On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Contains Nonbinding Recommendations

Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program

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Guidance for Industry and Food and Drug Administration Staff

Document issued on September 15, 2023

The draft of this document issued on May 6, 2022.

For questions about this document, contact Compliance and Quality Staff within OPEQ:Office of Product Evaluation and Quality/IO:Immediate Office at CaseforQuality@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

OMB Control No. 0910-0922
Current expiration date available at https://www.reginfo.gov
See additional PRA statement in Section VI of this guidance.

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2022-D-0109. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00020039 and complete title of the guidance in the request.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The FDA's Center for Devices and Radiological Health (CDRH) is issuing this guidance to describe its policy regarding participation in the Voluntary Improvement Program (VIP). The VIP is a voluntary program facilitated through the Medical Device Innovation Consortium (MDIC) that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. The VIP builds on the framework piloted through FDA's 2018 Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program)[1] and incorporates some of the successes and learnings from the pilot.[2] The VIP is only available to eligible manufacturers of medical devices regulated by CDRH and whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (including under sections 510(k), 513, 515, and 520).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] See 82 FR 61575.

[2] Please refer to the Case for Quality Pilot Report for additional information regarding the outcomes of the pilot program: https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality-pilot-activities.

II. Background

As captured in CDRH's 2016-2017 strategic priority to "Promote a Culture of Quality and Organizational Excellence,"[3] CDRH envisions a future where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Among its other regulatory activities, FDA evaluates manufacturers' compliance with regulations governing the design and production of devices. Compliance with the Quality System Regulation, 21 CFR Part 820, is a baseline requirement for medical device manufacturing firms.[4]

In an effort to elevate and enhance manufacturing practices and behaviors through which quality and safety of medical devices can be improved, FDA collaborated with various stakeholders, brought together through the MDIC public-private partnership, to develop the CfQ Pilot Program. FDA announced the voluntary Pilot Program in the Federal Register on December 28, 2017 (82 FR 61575). Details and results from the 2018 CfQ Pilot Program are outlined in MDIC's Case for Quality Pilot Report.[5]

As in the CfQ Pilot Program, the VIP oversees third-party appraisers who evaluate voluntary industry participants, and the VIP assesses the capability and performance of key business processes using a series of integrated best practices. The practices are detailed in the Information Systems Audit and Control Association (ISACA) Capability Maturity Model Integration (CMMI) system. CMMI provides a roadmap that guides improvement towards disciplined and consistent processes for achieving key business objectives, including quality and performance. The VIP uses a version of the CMMI appraisal appropriate for the medical device industry.[6] This appraisal tool is referred to as the Medical Device Discovery Appraisal Program (MDDAP) model.[7] The baseline appraisal using the MDDAP model covers 11 practice areas, such as Governance, Implementation Infrastructure, and Managing Performance and Measurement. Participants may adjust the practice areas on the subsequent appraisals compared to the baseline set to better align with the organizational improvement goals. As part of the VIP, and as in the

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[3] 2016-2017 Strategic Priorities: Center for Devices and Radiological Health, available at https://www.fda.gov/media/95317/download.

[4] On February 23, 2022, FDA proposed to amend the device QS regulation, 21 CFR part 820, to align more closely with international consensus standards for devices (87 FR 10119; available at https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments). Specifically, FDA proposed to withdraw the majority of the current requirements in part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices- Quality management systems for regulatory purposes, in part 820. As stated in that proposed rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. FDA intends to finalize this proposed rule expeditiously. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.

[5] The Case for Quality Pilot Report is available at: https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality-pilot-activities.

[6] Information about the CMMI system is available at: https://cmmiinstitute.com/.

[7] For additional information on the MDDAP, please see https://www.isaca.org/enterprise/medical-device-discovery-appraisal-program.

CfQ Pilot Program, the program provides firms and FDA with information about the firm's capability and performance for activities covered in the third-party appraisal.

III. Program Features

The VIP is a third-party quality maturity appraisal and continuous improvement program facilitated through the MDIC, which was developed to improve medical device design, production, and quality. The VIP is a voluntary program, not a regulatory requirement. The VIP evaluates a participating manufacturer's capability and performance in key business processes by having qualified, third-party appraisers discuss, observe, and review the participant firm's practices. The appraisers evaluate the firm's practices for the business processes established in the appraisal scope against the integrated best practices within the CMMI model. Then, based on the third-party appraiser's evaluation of a participant's practices, the VIP identifies the firm's strengths and potential opportunities for improvement. The VIP allows the third-party appraiser to share some of that information with FDA. For example, the Agency receives high-level appraisal scores for each assessed practice area, by firm name and location, as well as de-identified, aggregate information from the program.

