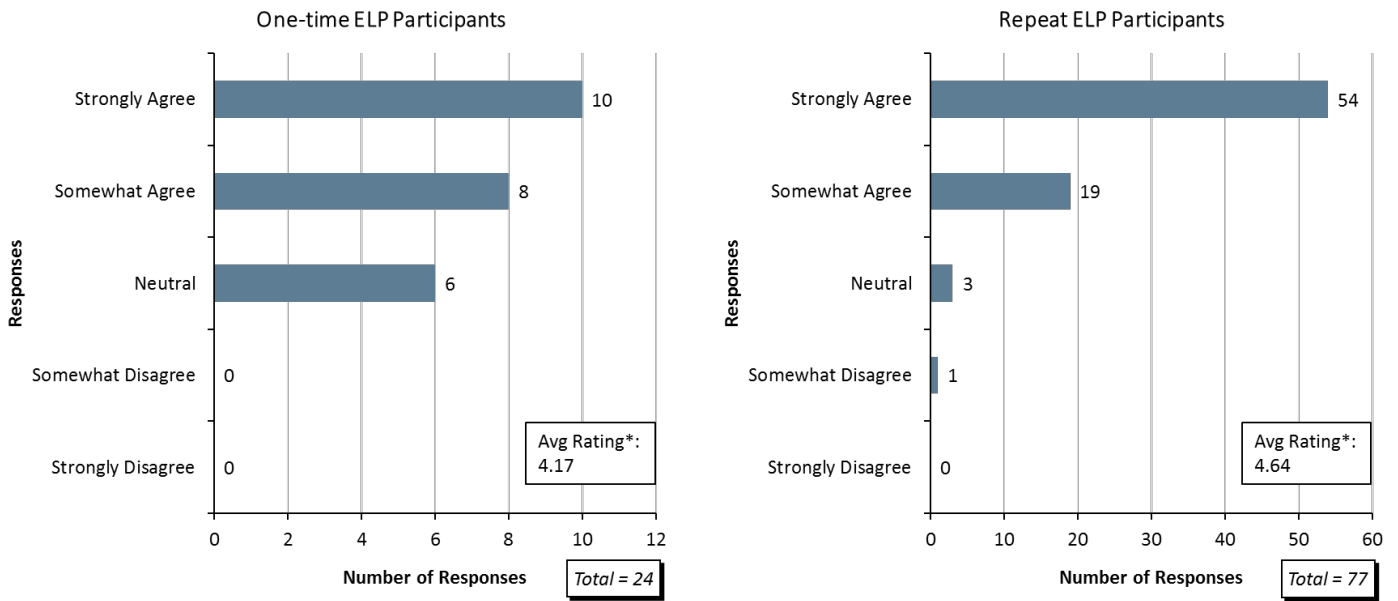
Interviews showed that staff who participated in ELP found their experiences valuable and beneficial to their work performing submission reviews. Booz Allen conducted a survey to confirm these insights with a larger population. The results demonstrated that the majority of ELP participants leveraged the insights gained from their experiences when conducting submission reviews, a feeling that was enhanced upon repeating ELP, as shown in Figure 3-9.



\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
Source: Survey conducted by Booz Allen

**Figure 3-9. Survey respondents’ agreement with the statement: I have used the insights from my ELP experience while conducting submission reviews**

In addition, staff were also interested in participating in more ELP opportunities, as demonstrated in Figure 3-10.

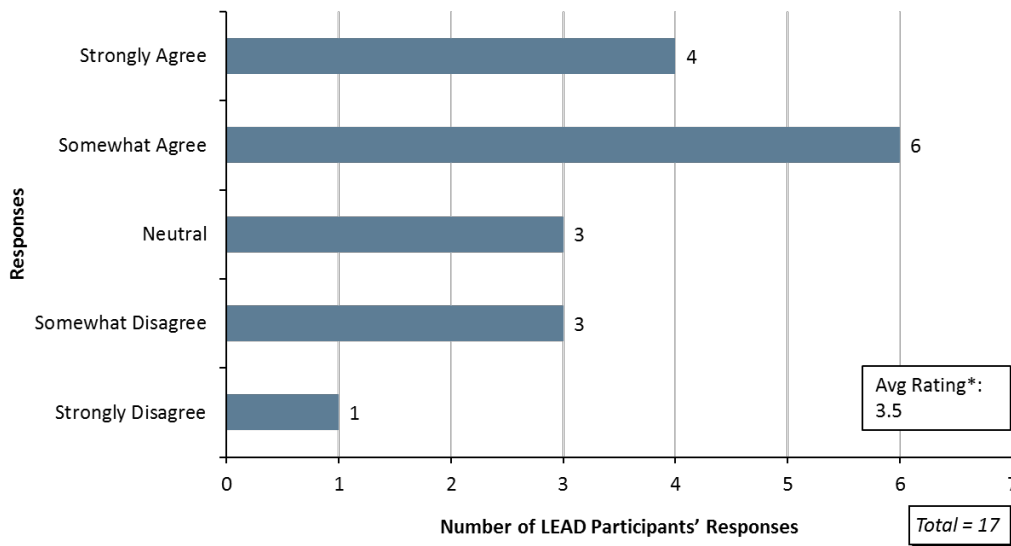


\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
 Source: Survey conducted by Booz Allen

**Figure 3-10. Survey respondents’ agreement with the statement: I would like to participate in more ELP opportunities**

*Leadership Enhancement and Development Program*

Interviews with Branch Chiefs demonstrated that LEAD helps managers learn more people skills and develop better management techniques. When Booz Allen surveyed CDRH staff on this insight, data confirmed that the majority of respondents who participated in LEAD agreed that the courses helped them develop better management techniques, as shown in Figure 3-11.



\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
 Source: Survey conducted by Booz Allen

**Figure 3-11. Survey respondents’ agreement with the statement: LEAD Program classes have helped me to develop better management techniques**

Interviewees also shared that LEAD courses could be improved by condensing the material and presenting the content in a shorter amount of time.

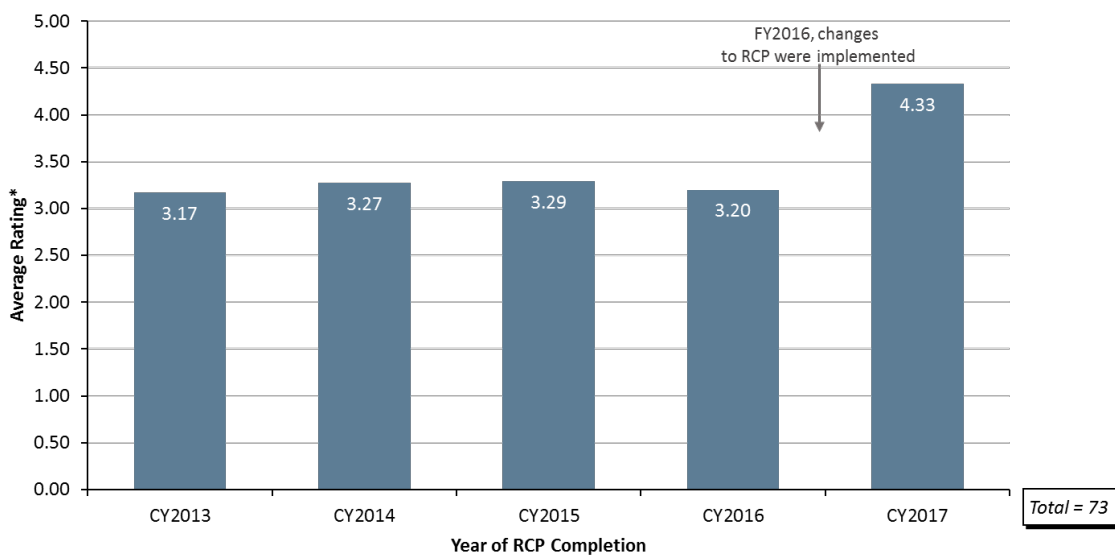


### Leadership Readiness Program

Only four surveyed staff members had taken LRP, and of those, two became managers. The two respondents who became supervisors found the course beneficial in helping them transition into their new roles and responsibilities. Available Kirkpatrick Level 2 data from July 2016 indicated that there was an improvement average of 23.9% from the pre- and post-test after completing training, indicating an increase of knowledge.

### IT Training

As of December 2017, ODE, OIR, OSB, and OSEL had 86%, 99%, 89%, and 97% IT system training completion rates, respectively, with an overall 91% completion rate across these offices. Interviews demonstrated that while the IT training modules were helpful, it was vital that new staff receive the training closer to the time of onboarding to be most beneficial. Staff are expected to navigate through the IT systems and start performing submission reviews almost immediately after onboarding. To understand the effectiveness of RCP's IT systems training, Booz Allen surveyed staff on their perception of how well they felt they could navigate, access, and use the CDRH IT systems (DocMan, CTS, Image2000+) to perform a 510(k) review after training completion. As above, the survey results are organized by the RCP year of completion to understand how attitudes toward the program have evolved over the last five years. The results are demonstrated in Figure 3-12.



\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
Source: Survey conducted by Booz Allen

**Figure 3-12. Survey respondents' agreement with the statement: After attending RCP, I could effectively navigate, access and use the CDRH IT systems (e.g., DocMan, CTS, Image 2000+) to perform a 510(k) review**

The enhancements made to the IT systems training content, the change in requirements to make the training mandatory, and the inclusion of this training into RCP in 2015 appear to have helped equip staff with the necessary IT skills to navigate through the systems when performing submission reviews. These results indicate that CDRH's implementation activities and efforts have been effective. Finally, the Cadre of Experts was concluded in 2016 due to the incorporation of the IT Systems training into RCP, anticipated modifications to the premarket systems in response to MDUFA IV, and the upcoming CDRH Digital Transformation.

### CONCLUSIONS

CDRH integrated Kirkpatrick Level 1 and 2 metrics for all curriculum-based premarket training programs. While the available Kirkpatrick Levels data show that the training programs are effective, there will be greater confirmation once Kirkpatrick Level 3 and 4 data are available for all premarket training. As outlined by the MDUFA IV Commitment Letter, FDA will achieve Kirkpatrick Levels 3 and 4 for curriculum-based premarket training by FY2020. CDRH is first capturing Levels 3 and 4 metrics for Least Burdensome training, including the Four-Part Harmony course and the Least Burdensome Provisions and Principles: Finding a Balance course before expanding to the full training programs. The analyses of a case study and survey data show that CDRH's leverage of the Kirkpatrick Level 1–3 data has helped CDRH

further improve RCP's content and length. Recent changes to RCP had a positive impact on providing reviewers the foundation and skills necessary to perform efficient submission reviews. Additional improvements, including the timing of administering RCP, could further enhance those results. Survey data for other formal training programs, such as ELP, LEAD, and LRP, indicate that each program improved knowledge transfer. CDRH improved the consistency of the IT systems training and established an assessment mechanism for continuously improving its formal training programs. The positive response to changes to RCP demonstrate that CDRH should continue to review and, when needed, implement changes to all formal training programs, ensuring they are effectively imparting knowledge to trainees.

## RECOMMENDATION 10: PROMOTION OF INFORMAL TRAINING

In Phase 1 of the Independent Assessment, Booz Allen found that due to the complexity of product submission scientific reviews, formal training programs can be limited in the extent to which they can impart knowledge and skills to participants. Survey results demonstrated that after completing formal training programs, only 56% of staff across ODE and OIR rated their understanding of MDUFA III processes as confident. Participation in subsequent informal trainings increased staff's confidence to 91%. These findings led to Recommendation 10: Promote informal training and knowledge sharing by seasoned staff for review staff and management to share division or science-specific review processes, lessons learned, and best practices.

### PHASE 2 FINDINGS – INITIAL RESULTS

In Phase 2, CDRH conducted five focus groups to identify existing practices and areas for improvement in the promotion and tracking of informal training. CDRH found variations among the programs and workgroups in the tracking, storage, and promotion of informal training events, materials, and announcements. To address this variability, CDRH developed the Center-level *Informal Training SOP*, which established consistent procedural guidelines for the development, delivery, tracking, and evaluation of informal training. In addition, CDRH created and automated the *CDRH Training for Transcript Credit* form, allowing staff to request and receive Learning Management System (LMS) credit for their informal training activities.

Booz Allen evaluated the initial results of CDRH's implementation efforts during Phase 2. Survey results demonstrated that 48% of managers were aware of the *Informal Training SOP* and *Training for Transcript Credit* form, with most becoming aware of the new procedural guidelines from meetings or email communications. Survey results also demonstrated that 37% of managers were familiar with the *CDRH Training for Transcript Credit* form to track informal training. These preliminary results indicated that, at the time, CDRH management was becoming aware of and familiar with enhancements made to the procedures, promotions, and tracking related to informal training.

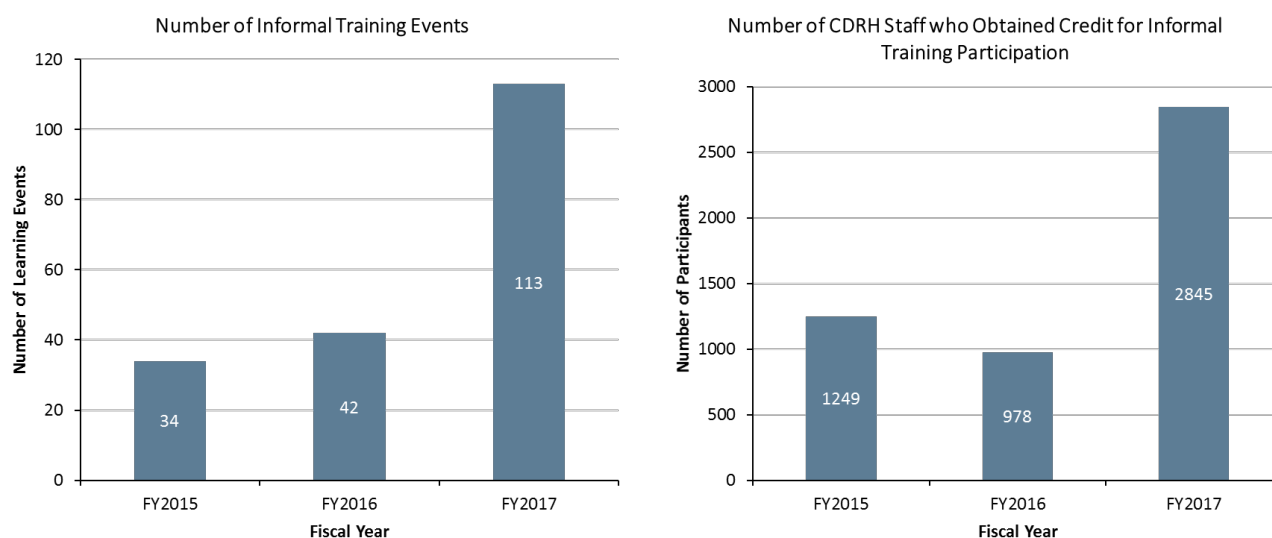
### OUTCOMES

Booz Allen assessed the effectiveness of CDRH's efforts to promote informal training by reviewing communications, analyzing the number of participants and number of informal trainings held, and interviewing staff involved in informal training. CDRH utilizes a number of different methods to communicate and promote informal training, including distribution in the CDRH Weekly Pulse newsletter, delivering presentations to Center staff, and informing CDRH training subject matter experts about the informal training process. These communications ensure that staff are aware of the process for tracking informal training delivered at the office, division, and branch levels and engage staff to reach out to DETD staff with questions about the informal training policy or the tracking form. Following the implementation of the *CDRH Informal Training Form*<sup>11</sup> in September 2016, DETD used a Managers All-Hands meeting to conduct a Center-wide training to promote informal training and use of the form. CDRH held additional trainings at each Office on these topics throughout 2017. In the past three years CDRH has taken significant efforts toward the communication and promotion of informal training among CDRH staff.