The site visit and/or analysis is not intended to be a regulatory inspection or an audit, and appraisers do not assess the firm's compliance with applicable regulatory standards. As part of the appraisal process, appraisers may review relevant information including, but not limited to, documents and systems, and conduct interviews. Appraisers do not make regulatory observations or findings. Although the VIP produces information conveyed to both the firm and to FDA, it does not issue a rating or a certification.

Participating manufacturing sites who demonstrate ongoing engagement with the program and sustained or improved capabilities and performance, may benefit from several opportunities that the VIP offers, following FDA's review of the site's appraisal, including:

- ***Opportunity for FDA Consideration in Risk-Based Inspection Planning*** – Section 701 of the FDA Reauthorization Act of 2017 (FDARA) amended section 510(h)(2) of the FD&C Act to require FDA inspections of device establishments to occur "in accordance with a risk-based schedule established by the Secretary." In establishing such a schedule, section 510(h)(4) requires FDA to consider the following factors: (1) the compliance history; (2) the record, history, and nature of recalls linked to the establishment; (3) the inherent risk of the device manufactured, prepared, processed at the establishment; (4) the inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years; (5) whether the establishment has been inspected by a foreign government or agency recognized under section 809; and (6) any other criteria deemed necessary and appropriate by the Secretary for the purposes of allocating inspection resources.

  While appraisals performed through the VIP do not constitute a new regulatory requirement or serve as an equivalent to an FDA inspection, FDA may consider information from a participant's appraisals, as appropriate, in risk-based inspection

planning. FDA retains the inspection authority granted under the FD&C Act and may conduct inspections at VIP sites, including, but not limited to surveillance, premarket, or for cause inspections as appropriate.

- ***Opportunity to Utilize a Modified Submission Format for Premarket Approval Application (PMA) and Humanitarian Device Exemption (HDE) 30-Day Change Notices for Modifications to Manufacturing Procedures or Methods of Manufacture*** – FDA intends to offer participating manufacturing sites the opportunity to submit 30-Day Change Notices for modifications to manufacturing procedures or methods of manufacture using a modified submission format. See Appendix A for additional information regarding content of the modified submission format. FDA intends to review changes related to quality improvements within 10 calendar days as resources permit. When appropriate, FDA may use the full 30-Day review time and, when such notice is inadequate, FDA intends to inform the applicant that a 135-Day PMA supplement or 75-Day HDE supplement must be submitted as defined by section 515(d)(5)(A) of the FD&C Act and 21 CFR 814.39(f) and 814.108. For more information generally regarding 30-Day Change Notices please refer to FDA's guidance titled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75- Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes."[8]

- ***Opportunity to Utilize a Modified Submission Format for PMA and HDE Manufacturing Site Change Supplements*** – FDA intends to offer participating manufacturing sites the opportunity to submit 180-Day PMA or 75-Day HDE Manufacturing Site Change Supplements using a modified submission format. See Appendix A for additional information regarding content of the modified submission format. FDA intends to review such supplements as resources permit within 25 calendar days. The site change should be to a site already accepted into the VIP. When appropriate, upon notification to the applicant, FDA may use the full 180-Day or 75-Day review time as defined by section 515(d)(5)(A)(i) of the FD&C Act and 21 CFR 814.39(a)(3), 814.108, and 814.114. For more information generally regarding 180-Day PMA or 75-Day HDE Manufacturing Site Change Supplements please refer to FDA's guidance titled "Manufacturing Site Change Supplements: Content and Submission."[9]

- ***Opportunity to Utilize a Modified Submission Format for PMA or HDE - Manufacturing Modules*** – FDA intends to offer participating manufacturing sites the opportunity to submit manufacturing modules for a PMA or HDE using a modified submission format for review by FDA staff. See Appendix A for additional information regarding content of the modified submission format. For more information generally regarding the submission format for PMA or HDE manufacturing modules please refer to

[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/30-day-notices-135-day-premarket-approval-pma-supplements-and-75-day-humanitarian-device-exemption

[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacturing-site-change-supplements-content-and-submission

FDA's guidance titled "Quality System Information for Certain Premarket Application Reviews."[10]

FDA aims to remain agile and continue to actively engage with MDIC to improve processes, features, and potential opportunities to participate in the VIP as the program generates new data and the program evolves. FDA may provide examples, share lessons learned, or expand innovative approaches with the participating organizations in order to continue to improve the effectiveness and efficiency of the VIP.

IV. Voluntary Improvement Program Operations

The VIP currently uses the Medical Device Discovery Appraisal Program (MDDAP), which is a tailored version of CMMI Performance Solutions, to evaluate the capabilities and performance of the medical device manufacturer's current business processes and objectives against the best practices outlined by the maturity model. While the VIP does not evaluate compliance with any regulatory requirements, the manufacturers' business processes are evaluated to determine if they support ongoing achievement of business objectives, including quality improvements. The MDDAP program is administered by ISACA[11], which also certifies and coordinates third-party appraisers, maintains the detailed results of the appraisals, and evaluates the collected data. ISACA is an independent body and has established certification procedures to prevent conflicts of interest for the third-party appraisers. To establish the scope of the appraisal, the appraisal team[12] is expected to meet with participants' staff and obtain information regarding work units, products manufactured, the number of employees, and the manufacturing volume. Appraisers use this information to help determine the evaluation strategy and appropriate sampling across products and processes. Appraisers may also use this information to evaluate the participant's business processes by comparing how participant manufacturers meet the best practices outlined by the maturity model. The appraisal team may use such information to identify opportunities to improve. This is intended to provide the participating manufacturer with data and granularity that reflects its own organizational performance against the practices outlined in the maturity model, and a roadmap to improve performance, increase quality, and enhance value. FDA also benefits by receiving a summary of the individual firm's information and aggregated information across all participating manufacturers. Additional details of the process for MDDAP appraisals can be found at https://www.isaca.org/enterprise/medical-device-discovery-appraisal-program#mddap-three-simple-steps. Finally, FDA understands that there are other potentially viable appraisal programs and may consider assessing those programs and their suitability for future use in the VIP.

A. VIP Eligibility

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-system-information-certain-premarket-application-reviews

[11] Information regarding the ISACA Medical Device Discovery Appraisal Program is available at: https://www.isaca.org/mddap.

[12] The appraisal team is comprised of a lead appraiser, who serves as the designated representative for the team, and additional appraisal team members determined by the scope of the appraisal, size of the participating organization, and appraisal duration.

The program has established enrollment and participation criteria for manufacturing sites. To participate in VIP, manufacturing sites should meet specified enrollment criteria. Manufacturing sites are also expected to meet additional participation criteria, including an MDDAP appraisal. Both the enrollment and participation criteria are available at https://www.isaca.org/enterprise/medical-device-discovery-appraisal-program#mddap-three-simple-steps. FDA intends to review and confirm an applicant's eligibility for enrollment in the VIP. Any current CfQ Pilot Program participants who wish to participate in the VIP do not need to reapply and are considered enrolled in the VIP unless they express an intention to withdraw (and subject to the principles outlined in Section V.C. below).

If a manufacturing site believes that it meets the enrollment criteria and would like to be considered for participation in the VIP, it may apply at http://medicaldevice.enrollment.sgizmo.com/s3/.

If you have questions regarding enrollment, contact FDA at CaseforQuality@fda.hhs.gov.

B. Additional Eligibility Considerations

Generally, to be eligible for the VIP, a manufacturer is expected to have a history of being in compliance with the applicable requirements of the FD&C Act and its implementing regulations. To make that determination, FDA may consider the firm's inspectional history, and, if applicable, other relevant information. On a case-by-case basis, VIP may consider enrolling manufacturing sites that do not have previous compliance history with the Agency, including for example: manufacturers that may not be responsible for complying with 21 CFR Part 820 (i.e., component manufacturers) and/or firms that do not meet all of the eligibility factors outlined above. These companies may be able to benefit from the VIP by building capability in their employees and processes and focusing on continuous improvement in the same way as the companies that have established a good compliance standing with the Agency. These companies may not be eligible for certain opportunities offered under the program, as noted in Section III above, until FDA has verified the manufacturer is in compliance with the FD&C Act and its implementing regulations.

C. VIP Participating Manufacturing Site Expectations

The VIP anticipates that participating manufacturing sites:

- Receive an annual appraisal.

- Engage with appraisers and commit to the mutually agreed upon appraisal process.[13]
    - Appraisers are encouraged to stop the appraisal at any time in the process if a manufacturer does not engage as the appraiser expects, or if the manufacturer fails to follow any of the appraisal process boundaries and expectations, mutually agreed upon during the appraisal scoping. The appraiser may follow its established process with the VIP, which may involve FDA.