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<sup>11</sup> The name changed from *CDRH Training for Transcript Credit* to *CDRH Informal Training Form* in June 2018

These promotions impacted the number of informal trainings logged with DETD. Figure 3-13 illustrates the increase in the number of informal trainings and participants that obtained credit from FY2015–FY2017, with the largest increase between FY2016 and FY2017, correlating with the Center-wide training focused on informal training promotion.



Source: CDRH DETD Data

**Figure 3-13. Number of informal training events and participants that obtained credit from FY2015 to FY2017**

Through interviews with CDRH staff, Booz Allen found that informal training is deeply embedded in CDRH’s culture. CDRH frequently holds informal trainings, including mentoring programs, lunch-and-learns, and rounds at the division level; these trainings cover general topics of interest as well as submission-specific discussions. Topics are determined by staff interest, and requests based on the perceived educational needs of teams or divisions. Attendance usually depends on interest in the topic and workload demands. Informal trainings are promoted primarily through emails. While organizers are aware of the ability to receive credit from DETD for these events, staff often do not request credit for reoccurring meetings, such as rounds, and therefore the training is not always recorded in DETD. Interviewees suggested providing a more simplified mechanism for staff to submit their informal trainings for credit and a system to recognize the people who are leading and organizing the events.

## CONCLUSIONS

Review of communication activities illustrates CDRH management’s commitment to actively and routinely promote informal trainings. The data demonstrate that staff are aware of and utilize the *Informal Training SOP* and the *CDRH Informal Training Form* to track informal training. Both the number of informal events and the participants attending registered informal events have increased from FY2015–FY2017. Interviews with instructors and managers demonstrated that informal training activities are frequent but may not always be recorded with DETD. Therefore, while the *Informal Training SOP* and the *CDRH Informal Training Form* are effective in tracking the informal training event, there are areas for improvement. Examples include creating a simplified mechanism to encourage staff to request credit after completing their events and implementing a system to recognize the people leading and organizing the informal training events. CDRH has already begun to address these concerns: in February 2018, CDRH launched an online informal training module to improve the process for obtaining credit for informal training. The module is accessible through the CDRH LMS. Informal training is embedded in the culture of CDRH and CDRH management recognizes that informal training is an extremely effective method of sharing knowledge. This is demonstrated through the high frequency of informal trainings held and management’s continued efforts to improve the process and ensure that all staff are aware of such valuable resources.

### 3.3 Submission Review: Sub-Process Management

The implementation projects outlined under the Program Outcome of “Sub-Process Management in Submission Review” aim to provide clarity and support to FDA staff and industry related to enhancements in select premarket review sub-

processes, including the RTA process, management of withdrawn submissions, interactions with sponsors, and eCopy submissions.

### **RECOMMENDATION 3: REFUSE TO ACCEPT (RTA) PROCESS IMPROVEMENT**

Booz Allen's Phase 1 Independent Assessment determined that more than half of the closed Traditional 510(k) submissions received during CY2013 received an RTA1 decision during the first cycle. These submissions were associated with overall longer review times. The highest frequency of missing or deficient elements during the RTA review occurred in the Administrative category of the RTA Checklist, indicating a need for increased sponsor awareness of administrative requirements for 510(k) submissions. These observations led to Recommendation 3: Optimize RTA process by improving awareness of and clarity around administrative requirements for 510(k) submissions.

#### **PHASE 2 FINDINGS**

During Phase 2 of the Independent Assessment, Booz Allen found that CDRH performed (1) an audit of the RTA program, (2) an analysis on feedback from industry on their perspective of the RTA process, and (3) a root cause analysis of the RTA process. Findings from these analyses prompted the Center to make specific revisions to their RTA policy. In August 2015, FDA distributed an updated *RTA Policy for 510(k)s* Guidance to FDA staff and industry, which became effective in October 2015. CDRH also revised the Administrative File SOPs and WI to ensure that staff address inconsistencies in submission document control specific to RTA Checklists. The updated Guidance clarified processes to reflect current review practices, streamlined RTA Checklists, and encouraged IR and reviewer discretion policies where appropriate.

#### **INITIAL RESULTS**

Booz Allen assessed initial results by reviewing CDRH training activities related to the RTA policy and RTA Checklist. We found that during August and September 2015, CDRH held internal training to ensure staff were prepared for the updated final RTA Guidance. Approximately 400 review staff attended the training. We also found that the RTA policies and Checklist are covered in RCP and are part of the new reviewer onboarding process. CDRH also provides trainings for additional updates. Before its July 2017 implementation, CDRH provided internal training on the RTA Addendum Pilot Program, which provides sponsors with early notification of observations made during the initial non-substantive RTA review through attachment of the RTA Addendum to the RTA1 Checklist. In March 2018, CDRH held an internal training on updates to the RTA Checklist to increase awareness of changes stemming from the 21<sup>st</sup> Century Cures Act and changes to the RTA Checklist that impact combination products. Externally, CDRH held training on the 510(k) process throughout 2017 and 2018, which covered the RTA process and Checklist. As demonstrated by the RTA-specific and general 510(k) process training, CDRH increased awareness of updated policies and changes to the RTA Checklist to both CDRH reviewers and to industry. This illustrates CDRH's ongoing efforts to improve the RTA process and ensure that all stakeholders are aware of any process changes.

#### **OUTCOMES**

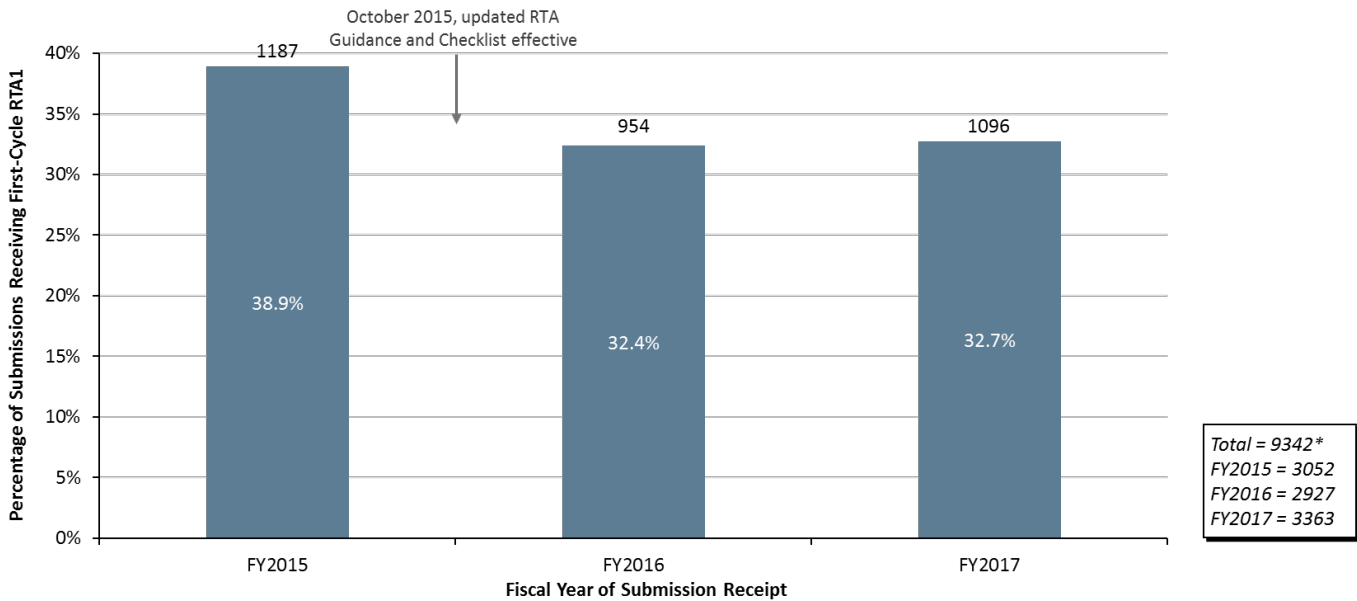
To assess the impact of the revised Guidance and Checklist on the RTA Review process, Booz Allen analyzed RTA in two ways: (1) performance data from the FY2015–FY2017 Receipt Cohort and (2) performance data and audit findings from the three MDUFA Audit Cohorts (FY2015–FY2017).

##### *Receipt Cohort*

As shown in Figure 3-14, our analysis of the Receipt Cohort revealed that from FY2015–FY2017, the first-cycle RTA1 rate for Traditional 510(k)s decreased from 39% to 32%. The decrease in decline decisions from FY2015–FY2016 correlates with the issuance of the updated RTA Guidance and Checklist. Similar results were seen in quarterly MDUFA Performance Reports for all 510(k)s,<sup>12</sup> which additionally show dramatic decreases in first-cycle decline decisions from FY2013 to FY2015.

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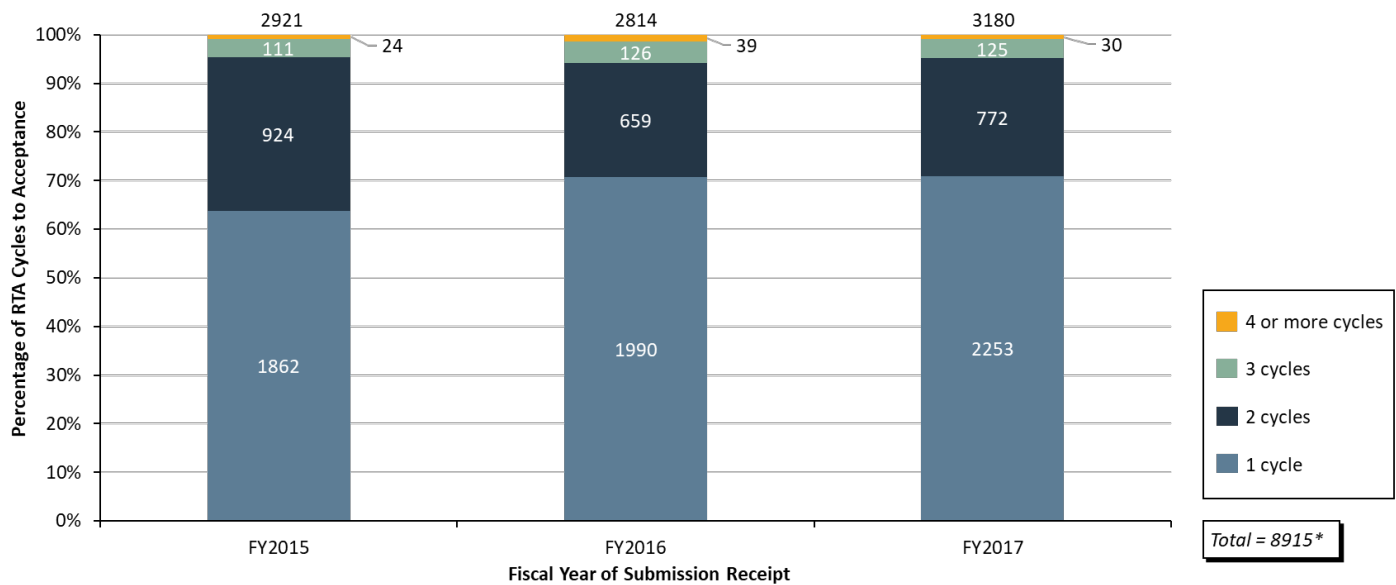
<sup>12</sup> [MDUFA III \(FY2013-2017\) Performance Report](#)



Source: FDA data systems

**Figure 3-14. Percentage of submissions receiving first-cycle RTA1 by fiscal year**

When analyzing the number of review cycles to acceptance, we found that the percentage of Traditional 510(k)s accepted on the first cycle increased from 64% in FY2015 to 71% in FY2017, as illustrated in Figure 3-15. The percentage of submissions that took two RTA cycles to acceptance decreased from 31% in FY2015 to 24% in FY2017, while the percentage and number of submissions that required three or more RTA cycles remained constant.



\*Excluding submissions that did not receive an RTA acceptance decision in the latest round of RTA review  
 Source: FDA data systems

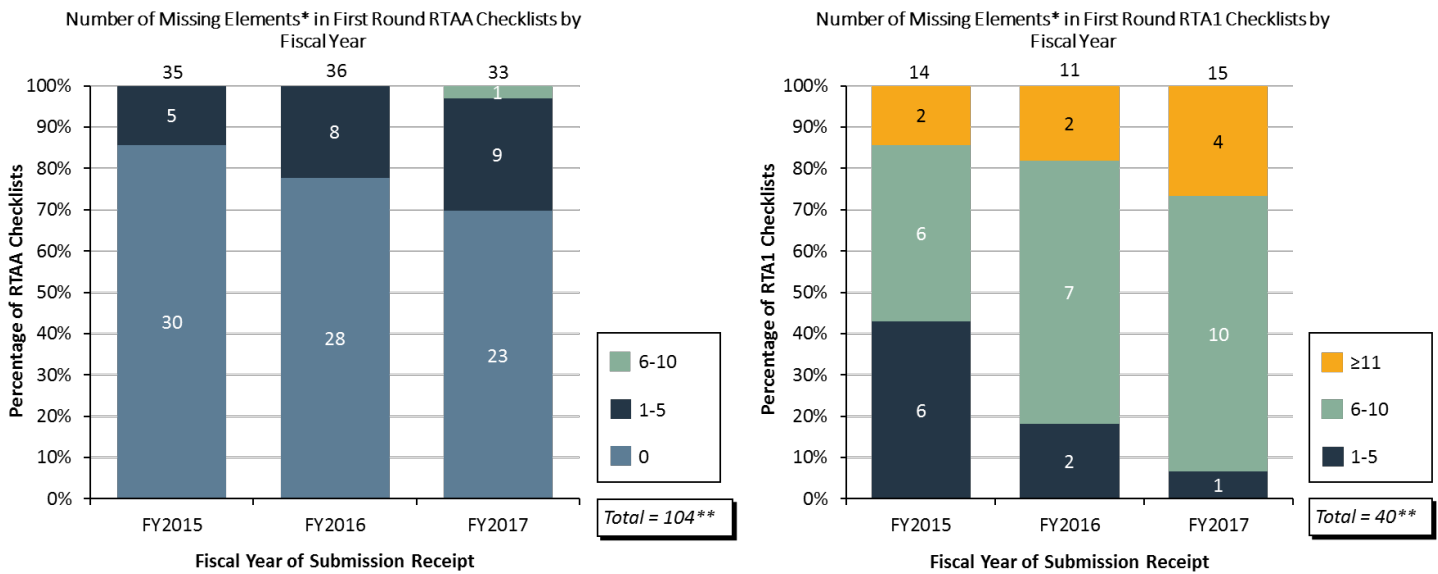
**Figure 3-15. RTA cycles to acceptance by fiscal year**

**MDUFA Audit Cohort**

Booz Allen analyzed RTAA and RTA1 Checklists with missing elements from the FY2015, FY2016, and FY2017 MDUFA Audit Cohorts to further understand the frequency of Checklists with missing elements and the number of missing elements per Checklist over time. As shown in Figure 3-16, the number of RTAA Checklists in the MDUFA Audit Cohorts containing one to five missing elements increased from FY2015 to FY2017 while the number of RTA1 Checklists containing six to 10 missing elements also increased. The average number of missing elements in RTAA Checklists was similar, 0.26 in FY2015 to 0.52 in FY2017, while the average number of missing elements in RTA1 Checklists increased from six in FY2015 to 11 in FY2017. Additionally, we observed that 100% of analyzed first-round RTA1 letters from



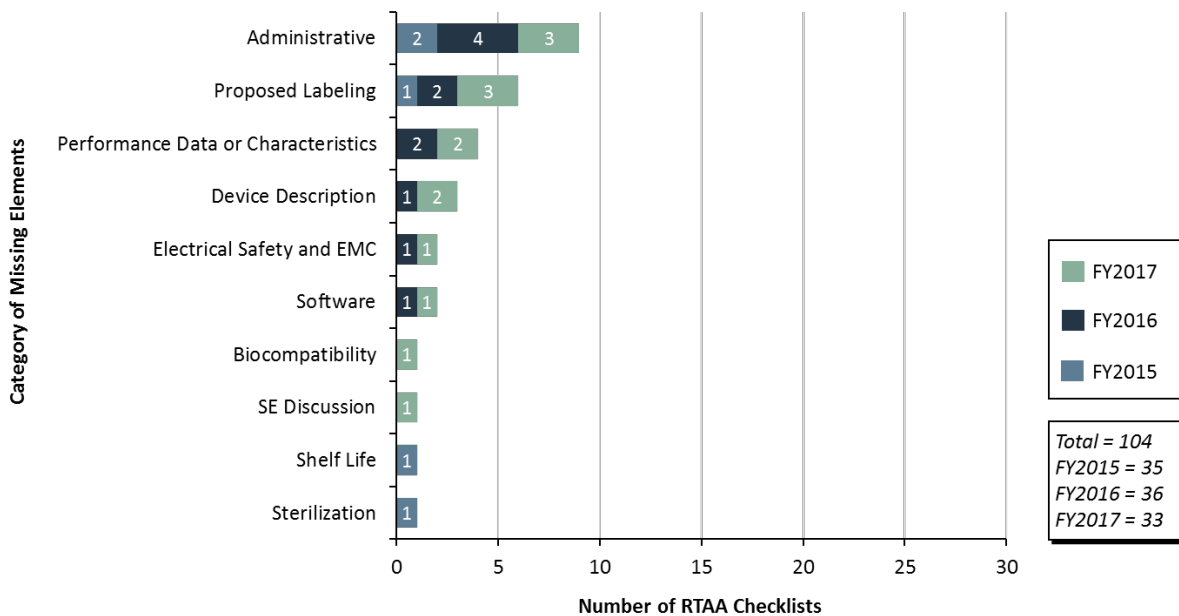
FY2015–FY2017 contained comments from CDRH reviewers, suggesting CDRH strives to provide sponsors with specific instructions to address missing elements. As a part of the MDUFA Cohort RTA analysis, we assessed the number of missing elements in seven second-round RTA1 decisions in FY2015–FY2017. In this second-round RTA1 analysis, the average number of remaining missing elements was 4.7.