[13] See https://www.isaca.org/enterprise/medical-device-discovery-appraisal-program

- Perform a quarterly progress check-in with lead appraisers.

- Submit quality performance measures according to the criteria set forth in the CMMI system and appraisal method. These measures fall into quality domains such as safety, effectiveness, reliability, and availability, but VIP does not prescribe individual performance measures, only that they be relevant to participants. Information provided by the participants establishes context for a given performance measure, including:
    - the quality objective of the measure
    - business objective of the measure
    - name or title of the measure
    - the level of the measure (e.g., product, aggregate, site)
    - how the measure is calculated
    - indications of improving performance
    - known limitations of the measure or data
    - why the measure matters/how the measure is used
    - how often the measure is captured
    - how often the measure is reported within the organization (i.e., daily, monthly, quarterly)

  Please refer to Appendix B for an illustrative example of how participants could define this performance measure information.

- Proactively notify FDA regarding product safety issues or recalls following all current regulatory requirements, including reporting (see also Section V.B. below).

D. VIP Process Flow

The process flow for participation in the VIP is as follows:

- Manufacturing sites apply to participate in the VIP through the application portal at http://medicaldevice.enrollment.sgizmo.com/s3/.

- The manufacturing site's application information is provided to FDA by the recognized third-party appraisal program. FDA intends to review a manufacturing site application within 5 calendar days and provide confirmation to the manufacturing site and the recognized third-party appraisal program of eligibility for participation in the VIP. If FDA does not agree that the manufacturing site has met the eligibility criteria for enrollment, the site will be notified accordingly.

- The third-party appraisal program notifies FDA when a contract for appraisal between recognized third-party appraisal program and the participating manufacturing site has been established and provides FDA with the appraisal schedule.[14]

- The participating manufacturing site and the recognized third-party appraisal program are expected to scope, coordinate, and execute the appraisal. Appraisals are targeted to be conducted within 90 calendar days from confirmation of enrollment.

- Recognized third-party appraisal program provides FDA appraisal summary within 30 calendar days of completing appraisal.

- Participating manufacturing site meets quarterly with lead appraiser for progress checks and provides quality performance metrics.

- Participating manufacturing site and recognized third-party appraisal program plan and schedule follow-up appraisal activities on an annual basis.

- FDA may consider recommendations from recognized third-party appraisal programs regarding frequency of these activities (appraisals, check-ins, and submission of quality performance measures) as participants demonstrate continuing engagement, increased performance, or capability in their business process.

V. FDA Activities and Engagement with VIP

FDA maintains representation on the VIP governance committee and provides input to overall program operation and changes. This ensures that VIP continues to align with FDA's expectations of improving participating manufacturing sites' capability and performance and that VIP provides value to industry stakeholders. VIP establishes information that a recognized third-party appraisal program should provide FDA, and that FDA intends to consider in the benefit-risk considerations FDA routinely uses to inform planning and FDA resource allocations, improve review efficiency, and may inform risk-based inspection planning, for firms that demonstrate capability and transparency around their manufacturing and product performance.

A. FDA Commitment to VIP Participating Manufacturing Sites

In response to the commitment by the participating manufacturing site to meet VIP expectations (Section IV.C) and to foster continuous improvement, safety, and transparency, FDA intends to:

- Engage proactively with participating manufacturing sites to resolve any issues (such as signals, potential safety issues, or recalls) according to the principles outlined in Section V.B. (Existing Regulatory Obligations and FDA Involvement).

[14] ISACA will work with the manufacturer to help determine scoping, schedule, and the logistics of the appraisal process.

- Contact and engage with participating manufacturing sites to discuss and resolve any issues brought to FDA's attention during an appraisal. If there is no resolution for such issues, the appraisal should end, and the participant may no longer continue to participate in the program. Please see Section V.C. below for information regarding withdrawal and removal of participants from the VIP.

B. Existing Regulatory Obligations and FDA Involvement

Participation in the VIP does not alter a firm's existing regulatory obligations under the FD&C Act, nor does it impact FDA's enforcement authority under the FD&C Act. As is always the case, the Agency retains discretion to take enforcement action when appropriate. FDA retains the inspection authority granted under the FD&C Act and may conduct inspections at VIP sites, including, but not limited to surveillance, premarket, or for cause inspections as appropriate. Participants are responsible for complying with all applicable laws and regulations, including the FD&C Act and its implementing regulations (including, but not limited to, 21 CFR 803, 806, 807, and 820). Information obtained through the course of the VIP is not intended to be a substitute for evidence collected during the course of an FDA inspection.