\*Excludes Organizational Elements  
 \*\*Excludes RTAN decisions or submissions for which Traditional 510(k) RTA Checklists were not available in DocMan  
 Source: Booz Allen Traditional 510(k) audit

**Figure 3-16. Number of missing elements in both first-round RTAA and RTA1 Checklists from FY2015 to FY2017**

Next, we analyzed the first-round RTAA and RTA1 Checklists to determine the leading categories of missing elements in FY2015 through FY2017. In FY2015, FY2016, and FY2017, the Administrative and Proposed Labeling categories had the most missing elements in first-round RTAA Checklists, as seen in Figure 3-17.

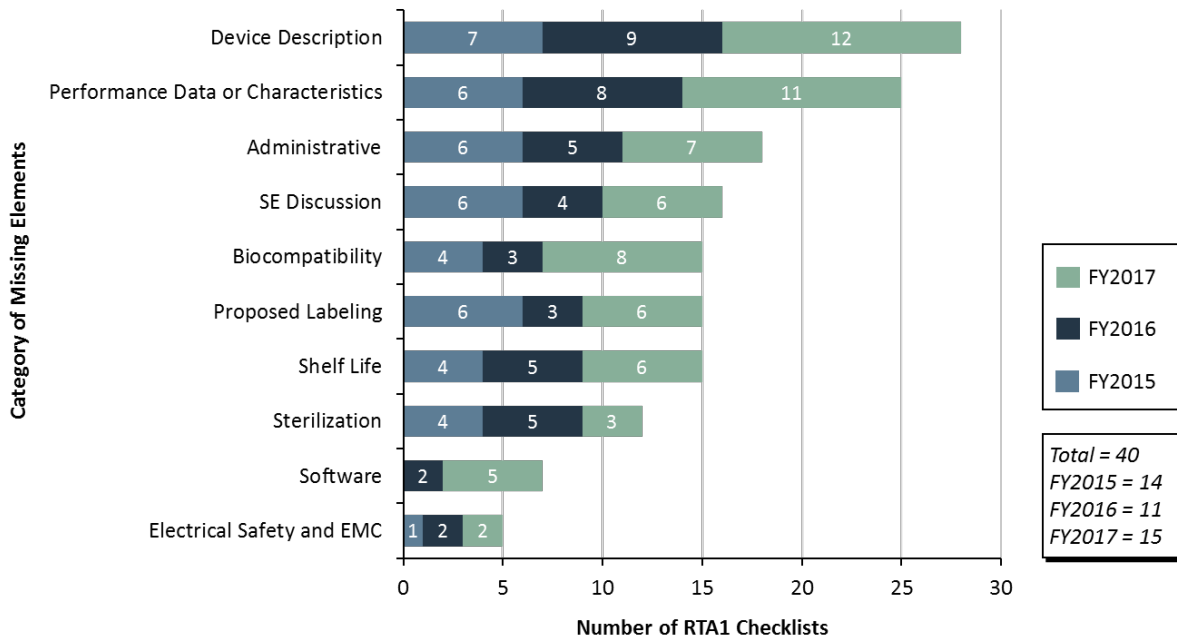


Source: Booz Allen Traditional 510(k) audit

**Figure 3-17. Top categories of missing elements in first-round RTAA Checklists in FY2015 to FY2017**

As seen in Figure 3-18, Device Description and Performance Data or Characteristics are the predominant categories of missing elements in RTA1 Checklists. This difference from the leading category seen in RTAA Checklists containing

missing elements demonstrates a change from a similar analysis in Phase 1, where the Administrative category had the highest frequency of missing elements in RTA1 Checklists.



Source: Booz Allen Traditional 510(k) audit

**Figure 3-18. Top categories of missing elements in first-round RTA1 Checklists in FY2015 to FY2017**

In both first-round RTAA and RTA1 Checklists, we also analyzed the comments provided by CDRH reviewers. In RTA1 Checklists, we observed that 100% of Checklists from FY2015–FY2017 (n= 40) contained comments from CDRH reviewers, suggesting CDRH strives to provide sponsors with specific instructions to address missing elements. In RTAA Checklists with missing elements (n= 23), we found 65% of Checklists contained comments from the Lead Reviewer stating the reviewers' intention to work with the sponsor to interactively address the missing items. The increase in the number of missing elements in RTAA Checklists, combined with the comments from Lead Reviewers stating that missing items will be addressed interactively, indicates increased use of the reviewer discretion policy.

To determine if interactions during the RTA phase impact RTA decision, Booz Allen analyzed the frequency of interactive communications during the RTA review phase. In the 100 submissions from the FY2015 and FY2017 MDUFA Audit Cohorts, we found interactive communications during the RTA phase occurred in 18% of submissions in FY2015 and 24% of submissions in FY2017. The rate of RTA1 was similar for those with and without communications, at 35% in FY2015 and 29% in FY2017. For more analyses related to interactive communications, see Recommendation 5: Sponsor Communications.

## CONCLUSIONS

Booz Allen found that CDRH provided training on multiple occasions to staff and industry on the 2015 updates to the RTA Guidance and Checklist. In addition, CDRH continues to provide training to staff and industry as the RTA Checklist continues to evolve. We found that from FY2015 to FY2017 the rate of first cycle RTA decline decisions decreased, as did the rate of submissions that took more than one cycle to acceptance. This correlates with the release of the updated RTA Guidance and Checklist. The number of missing elements in both RTAA and RTA1 Checklists increased; for RTAA Checklists this is linked to reviewers' efforts to work with sponsors to obtain missing elements interactively and apply the reviewer discretion policy. Our current analysis demonstrates that in comparison to Phase 1, Administrative is no longer the leading category of missing elements for submissions receiving an RTA1 decision. Reviewers are utilizing the RTA1 decision for submissions that cannot proceed into substantive review due to the level of missing elements in the submissions. Overall, CDRH improved the RTA process to increase first-cycle acceptance rates.

## RECOMMENDATION 4: WITHDRAWN SUBMISSIONS ANALYSIS

Booz Allen's Phase 1 Independent Assessment identified a 50% increase in withdrawal rates for the 510(k) Receipt Cohort of Traditional 510(k)s between the MDUFA II and MDUFA III timeframes. However, the withdrawal rate for the 510(k)s Accepted Cohort only increased by 0.82% from MDUFA II to MDUFA III. Analyses revealed that the increase in the Receipt Cohort withdrawal rate was attributed to 510(k)s being withdrawn during the RTA phase of review. It is likely that that reason for the increase in withdraw decisions during the RTA phase is that sponsors are able to request a refund of user fees before the submission is accepted. Additionally, Booz Allen found that 29% (26/90) of CY2013 Traditional 510(k)s withdrawn during the Post-SI phase were withdrawn with fewer than 10 days left on the review clock. Based on these findings, we provided CDRH with Recommendation 4: Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence.

### PHASE 2 FINDINGS

Booz Allen's Phase 2 Independent Assessment found that CDRH tracks withdrawals as part of premarket review performance metrics. CDRH conducted an in-depth root cause analysis of withdrawals and found that the majority of assessed withdrawn submissions had complex substantive AI deficiencies, which required additional time for sponsors to address fully. In November 2015, CDRH implemented the *Management Oversight of Critical Control Points for Premarket Review* SOP to enhance oversight of the entire premarket review process (as part of Recommendation 2: Decision-Making Consistency). In the same period, CDRH implemented a *Documenting & Processing Withdrawal Requests* WI to further standardize how the Center processes withdrawal requests and to enable continued monitoring and analysis of withdrawal trends.

### INITIAL RESULTS

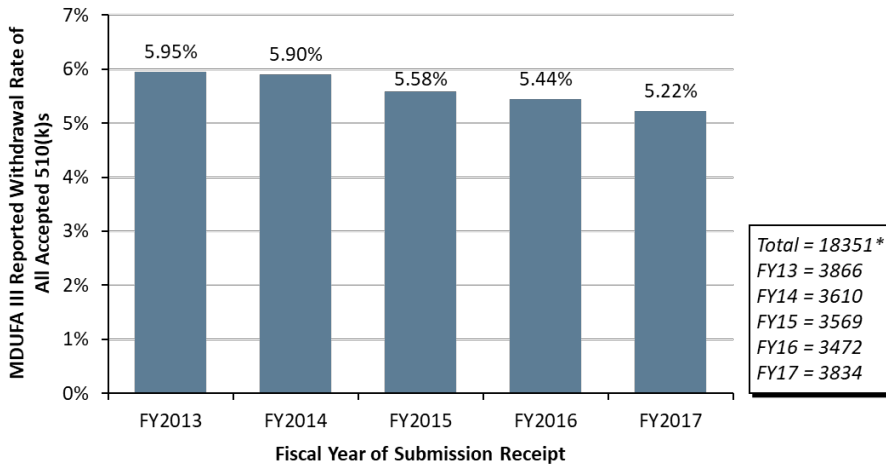
To evaluate initial results, Booz Allen ascertained the availability of training on the SOP and WIs related to withdrawals, including the additional *Q and A – Withdrawal of a 510(k)* WI, issued in May 2016. In April 2018, CDRH trained review staff on updated 510(k) procedures, including the withdrawal process, and provided internal web links to all procedural documents related to withdrawals. This shows that the Center took steps to increase awareness related to the withdrawal process.

### OUTCOMES

To assess if CDRH's procedural changes impacted the occurrence of withdrawals, Booz Allen first reviewed MDUFA Performance Reports that track the withdrawal rate of all 510(k)s after acceptance. Since FY2013, withdrawal rates slightly decreased for 510(k)s overall (Figure 3-19).<sup>13</sup> To further assess the impact of CDRH actions on the Traditional 510(k) Withdrawal process, Booz Allen analyzed withdrawals in two ways: (1) performance data from the FY2015–FY2017 Receipt Cohort to assess rate and timing of withdrawals and (2) performance data and audit findings from the two Withdrawn Audit Cohorts (FY2015 and FY2017) to evaluate withdrawal request oversight and documentation mechanisms.

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<sup>13</sup> [MDUFA III \(FY2013-2017\) Performance Report](#)

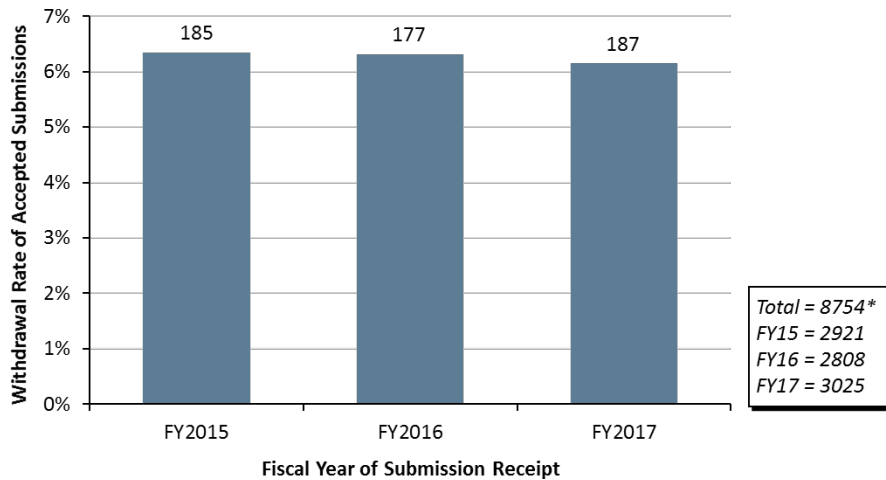


\*Data as of 6/30/2018. Six FY2016 and 136 FY2017 submissions were not yet closed  
 Source: MDUFA III Performance Report (September 2018)

**Figure 3-19. Withdrawal rate of all accepted 510(k)s by fiscal year, as published in the September 2018 MDUFA III Performance Report**

**Receipt Cohort**

Booz Allen measured the withdrawal rate of accepted Traditional 510(k) submissions in the FY2015–FY2017 Receipt Cohort. As illustrated in Figure 3-20, the withdrawal rate in the Receipt Cohort remained stable at approximately 6% from FY2015 to FY2017, suggesting that CDRH changes did not significantly affect withdrawals.

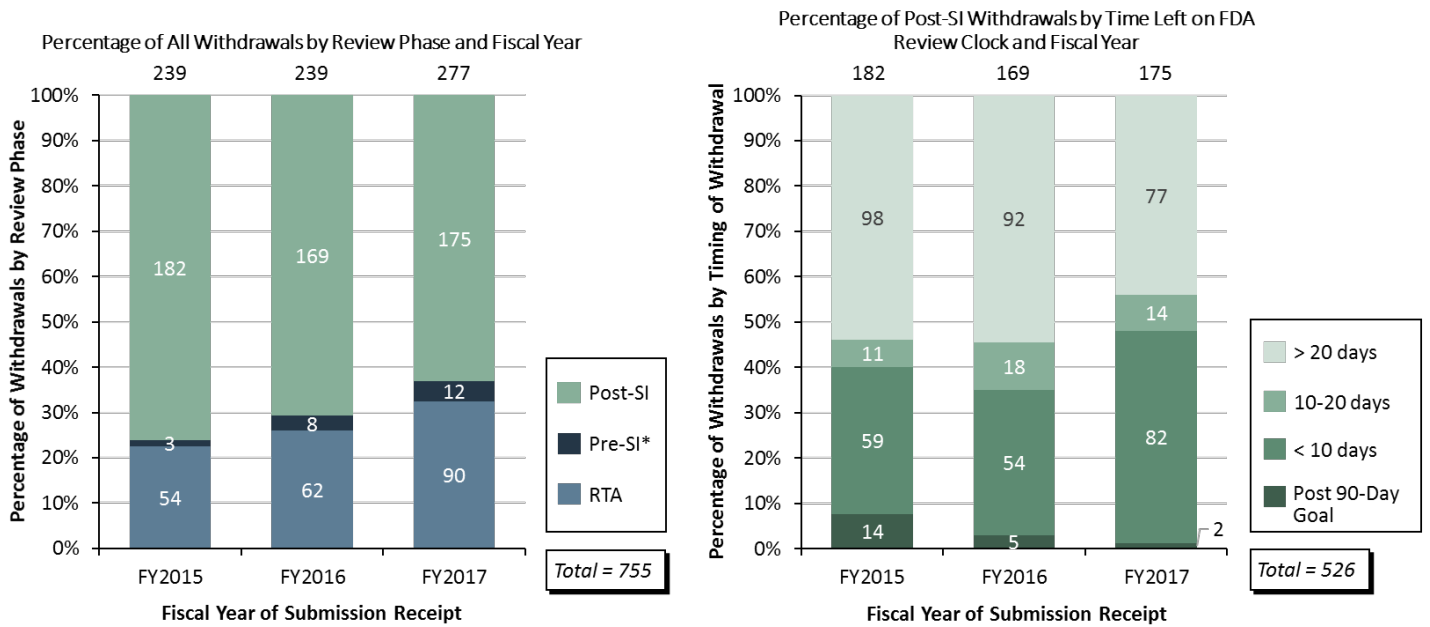


\*Accepted submissions only  
 Source: FDA data systems

**Figure 3-20. Withdrawal rate of accepted Traditional 510(k)s by fiscal year**

As shown in Figure 3-21, Booz Allen characterized the timing of withdrawn submissions. In our FY2015–FY2017 Receipt Cohort, we observed a 9% increase of withdrawals during the RTA phase.<sup>14</sup> Similar to our Phase 1 finding that 29% (26/90) of CY2013 Traditional 510(k)s withdrawn during the Post-SI phase were withdrawn with fewer than 10 days left on the review clock, we found submissions are still being withdrawn close to the end of the review. We determined that 47% (82/175) of FY2017 Post-SI withdrawals took place with fewer than 10 days left on the review clock. The timing of withdrawals later in the review clock can be the result of on-going efforts to address and resolve deficiencies. Alternatively, it can raise concerns about appropriate use of the process if all deficiencies are not able to be addressed during the MDUFA timeframe. However, the overall rate of Post-SI withdrawals has decreased from 76% (182/239) in FY2015 to 63% (175/277) in FY2017.

<sup>14</sup> Withdrawals that occur during the RTA Phase are not captured by MDUFA quarterly reporting



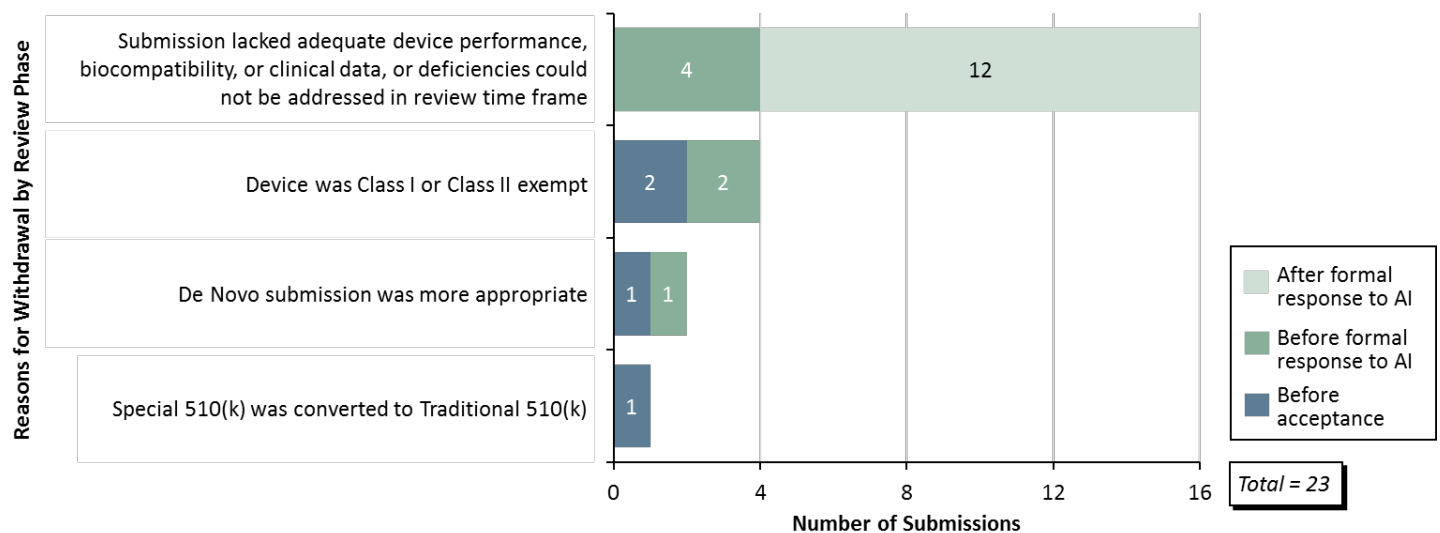
\*Including pre-SI and day of SI decision  
 Source: FDA data systems

**Figure 3-21. Timing of withdrawals in Traditional 510(k)s by fiscal year**

**Withdrawn Audit Cohorts**

Booz Allen first evaluated whether staff followed the procedures from the updated SOP and WI. We found that for all withdrawn submissions in the FY2015 and FY2017 Withdrawn Audit Cohorts, CDRH processed withdrawals with the appropriate decision code and concurrence in CTS and documented the official acknowledgement of withdrawal in DocMan. In these Cohorts, 98% of sponsor withdrawal requests were also filed in Image2000+. CDRH reviewers further provided optional documentation of withdrawal requests in the Administrative File in 52% of FY2015 and 56% of FY2017 submissions. These data show that the procedural documents formalized processes, already followed by staff, that ensure transparent and consistent management of withdrawal requests.

To better understand circumstances surrounding withdrawals, we assessed optional Administrative File memo documentation in the Withdrawn Audit Cohorts. Twenty-three of 50 memos included discussion of reasons for the withdrawal. As shown in Figure 3-22, we inventoried these reasons and determined the review phase of the withdrawals.



Source: Booz Allen audit of withdrawn Traditional 510(k) submissions

**Figure 3-22. Reasons for withdrawal by review phase**



More than half of submissions were withdrawn due to deficiencies and occurred after sponsors provided a formal response to an AI request. Some submissions were withdrawn because the Traditional 510(k) pathway was not applicable. Consistent with results of Booz Allen's Phase 1 Assessment and CDRH's root cause analysis of withdrawn submissions, our findings suggest that sponsors' inability to resolve substantive issues remains the most common reason for withdrawal.

## CONCLUSIONS

Booz Allen found that CDRH staff are following updated withdrawal documentation and oversight procedures that formalized processes already followed by staff. This coincided with a steady rate of Traditional 510(k) withdrawals from FY2015–FY2017. However, many withdrawals continued to occur close to the MDUFA goal date. These observations suggest that CDRH has managed withdrawals through consistent mechanisms which have led to a decrease in the post-SI withdrawal rate. However, those mechanisms did not directly impact the occurrence of withdrawals with fewer than 10 days on the review clock.

Our audit suggests that issues related to substantive deficiencies remain the most common reason behind sponsors' withdrawal requests. The reason surrounding the withdrawal was documented in fewer than half of the submissions within the withdrawn audit cohorts. If CDRH has knowledge of the reason for withdrawal, ensuring that the reason is documented in the Administrative File would support more consistency to CDRH's management of the withdrawal process. The Center will perform a MDUFA IV audit of withdrawn submissions to further understand trends related to these submissions. The audit may allow CDRH to develop a more complete understanding of reasons behind withdrawals from both the review staff and sponsor perspectives, with a particular focus on withdrawals that occur close to the MDUFA goal date. Additionally, to further assist sponsors' with resolving substantive deficiencies CDRH has implemented two new programs in FY2018 to promote earlier resolution of substantive issues during review: (1) the previously described RTA Addendum program (see Recommendation 3: Refuse To Accept (RTA) Process Improvement), and (2) the Day 10 Call program that provides sponsors the opportunity to hold a teleconference with the Lead Reviewer to discuss deficiencies within 10 days of issuance of an AI letter. Both of these programs were piloted beginning in July 2017 and implemented Center-wide in June 2018. In addition, in February 2018, CDRH began piloting (within ODE) a Least Burdensome Flag program that allows applicants to flag instances where they believe AI requests are not least burdensome or that they are being held to an inappropriate review standard.

## RECOMMENDATION 5: SPONSOR COMMUNICATIONS

Booz Allen's Phase 1 Independent Assessment found that increased interactive communications with sponsors may contribute to shorter Total Time to Decision (TTD) during premarket review. Review divisions that communicated more frequently with sponsors throughout the course of the review and before SI decisions had shorter average TTD and issued fewer SI deficiencies. These observations led to Recommendation 5: Implement a consistent practice for communicating early and frequently with sponsors during the Substantive Review phase to address and resolve potential issues prior to Substantive Interaction.

## PHASE 2 FINDINGS

During Phase 2, Booz Allen found that CDRH implemented procedural documents and provided staff training to promote more frequent and earlier interactive communications with sponsors. In October 2015, CDRH implemented the *Interactive Review During the Review of 510(k) Submissions* WI to guide staff on best practices for interactively communicating with sponsors throughout each stage of premarket review. Procedures to document interactive communications with sponsors were specified as part of the *Compiling the Administrative File for Premarket Submission Decisions* SOP. At the time of implementation of these procedural documents, CDRH provided in-person and on-demand online training to managers and staff on the new policies and practices pertaining to interactive communications with sponsors.

## INITIAL RESULTS

Booz Allen assessed initial results by evaluating the availability of training provided on updated interactive review procedures. Beyond the training at implementation of the WI and SOP, we found that one branch also held and received

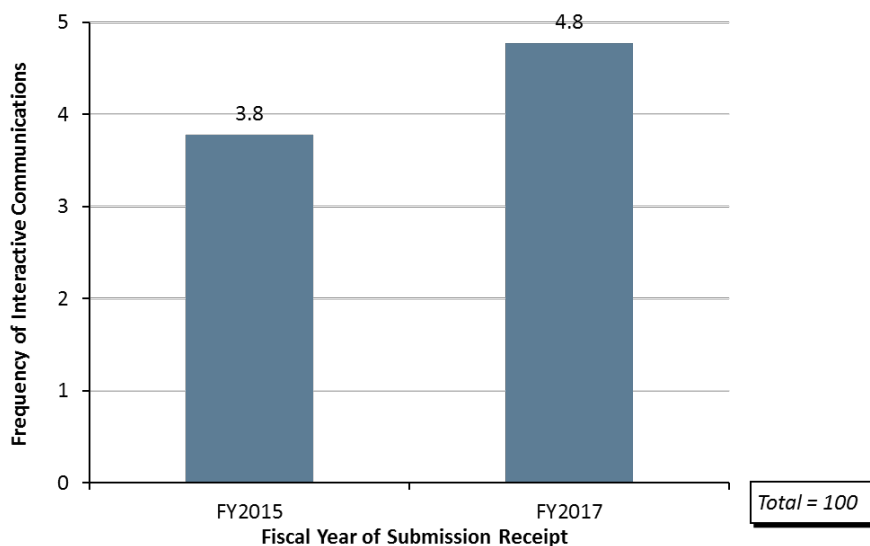
DETD credit for an informal training on interactive communications with sponsors. These formal and informal training activities suggest that CDRH improved staff awareness of updated procedures for interactive communications.

## OUTCOMES

To assess the impact of updated interactive communications procedures, Booz Allen analyzed CDRH-sponsor communication records in the 50 FY2015 and 50 FY2017 MDUFA Audit Cohort submissions. We focused on the documentation, frequency, and timing of CDRH-sponsor interactions, and sponsor response time to CDRH's interactive requests for substantive information before and after CDRH implemented the updated procedural documents. We excluded from our analysis information not solicited by FDA, communications unrelated to premarket review, and official correspondence such as RTA1 notifications or AI requests.

Although the need for interactive communications will vary by submission, our analysis revealed that reviewers and sponsors engaged interactively in 86% of FY2015 and 88% of FY2017 audited submissions. CDRH reviewers interacted with sponsors primarily through emails, with some additional communication by phone calls or teleconferences. We found documentation of interactive email records in the Administrative Files of 100% of submissions that had interactive email communications (as described in Figure 3-6 in Recommendation 1b\*: Document Control Enhancements), suggesting that the SOP and WI formalized processes that staff already practiced.

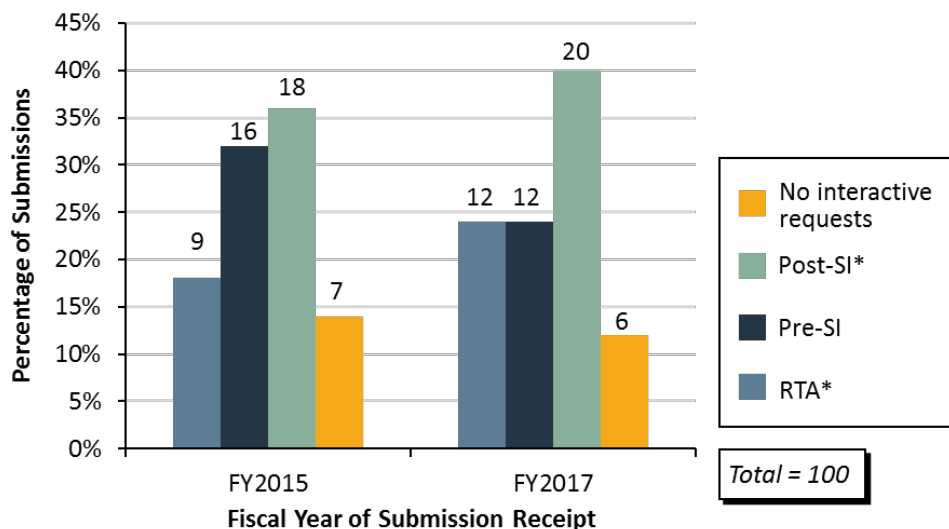
As shown in Figure 3-23, CDRH and sponsors interacted slightly more frequently (averaging 4.8 rounds/submission) in the FY2017 Audit Cohort than in the FY2015 Audit Cohort (averaging 3.8 rounds/submission), with rounds of interaction ranging from zero to 15 rounds in FY2015 and zero to 24 in FY2017. This is consistent with CDRH's revised policies impacting interactions with sponsors.



Source: Booz Allen Traditional 510(k) audit

**Figure 3-23. Average frequency of CDRH-sponsor interactions by fiscal year**

We found that the timing of interactive communications with sponsors, as indicated by the review phase when CDRH initiated the first interactive request for substantive information in each submission, remained relatively consistent, with a slight shift towards first interactions occurring during RTA in FY2017 (24% of audited submissions) as compared to FY2015 (18% of audited submissions). These results are shown in Figure 3-24. In both FY2015 and FY2017, similar numbers of submissions had first interactions prior to SI decision (including RTA and pre-SI phases) or during Post-SI review.



\*Including when submissions are on hold during the respective review phase  
 Source: Booz Allen Traditional 510(k) audit

**Figure 3-24. Timing of first interactive request by fiscal year**

As shown in Table 3-1, Booz Allen found that the number of communications in each review phase was slightly higher in the FY2017 MDUFA cohort than in the FY2015 cohort and that 68% of interactions took place in the Post-SI phase. These observations are similar to our Phase 1 finding that the majority of communications occurred during the MDUFA/IR phase of review, suggesting that CDRH’s new policies did not drastically alter the timing of initial interactive communications with sponsors.

**Table 3-1. Total rounds of sponsor interactions by review phase and fiscal year**

| REVIEW PHASE | FY2015     | FY2017     |
|--------------|------------|------------|
| RTA          | 10 (5%)    | 18 (8%)    |
| Pre-SI       | 52 (28%)   | 58 (24%)   |
| Post-SI      | 127 (67%)  | 163 (68%)  |
| <b>Total</b> | <b>189</b> | <b>239</b> |

Booz Allen measured sponsor response time to CDRH’s interactive communications and found that the average sponsor response time increased from FY2015 to FY2017. Although variable among requests, on average, sponsors took 3.3 days in FY2015 and 5.3 days in FY2017 to ask clarifying questions or provide substantive responses to CDRH’s interactive requests.

We also found that in accordance with the *Interactive Review During the Review of 510(k) Submissions* WI, reviewers provided deadlines for sponsor responses in 61% of interactive requests in FY2017, compared to 51% in FY2015. This suggests that CDRH’s processes of facilitating interactive issue resolution during review are more standardized.

## CONCLUSIONS

CDRH provides training to staff on CDRH-sponsor interactions during premarket review. In our MDUFA Audit Cohorts, we found trends toward increased interactive frequency and increased sponsor response time to interactive communications in FY2017 compared to FY2015. There was a slight shift of interactive communications being initiated during the RTA phase. However, in most cases, CDRH initiated interactive communications occurred at similar times during the review phase for FY2015 and FY2017 audited submissions.

CDRH has implemented two new programs in FY2018, both piloted beginning in July 2017, to enhance the interactive process related to official communications. The RTA Addendum program (see Recommendation 3: Refuse To Accept (RTA) Process Improvement and Recommendation 4: Withdrawn Submission Analysis) allows sponsors to plan for the substantive review and future interactions. The Day 10 Call program (see Recommendation 4: Withdrawn Submission Analysis) provides sponsors the opportunity to hold a teleconference with the Lead Reviewer within 10 days after the

issuance of an AI letter, providing sponsors the opportunity to address or clarify any uncertainties before preparing the formal AI response. Evaluation of these programs will allow CDRH to determine the impact these programs have on improving issue resolution during review. While the MDUFA IV Commitment Letter already describes a focus on increased interactive communications with sponsors overall, Booz Allen recommends that CDRH continues to also promote processes to address substantive issues with sponsors during early stages of review.<sup>15</sup>

## RECOMMENDATION 7: ECOPY GUIDANCE

Booz Allen’s Phase 1 Assessment identified inconsistencies in the structure and quality of sponsor eCopy submissions. CDRH staff feedback indicated that improved consistency in the structure and quality of eCopy submissions would enable more efficient review. These findings led to Recommendation 7: Provide increased clarity to applicants beyond existing eCopy Guidance to enhance organized submission structure.

### PHASE 2 FINDINGS

During the Phase 2 Independent Assessment, Booz Allen found that FDA took several steps to improve the clarity of the eCopy submission process. On December 3, 2015, FDA updated the *eCopy Program for Medical Device Submissions Guidance (eCopy Guidance)*,<sup>16</sup> previously issued on October 10, 2013. In the updated Guidance, FDA provided technical recommendations for generating files with navigation support, including bookmarks, hyperlinks, and searchable text. The updated Guidance also described FDA’s eCopy Validation Module,<sup>17</sup> a voluntary online tool that helps sponsors determine if an eCopy submission meets the structural specifications described in the Guidance. Beyond the Guidance update, CDRH also intended to create searchable PDFs from initially non-searchable PDFs submitted by sponsors through optical character recognition.

### INITIAL RESULTS

To assess initial results of FDA’s implementation activities, Booz Allen evaluated the implementation of the updated eCopy Guidance and enhancements to the eCopy Validation Module. The December 2015 eCopy Guidance adds to and clarifies the procedural recommendations for creating an eCopy submission. Additionally, the eCopy Validation Module provides sponsors the option to validate their eCopies before submission. To improve the effectiveness of the eCopy Validation Module, CDRH monitors the top sponsor errors occurring during eCopy submission to FDA. The most frequent errors in eCopy submission, such as invalid naming convention of files and folders, placement of folders in non-root directories, incorrect numbering of PDF files, and placement of non-PDF files outside of folders, were consistent from 2013 to 2017. Therefore, CDRH updated the eCopy Validation Module in 2017 to address these top sponsor errors by including new validation rules regarding file names and numbering, folder names, and folder structures. In addition, CDRH made numerous enhancements to the error messages in the eCopy Program (i.e., Validation Module, eLoader and eSubmitter) to provide sponsors with more specific instructions on how to revise their eCopies to meet the technical standards specified in the eCopy Guidance, as shown in Table 3-2.

**Table 3-2. Enhancements to eCopy program error messages**

| PREVIOUS MESSAGE  | UPDATED MESSAGE  |
|---|--|
| Error in the submission package file(s) due to prohibited characters in pdf file name | The following file(s) or folder(s) have an invalid naming convention containing one or more prohibited characters and will need to be adjusted to conform with the submission naming standards. Legal characters that can be included are as follows: English alphanumeric characters (i.e., A-Z, a-z, 0-9), underscores, dashes, curly quotes, square and curly braces, dollar sign, plus sign, equal sign, parenthesis, at sign, caret, ampersand, percent, exclamation point, comma, semi-colon, period and spaces. Filename* |

<sup>15</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022

<sup>16</sup> [eCopy Program for Medical Device Submissions – Guidance for Industry and Food and Drug Administration Staff](#)

<sup>17</sup> [eCopy Validation Module. Description and download links](#)

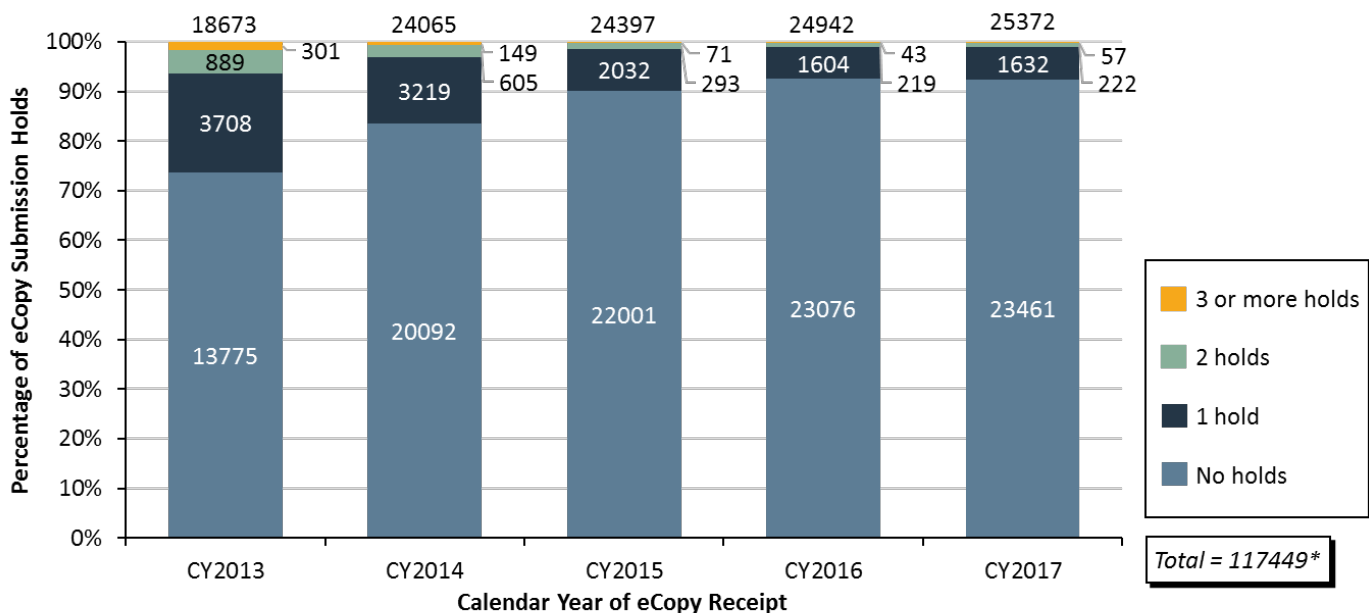
| PREVIOUS MESSAGE  | UPDATED MESSAGE   |
|---|---|
| Error in the submission package file(s) due to length of file or folder names       | The following file(s) or folder(s) have an invalid name which exceeds 125 characters (Including spaces): Filename or Folder name* |
| Error in the submission package file(s) due to with set with future expiration date | The following file(s) are not allowed by eCopy since the file has an embedded plugin which is not supported in eCopy: Filename*   |
| Error in the submission package file(s) due to corrupt/damaged file                 | The following file(s) are not allowed by eCopy since the file is corrupted or damaged: Filename*                                  |
| Error in the submission package file(s) due to password protected pdf file          | The following file(s) are not allowed by eCopy due to file being protected by a password: Filename*                               |

\*Specific file or folder names are provided to direct sponsors to the exact eCopy components containing the error

The revised eCopy Guidance and the enhancements to the eCopy Validation Program illustrate FDA’s continued efforts to understand the challenges that sponsors face during eCopy submission and to improve the clarity of the eCopy submission process.

### OUTCOMES

Booz Allen evaluated the impact of the updated eCopy Guidance and eCopy Validation Module by analyzing the rate of eCopy holds from CY2013 to CY2017. For submission types that require eCopies (including original submissions, supplements, or amendments of 510(k)s, PMAs, De Novo requests, and Q-Submissions), a submission that does not meet the technical standards specified by FDA is placed on an eCopy hold until a valid eCopy is received. As shown in Figure 3-25, the percentage and number of submissions without any eCopy holds increased from 74% in CY2013 to 92% in CY2017. During the same period, the percentage of eCopy submissions that underwent more than one hold (eCopies that required multiple rounds of correction to meet FDA’s technical standards) decreased from more than 6% to approximately 1%, suggesting that sponsors became more proficient at addressing issues in initially-deficient eCopies.



\*Includes mandatory and voluntary eCopies of all original submissions, amendments or supplements  
Source: FDA data systems

**Figure 3-25. Number of submissions undergoing eCopy holds by number of holds and calendar year**

The trend in eCopy holds indicates that sponsors are increasingly aware of FDA’s procedural recommendations and technical standards regarding the generation and submission of eCopies. Because the number of eCopy holds improved

before the 2015 update to the Guidance, it is likely that sponsor familiarity with eCopy submission also impacted eCopy hold rates.

According to an internal CDRH analysis, the updates to the eCopy Guidance did not increase the number of submissions with bookmarks. The Center postulates that this could be because submissions are often split into several PDFs, and bookmarks cannot be made across files. By implementing the Digital Transformation and electronic submission changes outlined in the MDUFA IV Commitment Letter, CDRH will be able to pursue updates that will aid reviewers in their review.

## CONCLUSIONS

As demonstrated by Booz Allen’s analysis of the implementation of the updated eCopy Guidance, the enhancements to the eCopy Validation Module, and the trend of eCopy holds, FDA addressed many initial challenges of the eCopy Program. FDA provided sponsors with clearer procedural recommendations and technical specifications regarding eCopies through the implementation of the December 2015 updated eCopy Guidance. To further guide sponsors in submitting eCopies that meet the technical standards specified in the Guidance, CDRH deployed and continuously enhances the eCopy Validation Module based on analysis of applicant errors during eCopy submission. These actions appear to have increased clarity of the eCopy submission process, as reflected in the continuously decreasing incidence of eCopy holds. With more than 90% of submissions providing initially valid eCopies in 2017, the eCopy Program attained a high level of efficiency and maturity.

Per FDA’s commitment under MDUFA IV to create electronic submission templates, the process of sponsor submission will continue to evolve. Additionally, the proposed rule announced in September 2018 would remove the requirement for sponsors to submit paper copies of their applications, further streamlining the submission process.<sup>18</sup>

## 3.4 Submission Review: Quality Management

The implementation projects aligned under “Quality Management in Submission Review” aim to make quality-focused changes to the premarket review process to improve decision-making consistency.

### RECOMMENDATION 1C\*: REVIEW PROCESS QUALITY METRICS

During the Phase 1 Independent Assessment, Booz Allen found that CDRH senior management placed significant emphasis on MDUFA goal milestones for managing review process performance. Audits and analyses performed by CDRH revealed that several submissions that did not meet the MDUFA performance goal also missed interim milestones. These observations led to Recommendation 1c: Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate CPI.

## PHASE 2 FINDINGS

Booz Allen’s Phase 2 Independent Assessment found that CDRH completed gap analyses of review process performance management and identified a set of metrics to further support premarket review CPI. CDRH selected five premarket review areas for monitoring and CPI: RTA decisions, Advisory Panel, Consult Review, SI, and Final Decision. For each area, CDRH proposed short-term, long-term, and validation measures to enable well-rounded review performance evaluation and management.

## INITIAL RESULTS

Booz Allen evaluated initial results by assessing the adoption and tracking of premarket review process metrics. We found that while publicly reported MDUFA metrics<sup>19</sup> continue to serve as the foundation for CDRH’s review process performance management, they are complemented by a set of internal metrics refined from the initial measures that

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<sup>18</sup> [Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Allowed in Electronic Format](#) (September 2018)

<sup>19</sup> [MDUFA Quarterly Performance Reports](#) (September 2018)

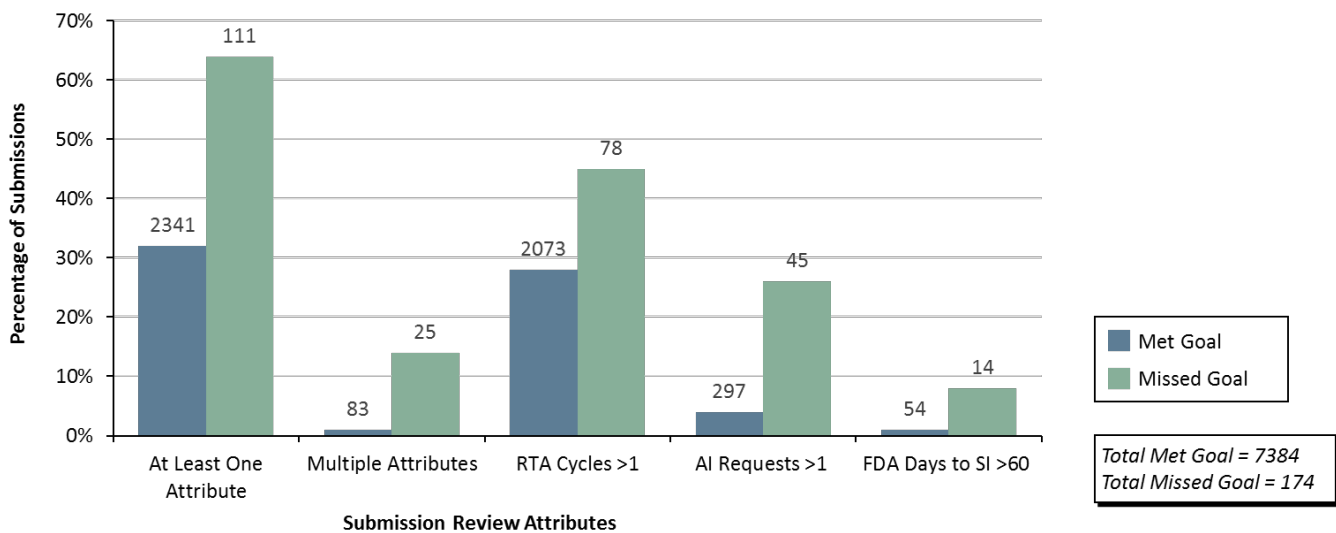


CDRH proposed in Phase 2. CDRH reports MDUFA performance metrics, both publicly through quarterly reports and internally on a weekly-to-monthly basis, by analyzing data retrieved from CARS. The internally tracked metrics enable CDRH branch managers to prioritize additional oversight of review sub-processes specific to each branch’s needs. To further support internal analysis and visualization of premarket review performance, CDRH is developing and refining additional business objects dashboards. The consistent reporting of MDUFA metrics, combined with more frequent internal tracking of review performance, support MDUFA stakeholder engagement and CDRH’s premarket review performance management.

## OUTCOMES

To assess outcomes, Booz Allen evaluated the effectiveness of interim premarket review performance metrics and obtained CDRH management feedback on the impact of performance metrics on premarket review CPI.

Booz Allen analyzed performance data from the FY2015–FY2017 Traditional 510(k) Receipt Cohort to identify review attributes that differentiate submissions that met or missed the MDUFA performance goal of 90 FDA Days to Final Decision. Among the 7,558 submissions with MDUFA decisions, only 174 (2%) missed the 90-day goal. Of the submissions that missed the 90-day goal, 29% missed by five or fewer days, 37% missed by six to 10 days, and 34% missed the goal by more than 10 days. As shown in Figure 3-26, compared to submissions that met the goal date, those that missed the goal were more likely to possess at least one of the following interim review attributes: more than one RTA cycle, more than one AI request, or more than 60 FDA Days until SI. More than one AI request or more than 60 FDA Days to SI appeared to be stronger indicators than more than one RTA cycle. While 64% of submissions that missed the review goal had one of these attributes, many submissions were not flagged by these specific metrics.



Source: FDA data systems

**Figure 3-26. Percentage of submissions with identified review attributes by goal status**

As demonstrated in Figure 3-26, interim review attributes can serve as potential indicators to inform submission-level performance management to meet MDUFA performance goals. The highlighted attributes are tracked based on existing 510(k) review metrics that CDRH publicly reports in MDUFA Quarterly Reports and that are internally monitored.

Booz Allen sought CDRH management feedback to further understand the impact of review performance metrics on premarket review CPI. CDRH office and division leaders noted that the defined set of MDUFA performance metrics provide valuable baselines to assess the Center’s premarket review performance trends. The publication of MDUFA Quarterly Reports serve as an opportunity for CDRH leadership to review the Center’s premarket review performance. Utilizing the MDUFA Quarterly Reports and the associated performance reviews, offices and divisions perform analysis of premarket review performance and conduct internal meetings to address any performance issues or trends.

CDRH also collected ODE staff feedback to design and launch a series of programs (initiated as pilots) aimed at improving TTD performance. Two programs modified based on staff feedback were the previously described RTA Addendum and

Day 10 Call programs (see Recommendation 3: Refuse To Accept (RTA) Process Improvement and Recommendation 4: Withdrawn Submission Analyses, and Recommendation 5: Sponsor Communications), both of which were piloted beginning in July 2017 and implemented Center-wide in June 2018. CDRH continuously evaluates the outcomes of and staff feedback regarding these pilots and intends to refine these programs in support of premarket review CPI in the future.

Office and division leaders suggested two potential areas for improvement to further support the Center's premarket review CPI. First, advanced analytics and modeling of CDRH's review performance data may identify additional review attributes to enable predictive performance management on the submission level. While current metrics inform retrospective trend analysis and prospective performance management in CDRH divisions and branches, CDRH managers noted that additional measures or tools to support the management of each submission and to preemptively identify and address performance issues would benefit the Center. Second, tools that visualize MDUFA and internal metrics in real-time may help streamline review performance management at all levels within the Center and enable management intervention during submission review.

## CONCLUSIONS

CDRH leadership is committed to premarket review performance management and CPI, as reflected by the Center's frequent internal review and analysis of review performance. The tracking and reporting of MDUFA performance metrics and the internal monitoring of additional metrics enabled CDRH to perform efficient premarket review, contributing to a high percentage (98%) of Traditional 510(k)s meeting the MDUFA performance goal of 90 FDA Days to Final Decision during FY2015–FY2017. Analysis of attributes of submissions that missed the 90-day goal highlights the potential of review performance metrics to identify these submissions. Additional resources, such as metrics that are more predictive in nature and visualization tools that enhance the tracking and analysis of performance metrics, may further augment performance management as CDRH continues to improve the premarket review process.

## RECOMMENDATION 2: DECISION-MAKING CONSISTENCY

During Phase 1, Booz Allen reviewed issues previously identified during the MDUFA II timeframe and found that inconsistent decision-making throughout the review process remained a concern in MDUFA III. Concerns included a lack of transparency regarding AI thresholds and referencing outdated guidances or non-finalized standards. These findings led to Recommendation 2: Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process.

## PHASE 2 FINDINGS

During the Phase 2 Independent Assessment, we found that CDRH had taken a number of actions aimed to improve decision-making consistency. One of the most significant changes was the creation of the 510(k) SMART memo template to guide reviewers during the premarket review process. This template provides suggested language and regulations relevant to submission information. Additionally, the Center created and deployed the *Management Oversight of Critical Control Points* SOP. This SOP outlines management responsibilities at each stage in the review process, including concurrence and review of findings and recommendations for quality and scientific/regulatory appropriateness in LR memos. Finally, while business process maps for most review types existed, CDRH created a business process map to guide biocompatibility review with the intention for it to potentially be applied to reviews in other cross-cutting areas.

## INITIAL RESULTS

To assess initial results of CDRH's implementation activities, Booz Allen documented additional actions taken toward improving decision-making consistency and evaluated staff awareness of CDRH-established resources and mechanisms.

### *SMART Memo*

After a period of voluntary use, mandatory use of the 510(k) SMART memo began in ODE in October 2015.<sup>20</sup> From September 2015 through April 2018, CDRH provided the following trainings on the 510(k) SMART memo:

- ODE Premarket Rounds (September 2015, January 2017)
- Required ODE division-level trainings (October 2015, January – May 2016, August – October 2017)
- ODE online on-demand training (available beginning December 2015, updated February 2017)
- RCP Training incorporating SMART memo template material (beginning July 2016)
- Premarket Rounds Cybersecurity subtemplate training (August 2016)
- Premarket Rounds Wireless Technology subtemplate training (June 2017)
- DNPMD Division Reps Detailed Training (November 2017)
- IVD 510(k) Beta to OIR Division Reps (March 2018)
- CDRH Premarket Q/A Training (April 2018)

Based on the required trainings on this topic and feedback obtained from Branch Chief and Lead Reviewer interviews, it appears that staff are well aware of this resource.

### *Management Oversight*

In November 2015, CDRH introduced the *Management Oversight of Critical Control Points in Premarket Review* SOP. According to Branch Chief interviews, managers are aware of this SOP. Interviewees believe that this SOP formalized processes that were already common practices across the Center.

### *Guidance Development*

According to interviews and free-response survey questions, CDRH staff believe that guidances improve decision-making consistency. CDRH is making continuous efforts to provide guidances to aid reviewers and industry. MDUFA quarterly reports show that over the MDUFA III timeframe, CDRH issued 241 draft guidances, guidance updates, and final guidances. Approximately half were device-specific.

### *Biocompatibility*

Of the cross-cutting areas of premarket review, CDRH focused on improving consistency of biocompatibility review before expanding to additional cross-cutting areas. To that end, on June 16, 2016, FDA released the final *Use of International Standard ISO 10993-1 “Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process”* Guidance. Following Guidance release, CDRH offered required general training and voluntary biocompatibility risk assessment training to all ODE and OSEL review staff and managers responsible for lead or consulting biocompatibility reviews. There were 435 and 136 participants for the two courses, respectively. Since then, CDRH has offered these trainings in an online, on-demand format.

CDRH also piloted a Biocompatibility Focal Point Program (FPP) in November 2016 to promote quality and consistency in premarket review practices. Through this program, reviewers obtain a base level of knowledge to perform biocompatibility reviews that only require core competencies. Select staff, including designated focal points who have advanced expertise, receive additional competency training to assist in more complicated reviews. Focal points work with reviewers to determine the type of review needed and identify appropriate consultants. The Center expanded the FPP in August 2017 to all ODE divisions. According to the Booz Allen administered survey, 93% of ODE respondents that perform or oversee biocompatibility reviews and consults are familiar with the biocompatibility FPP.

## OUTCOMES

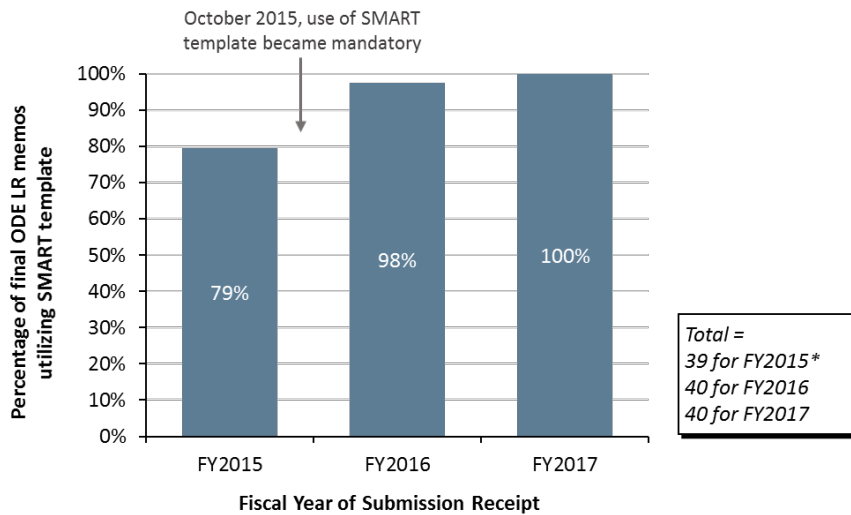
To assess outcomes related to decision-making consistency, Booz Allen evaluated the use of CDRH-developed resources and mechanisms as well as staff feedback on the impact of these resources on the premarket review process.

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<sup>20</sup> ODE mandated use of the De Novo SMART memo in January 2017 and the Q-submission SMART memo for Pre-Submissions in October 2017. Online template training became available February 2017. A period of voluntary use preceded mandatory use in each case.

### SMART Memo

Booz Allen assessed adoption of the 510(k) SMART memo in ODE in the FY2015, FY2016, and FY2017 MDUFA Audit Cohorts. As shown in Figure 3-27, once use of the SMART memo became mandatory in ODE, adoption was close to 100%. Even in FY2015 when use of the template was still voluntary, 79% of final ODE LR memos used the template.

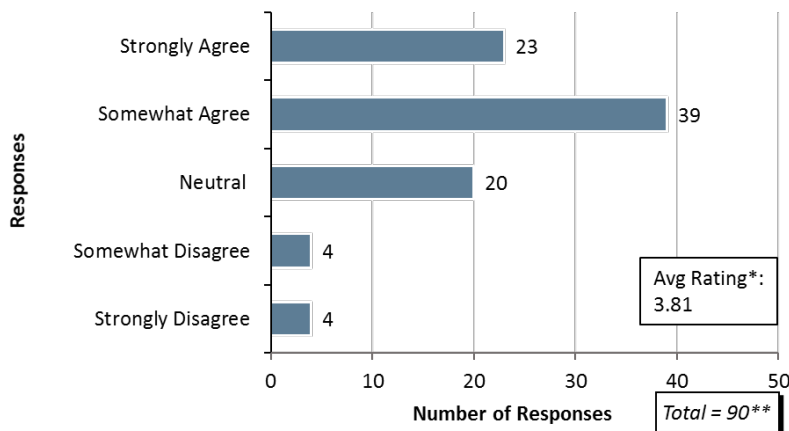


\*Final Lead Reviewer Memo could not be located in DocMan for one FY2015 submission  
Source: Booz Allen Traditional 510(k) audit

**Figure 3-27. ODE adoption of SMART memo by fiscal year**

These results are similar to ODE’s audit of 14 Traditional 510(k) submissions from 2015 and 50 from 2017, which showed an increase in use of the SMART memo from 64% to 100%. At the time of this assessment, in most OIR divisions, use of the Traditional 510(k) SMART memo template was not yet mandatory and was not analyzed.<sup>21</sup> Although use of the SMART memo has been voluntary in OIR’s Division of Radiological Health (DRH), Booz Allen found 100% adoption in FY2015, FY2016, and FY2017 in a total of 15 audited submissions.

Staff are using the 510(k) SMART memo and, as demonstrated in Figure 3-28, most survey respondents believe that the 510(k) SMART memo has improved decision-making consistency. This is consistent with feedback from interviewed Branch Chiefs and Lead Reviewers.

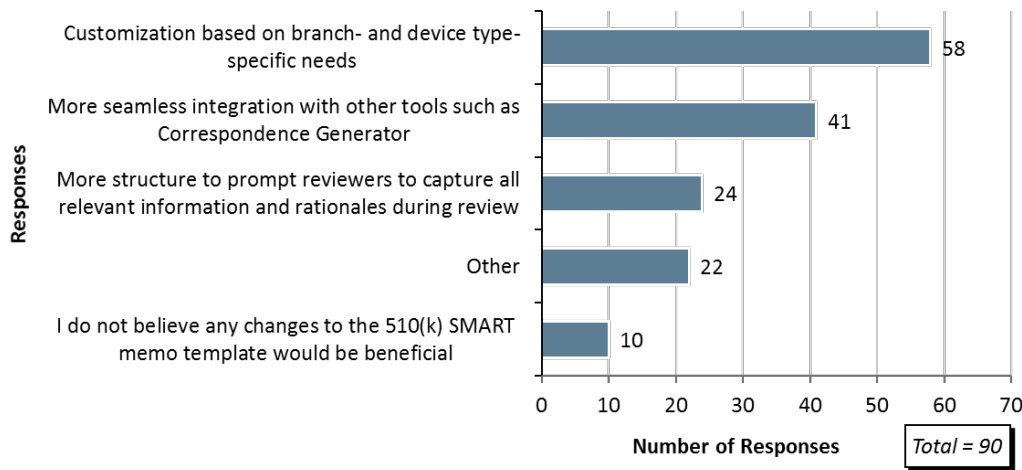


\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree  
\*\*Excluding 46 respondents who did not use or oversee staff who use the SMART memo template for 510(k) Lead Reviewer memos  
Source: Survey conducted by Booz Allen

**Figure 3-28. Survey respondents’ agreement with the statement: The 510(k) SMART memo template has improved the consistency of 510(k) review**

<sup>21</sup> CDRH and OIR are in the process of developing a Smart template for IVD 510(k) reviews. The template is currently in a pilot phase.

CDRH continues to update the 510(k) SMART memo to further improve decision-making consistency. In combination with the Biocompatibility Guidance and FPP, CDRH updated the biocompatibility section of the memo. As displayed in Figure 3-29, when asked what additional changes would be beneficial, survey respondents prioritized customization of the 510(k) SMART memo based on branch- and device type-specific needs, and more integration with other tools such as the Correspondence Generator. Booz Allen included specific options in the survey based on feedback from interviewees and it appears that these two potential improvements would be most supported by CDRH review staff.



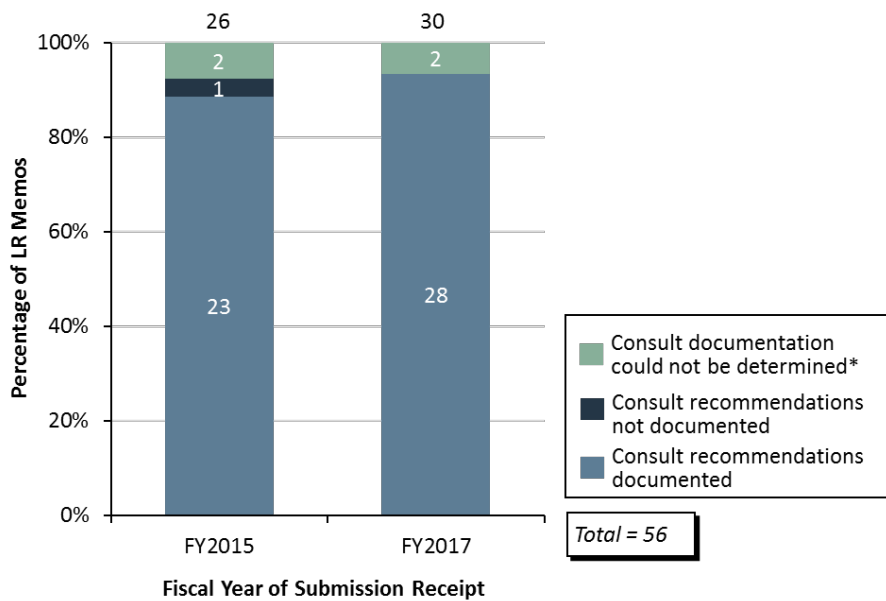
Note: Two respondents that selected they did not believe changes to be beneficial also selected one of the preceding options  
 Source: Survey conducted by Booz Allen

**Figure 3-29. Survey responses to the question: Which (if any) of the following changes to the 510(k) SMART memo template would be beneficial? (select all that apply)**

Topics covered by the “Other” category included the ability to link with other systems (e.g., from CTS or directly with the submission contents), increased flexibility for device specific issues and more “optional” structure, and comments that the current memo is too long and burdensome.

### Management Oversight

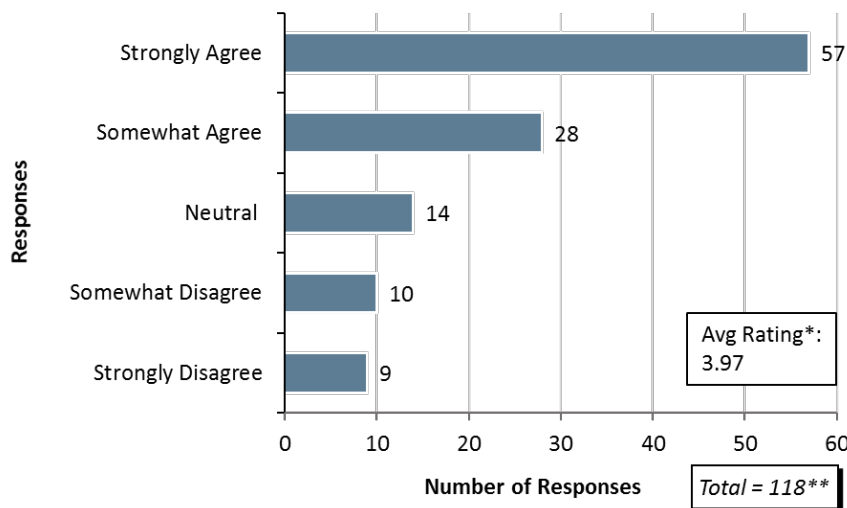
CDRH’s *Management Oversight of Critical Control Points in Premarket Review SOP*, effective November 27, 2015, outlines procedures for concurrence at critical control points (CCPs) (i.e., RTA1, AI, and Final Decision) during review and for evaluation of acceptable review quality and appropriate scientific and regulatory recommendations in LR memos. To evaluate the change in adherence to procedures in the SOP, Booz Allen first assessed documentation of concurrence at CCP in FY2015 and FY2017 submissions from the MDUFA Audit Cohort. Since concurrence is built into the review workflow, we saw 100% documented concurrence in CTS at CCPs, even in FY2015 before the SOP became effective. Next, we evaluated whether the LR memo incorporated descriptions of consults that were logged in CTS. In the FY2015 and FY2017 MDUFA Audit Cohorts, we found 26/50 (52%) submissions in FY2015 and 30/50 (60%) in FY2017 had consults. As demonstrated in Figure 3-30, for submissions where consult documentation could be determined, Booz Allen found that 23/24 (96%) of FY2015 submissions had consult recommendations documented in the LR memo. This provided a high baseline before SOP implementation and documentation rose to 28/28 (100%) in FY2017. We concluded that managers adhere to the *Management Oversight of Critical Control Points in Premarket Review SOP*.



\*Documentation of consult recommendations could not be determined in four submissions with consults listed in CTS where consult memos were not included in DocMan records  
 Source: Booz Allen audit of Traditional 510(k) submissions that had consult reviews in CTS, excluding non-signatory consults and one submission where only draft LR memo was available

**Figure 3-30. Documentation of consult recommendations in Lead Reviewer memo by fiscal year**

Booz Allen surveyed staff to see if they believe they receive consistent feedback and/or oversight during premarket review. As illustrated in Figure 3-31, 72% (85/118) of respondents indicated that they are receiving consistent feedback.



\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree

\*\*Excluding 18 respondents who did not produce premarket review memos or letters

Source: Survey conducted by Booz Allen

**Figure 3-31. Survey respondents' agreement with the statement: In recent years, my managers have provided consistent feedback and/or oversight for the memos and letters I wrote during interim and final steps of premarket review**

### Biocompatibility

Following issuance of the final *Use of International Standard ISO 10993-1 "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process"* Guidance, CDRH provided two trainings on the Guidance. As illustrated in Table 3-3, base knowledge before the training was quite high and increased to scores over 90% after reviewers participated in the training. These data demonstrate that participants are leaving training with the intended

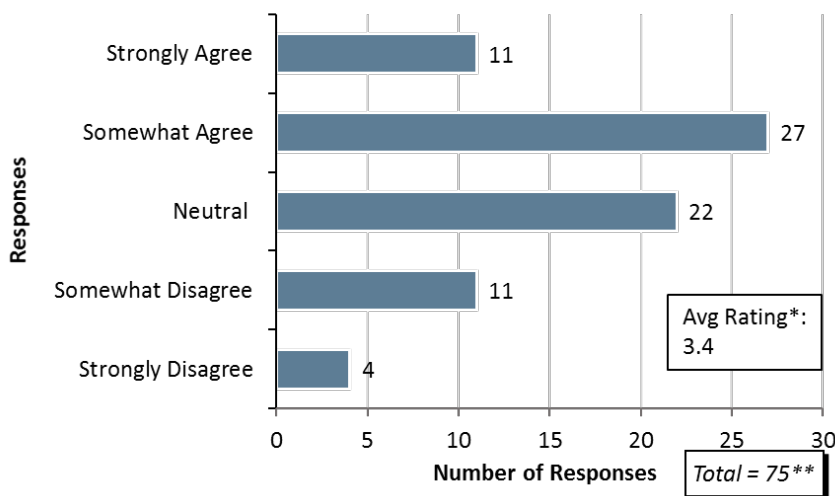


knowledge. For future training offerings, CDRH could consider adding more advanced content since the base knowledge was initially high.

**Table 3-3. Biocompatibility training test scores**

| TRAINING COURSE                                     | PRE-TEST SCORES | POST-TEST SCORES |
|---|-----------------|------------------|
| Mandatory Biocompatibility General Training         | 81%             | 92%              |
| Voluntary Biocompatibility Risk Assessment Training | 80%             | 91%              |

CDRH also evaluated their pilot biocompatibility FPP before expanding the program premarket-wide. In a CDRH-issued survey of pilot participants, 78% of the 68 respondents felt that the biocompatibility FPP pilot had increased consistency. To determine staff reaction to the biocompatibility FPP once it was expanded, Booz Allen again surveyed staff on the impact of the FPP on consistency. As shown in Figure 3-32, we found that approximately half (38/75) of survey respondents think the FPP has improved consistency of biocompatibility reviews and consults.



\*The average ratings are weighted averages on a scale of 1-5; 1: strongly disagree, 2: somewhat disagree, 3: neutral, 4: somewhat agree, 5: strongly agree

\*\*Excluding 53 respondents who did not perform or oversee biocompatibility reviews/consults and eight who were unfamiliar with the FPP

Source: Survey conducted by Booz Allen

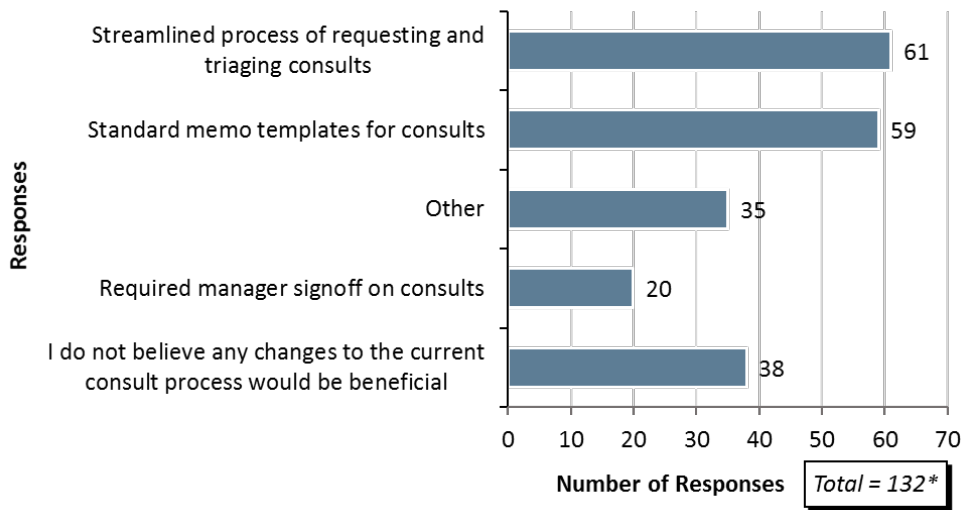
**Figure 3-32. Survey respondents' agreement with the statement: The Biocompatibility Focal Point Program (FPP) has improved the consistency of biocompatibility reviews and consults**

To determine if the FPP is being used as intended, CDRH performed an in-depth analysis of recent ODE biocompatibility reviews. CDRH found that reviewers followed the FPP procedures in 29/31 biocompatibility reviews. These data demonstrate that reviewers performed their own biocompatibility review only when core competencies were required for review (Tier 1). When more complex Tier 2 (moderate complexity) or Tier 3 (high complexity) reviews were required, staff requested biocompatibility consults appropriately. These results are in line with interview responses from biocompatibility focal points who believe the program is being utilized as intended. Interviewees also outlined additional program details that they believe are further improving consistency of biocompatibility review, such as monthly meetings to discuss complex biocompatibility issues. A subset of interviewed reviewers commented that after implementation of the final Biocompatibility Guidance, their reviews became more consistent with those of the rest of CDRH but were less consistent with the previous policy for some specific device-types.

### Consults

Booz Allen asked survey respondents if they believe specific changes to the consult process would benefit decision-making consistency. As shown in Figure 3-33, we found that the majority of respondents would like to see a streamlined process of requesting and triaging consults and/or standard memo templates for consults, while almost a third of

respondents do not want to see changes to the consult process. Themes from “Other” included better management of consultant workload, clearer expectations of consult timeline, the addition of signoff from qualified individuals, and better training for consultants. Based on these results, there appear to be opportunities to further improve the consult process.



Note: Three respondents that selected they did not believe changes to be beneficial also selected one of the options other than “Other”  
 \*Excluding four respondents who did not perform, request, or oversee consults  
 Source: Survey conducted by Booz Allen

**Figure 3-33. Survey responses to the question: Which (if any) changes to the MDUFA premarket submission consult process would be beneficial (for consults within or across CDRH division and offices; excluding consults to/from CBER or CDER)? (select all that apply)**

*Additional Information Letters*

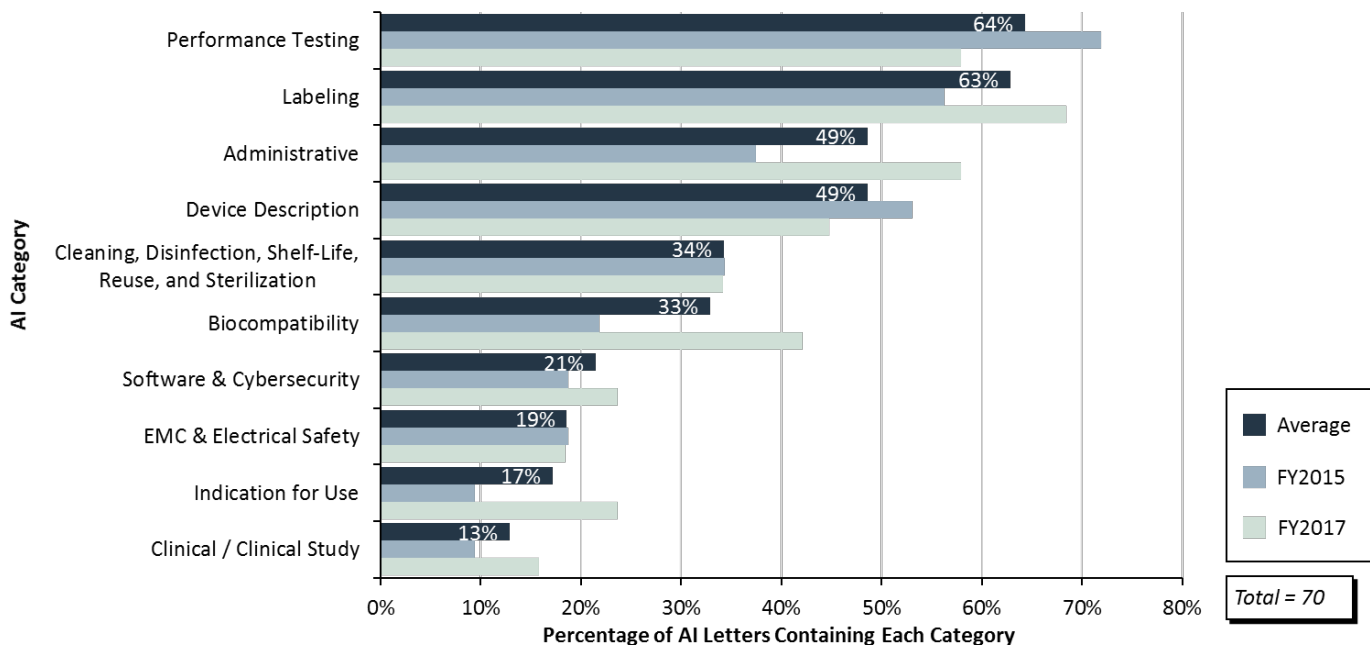
To determine the impact of CDRH staff adoption of mechanisms aimed at improving decision-making consistency, Booz Allen analyzed AI letters from the FY2015 and FY2017 MDUFA Audit Cohorts. The Audit Cohorts contained 79 AI letters: 37 from FY2015 and 42 from FY2017. As shown in Table 3-4, we found that the average number of deficiencies per letter was similar between FY2015 and FY2017. The average pages per letter and the average reviewer designated deficiency categories per letter slightly increased in FY2017, as compared to FY2015.

**Table 3-4. AI letter characteristics**

| CHARACTERISTICS                            | FY2015 | FY2017 |
|--|--------|--------|
| Average Deficiencies per Letter*           | 9.8    | 10.3   |
| Average Pages per Letter                   | 3.8    | 5.4    |
| Average Deficiency Categories per Letter** | 3.8    | 5      |

\*Does not include subparts of each deficiency  
 \*\*Category analysis only includes 70 letters in which deficiencies were categorized by the reviewer  
 Source: Booz Allen Traditional 510(k) audit

When Booz Allen assessed the top 10 categories of deficiencies in the audited AI letters, we found that the most common review designated deficiency categories were Performance Testing and Labeling (Figure 3-34). Results for the top four categories were similar to the Phase 1 analysis. In FY2017, the frequency of AI letters containing deficiencies in Administrative, Biocompatibility, and Indication for Use categories increased as compared to FY2015. While the content of these letters is device- and submission-specific, this analysis shows areas in which deficiencies often are included in AI requests.



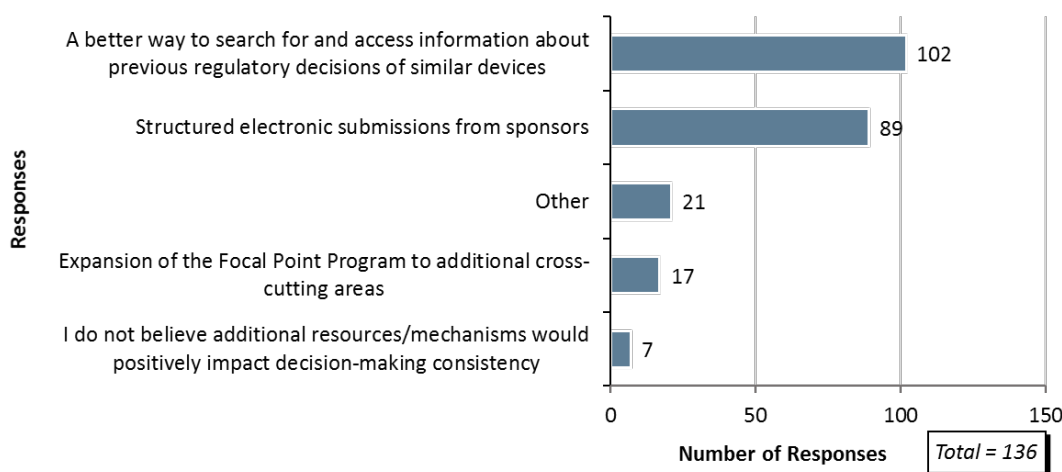
Category analysis only includes 70 letters in which deficiencies were categorized by the reviewer  
 Source: Booz Allen Traditional 510(k) audit

**Figure 3-34. Top 10 reviewer designated categories of AI letter deficiencies**

Booz Allen’s limited sample analysis suggests that while FY2017 AI letters do not contain more issues, they include many different types of deficiencies. Under recent Least Burdensome provisions,<sup>22</sup> major and minor deficiencies will be differentiated. This will allow future evaluations of AI letters to better characterize deficiencies.

*Overall*

As demonstrated above, surveyed staff believe that specific resources and mechanisms have improved decision-making consistency. They also believe that, as a whole, CDRH-provided resources improved premarket review decision-making consistency. Booz Allen also surveyed staff to determine if certain overarching changes, derived from interview responses, would benefit decision-making consistency. As illustrated in Figure 3-35, most respondents would like a better way to search for and access information about previous regulatory decisions of similar devices and structured electronic submissions from sponsors.



Source: Survey conducted by Booz Allen

**Figure 3-35. Survey responses to the question: Which (if any) of the following would positively impact premarket review decision-making consistency? (select all that apply)**

<sup>22</sup> [Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions – Guidance for Industry and Food and Drug Administration Staff](#)

At the end of the survey, Booz Allen provided the opportunity for respondents to provide unstructured overall feedback. Much of the open feedback related to specific questions. For example, some of the responses referred to overhauling the IT system to create an all-in-one program that centrally houses all submission information and allows for better search capabilities. Some survey responses commented on the impact of more than one topic; for example, some respondents felt that the implementation of multiple pilots and process changes in a short period of time can make it difficult to perform their reviews efficiently.

## CONCLUSIONS

Staff are aware of and use CDRH-developed resources and mechanisms aimed at improving review consistency, including the SMART memo, the biocompatibility FPP, and structured management oversight. Adoption of the 510(k) SMART memo was close to 100% in applicable divisions. Since the expansion of the biocompatibility FPP, staff are performing tiered reviews as intended, and managers appear to be providing consistent feedback at CCPs throughout the premarket review process. Overall, staff believe that these resources are improving decision-making consistency and that some fine-tuning could further improve consistency. As the Center expands the FPP into magnetic resonance, electromagnetic compatibility, and other cross-cutting areas, they can learn from the successes and best practices of the biocompatibility FPP.

Two new large changes that staff believe would be impactful are improved means to search for and access information about previous regulatory decisions of similar devices, and structured electronic submissions from sponsors. Digital Transformation may provide an opportunity for CDRH to re-evaluate and update the software programs that sponsors use to further streamline premarket review. Regarding structured electronic submissions, in September 2018, CDRH introduced their new Quality in 510(k) Review Program Pilot to help determine if FDA’s eSubmitter will improve efficiency of reviews.<sup>23</sup> Additionally, under MDUFA IV, FDA will develop electronic submission templates for industry. CDRH is aware that these larger changes may increase review efficiency and increase decision-making consistency and is pursuing some of these enhancements.

## 4. PROPOSED NEXT STEPS

Booz Allen identified areas where CDRH could build upon the recommendations already addressed.

To achieve the reduced TTD goals under MDUFA IV, FDA and industry must work together to benefit from efficiencies gained under MDUFA III. While performing the MDUFA IV Phase 1 Independent Assessment, Booz Allen observed areas for additional improvements to further optimize the premarket review. Addressing these areas would allow CDRH to capitalize on its previous successes and further enhance its business processes. We outline our key observations and potential actions in Table 4-1.

**Table 4-1. Observations and potential actions identified by Booz Allen to improve CDRH review of sponsor submissions**

| IMPACT AREA     | KEY OBSERVATION   | POTENTIAL ACTIONS   |
|-----------------|---|---|
| CDRH Operations | CDRH relies on multiple IT systems to perform medical device submission review  | FDA should consider consolidating or enhancing the integration of CDRH’s IT systems to provide an all-in-one location for pre- and post-market information.   |
|                 | Tools to assign workload do not include specifics that affect the required effort to perform a review of a submission | FDA should consider building workload tools that more accurately reflect the level of effort required for submission review to include submission nuances such as bundling or the inclusion of clinical data. |

<sup>23</sup> [Quality in 510\(k\) Review Program Pilot](#)

| IMPACT AREA         | KEY OBSERVATION   | POTENTIAL ACTIONS  |
|---------------------|---|--|
| CDRH Staff Training | Staff believe that the timing of RCP could be further optimized   | RCP is currently administered in-person every two months for a total of six cohorts being offered per year. To accommodate different onboarding schedules, FDA should consider providing more online, on-demand training or more frequent in-person sessions for RCP.  |
| Submission Review   | The withdrawal rate of accepted submissions has been steady for the past several years  | FDA is required to perform a MDUFA IV withdrawal audit to be completed by FY2022. FDA should consider focusing their analysis on submissions that are of most concern to industry (i.e., submissions withdrawn close to the end of the FDA review clock and/or submissions that are resubmitted shortly after withdrawal and receive a final decision quickly thereafter). |
|                     | Interactive communications with sponsors often begin after the SI decision  | FDA should continue to promote earlier interactions with sponsors to begin resolving submission issues earlier in the review process.  |
|                     | Review performance metrics are usually used retrospective to identify trends  | To enable identification of submissions in real-time that require corrective actions, FDA should consider using enhanced analytics and expanded visualizations to develop metrics that are predictive. This will help prevent missing MDUFA goal dates or having longer than expected TTD.   |
|                     | Staff believe that better search capabilities for language used in past regulatory decisions will positively impact decision-making consistency | FDA should consider prioritizing enhancements to the review systems to allow staff to access submission information from past reviews more easily.   |
|                     | Staff believe that structured electronic submissions will positively impact decision-making consistency   | FDA should continue to develop resources to aid sponsors in providing structured electronic submissions with the ultimate goal of increased consistency and efficiency for review staff.   |

While there were also some more focused suggestions for improvement from staff that FDA should consider, we believe that an initial focus on the recommendations outlined above will have widespread impact on the premarket review process. With CDRH's OPEQ pilot and Digital Transformation, the Center will be undergoing many changes simultaneously, to keep up with evolving technology and internally/externally driven demands. The Center should carefully manage the impact that these and any additional changes may have on staff to ensure smooth implementation and adoption.

## 5. APPENDIX

### 5.1 Glossary

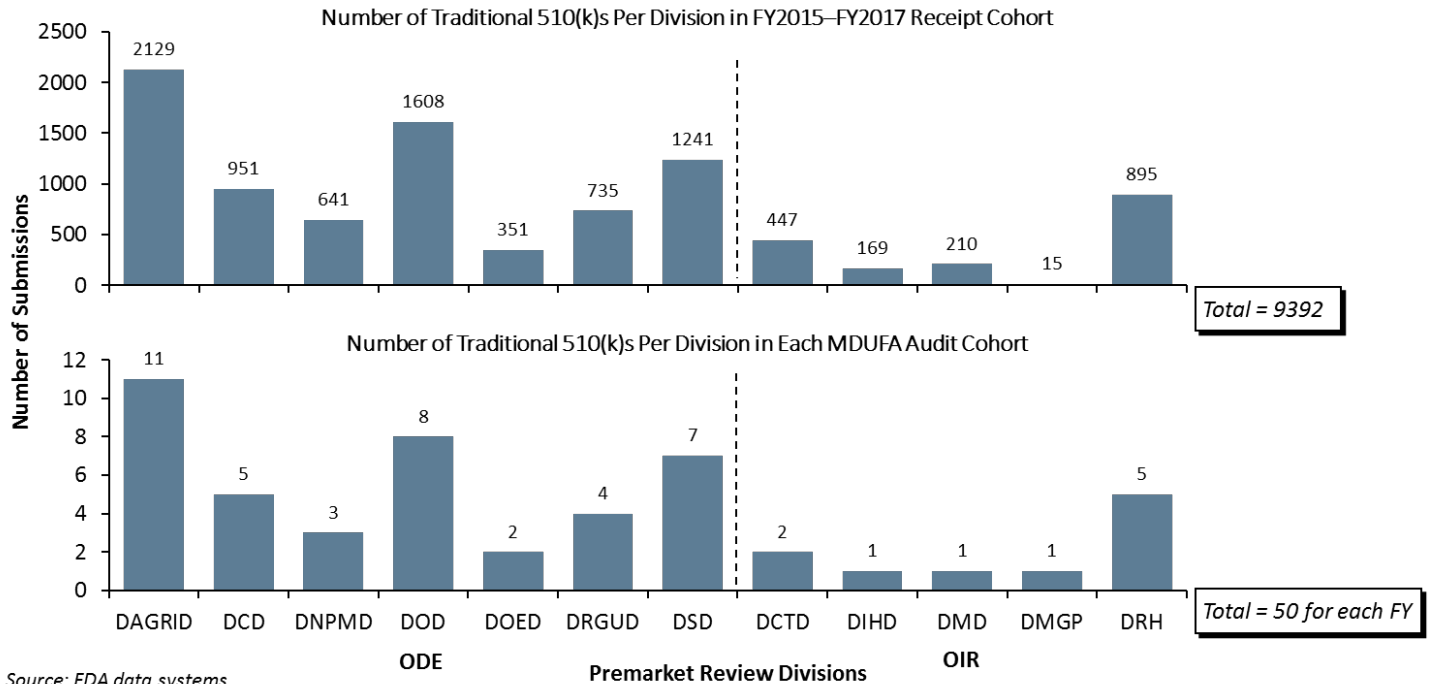
**Table 5-1. Glossary of abbreviations and acronyms**

| ABBREVIATION OR ACRONYM | DEFINITION  |
|-------------------------|---|
| 510(k)                  | Premarket Notification  |
| AdvaMed                 | Advanced Medical Technology Association   |
| AI                      | Additional Information  |
| CAPA                    | Corrective and Preventative Actions   |
| CARS                    | CDRH Ad Hoc Reporting System  |
| CCP                     | Critical Control Point  |
| CDRH                    | Center for Devices and Radiological Health  |
| CPI                     | Continuous Process Improvement  |
| CTS                     | Center Tracking System  |
| CY                      | Calendar Year   |
| DAGRID                  | Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices |
| DCD                     | Division of Cardiovascular Devices  |
| DCS                     | Document Control System   |
| DCTD                    | Division of Chemistry and Toxicology Devices  |
| DETD                    | Division of Employee Training and Development   |
| DIHD                    | Division of Immunology and Hematology Devices   |
| DMD                     | Division of Microbiology Devices  |
| DMGP                    | Division of Molecular Genetics and Pathology  |
| DNPMD                   | Division of Neurological and Physical Medicine Devices  |
| DOD                     | Division of Orthopedic Devices  |
| DOED                    | Division of Ophthalmic and Ear, Nose and Throat Devices   |
| DRGUD                   | Division of Reproductive, Gastro-Renal, and Urological Devices                                  |
| DRH                     | Division of Radiological Health   |
| DSD                     | Division of Surgical Devices  |
| ELP                     | Experiential Learning Program   |
| FDA                     | Food and Drug Administration  |
| FPP                     | Focal Point Program   |
| FY                      | Fiscal Year   |
| IDE                     | Investigational Device Exemption  |
| IR                      | Interactive Review  |
| IT                      | Information Technology  |
| LEAD                    | Leadership Enhancement and Development  |
| LMS                     | Learning Management System  |



| ABBREVIATION OR ACRONYM | DEFINITION   |
|-------------------------|--|
| LR                      | Lead Reviewer  |
| LRP                     | Leadership Readiness Program                           |
| MDMA                    | Medical Device Manufacturers Association               |
| MDUFA                   | Medical Device User Fee Amendments                     |
| MDUFMA                  | Medical Device User Fee and Modernization Act          |
| MITA                    | Medical Imaging and Technology Alliance                |
| NSE                     | Not Substantially Equivalent                           |
| OC                      | Office of Compliance                                   |
| ODE                     | Office of Device Evaluation                            |
| OIR                     | Office of In Vitro Diagnostics and Radiological Health |
| OPEQ                    | Office of Product Evaluation and Quality               |
| OSB                     | Office of Surveillance and Biometrics                  |
| OSEL                    | Office of Science and Engineering Laboratories         |
| PITSC                   | Premarket IT Steering Committee                        |
| PMA                     | Premarket Approval                                     |
| QM                      | Quality Management                                     |
| QMB                     | Quality Management Board                               |
| RCP                     | Reviewer Certification Program                         |
| RTA                     | Refuse to Accept                                       |
| RTA1                    | Refuse to Accept – Decline Decision                    |
| RTAA                    | Refuse to Accept – Approval Decision                   |
| SE                      | Substantially Equivalent                               |
| SI                      | Substantive Interaction                                |
| SOP                     | Standard Operating Procedure                           |
| TTD                     | Total Time to Decision                                 |
| UAT                     | User Acceptance Testing                                |
| WI                      | Work Instructions                                      |

## 5.2 Characteristics of FY2015–FY2017 Receipt Cohort and MDUFA Audit Cohorts



**Figure 5-1. Number of Traditional 510(k)s in the FY2015–FY2017 Receipt Cohort and each MDUFA Audit Cohort by division**

**Table 5-2. Comparison of key characteristics of FY2015–FY2017 Receipt Cohort and MDUFA Audit Cohorts**

|   | Receipt Cohort | FY2015 MDUFA Audit Cohort | FY2016 MDUFA Audit Cohort | FY2017 MDUFA Audit Cohort |
|---|----------------|---------------------------|---------------------------|---------------------------|
| Number of submissions   | 9392           | 50                        | 50                        | 50                        |
| Number of submissions with MDUFA decisions (SE/NSE)                   | 7558           | 50                        | 50                        | 50                        |
| Rate (number) of SE decisions in submissions with MDUFA decisions     | 96% (7238)     | 98% (49)                  | 90% (45)                  | 94% (47)                  |
| Rate (number) of NSE decisions in submissions with MDUFA decisions    | 4% (320)       | 2% (1)                    | 10% (5)                   | 6% (3)                    |
| Rate (number) of first-cycle RTA1 in submissions with MDUFA decisions | 28% (2151)     | 28% (14)                  | 22% (11)                  | 30% (15)                  |
| Rate (number) of AIs in submissions with MDUFA decisions              | 76% (5780)     | 72% (36)                  | 74% (37)                  | 82% (41)                  |

## About Booz Allen

Booz Allen Hamilton has been at the forefront of strategy and technology for more than 100 years. Today, the firm provides management and technology consulting and engineering services to leading *Fortune* 500 corporations, governments, and not-for-profits across the globe. Booz Allen partners with public and private sector clients to solve their most difficult challenges through a combination of consulting, analytics, mission operations, technology, systems delivery, cybersecurity, engineering, and innovation expertise.

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