If issues (such as safety) are brought to FDA's attention during a firm's participation in the VIP program, FDA intends to collaborate with participating manufacturing sites first to mitigate the impact of the issue, then to identify and to implement the most effective and efficient resolution which may include an action plan and regular communication. In addition to notifying the relevant FDA Medical Device Program Division, the participating manufacturing site should also contact the review team in the appropriate Office of Health Technology (OHT) within CDRH's Office of Product Evaluation and Quality (OPEQ), as well as the Case for Quality team at CaseforQuality@fda.hhs.gov, to facilitate working interactively with FDA to address the identified issues that may impact participation in VIP.

If FDA, in its discretion, determines that there has been significant and satisfactory progress towards resolution or it has been completed in the established timeline, no additional action is recommended from a VIP perspective and program opportunities available to participants continue. However, if FDA, in its discretion, determines that there has not been significant and satisfactory progress towards a resolution or the issue escalates into a serious injury or death, FDA may consider limiting program opportunities and/or recommending removal from participation in VIP as outlined in Section C below.

C. Withdrawal and Removal from the VIP After Acceptance

The VIP is a voluntary program and participants may choose to withdraw from participation at any time by providing notice to the recognized third-party appraisal program or by notifying FDA at CaseforQuality@fda.hhs.gov. Withdrawal from the VIP may affect the opportunities provided by FDA (as identified in Sections III and IV of this guidance). Participants who withdraw from the VIP may be eligible to enroll again at a later time.

FDA and VIP participants have a shared goal to proactively and quickly address quality issues or safety risks that arise during program participation through collaboration and communication. FDA may remove participating manufacturing sites from the VIP if participants do not engage with FDA on certain issues as noted in Section V.B., or for any other reason that FDA determines is in the best interest of the public health.

A participating manufacturing site in the VIP who may not be fulfilling the expectations or commitments, such as by,

- missing a check point or delaying the checkpoint by greater than 60 calendar days without communication with the third-party appraiser;
- not providing performance measures or delaying performance measures by greater than 60 calendar days without communication with the third-party appraiser;
- delaying appraisal or reappraisal by greater than 90 calendar days without communication and agreement by FDA;
- providing false or misleading information; or
- not fulfilling financial commitments to the third-party appraiser or delaying payments by greater than 30 calendar days unless otherwise agreed on by the third-party appraiser

may be subject to principles outlined in Section V.B., and, if appropriate, may have their eligibility for the program opportunities noted above (Section III) suspended for a period of time depending upon the issues identified, until the VIP determines that the participant is progressing sufficiently towards resolving these issues. If the participant and FDA cannot resolve any such issues by utilizing the principles and procedures described in Section V.B. of this guidance, FDA may recommend a participant's removal from the VIP. Typically, participants who have been removed from the VIP may not be eligible to enroll in the program again until any outstanding issues have been resolved and verified by FDA.

VI. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated to average 28 hours (rounded). Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff, Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number

for this information collection is 0910- 0922 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

Appendix A: Modified Submission Formats

Through guidance documents, FDA has made recommendations for some information that would be useful to include in certain submission types (i.e., PMA/HDE 30-Day Change Notices, PMA/HDE Manufacturing Site Change Supplements, PMA/HDE Manufacturing Modules). FDA anticipates that, in the course of the VIP, it will gain insights into the participant's manufacturing processes and control capabilities that would likely address some recommendations for these regulatory submissions. Thus, participants in the VIP may be able to avail themselves of efficiencies that might prevent duplicate information and/or allow for least burdensome submissions[15] to the FDA.

30-Day Change Notice Submissions

Recommendations for content to be included in a 30-Day Change Notice are listed in FDA's guidance titled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75- Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes."[16] FDA anticipates that, during the course of the VIP, participants may provide FDA with information that will likely address some FDA recommendations regarding 30-Day Change Notices. The results of the appraisal and the VIP performance metrics may provide FDA with an understanding of the participating site's control capabilities and sufficient assurances to make a knowledgeable judgment about the quality control used in the manufacture of the device. FDA has created a modified submission format available to VIP participants for addressing the remainder of those recommendations.

- The VIP appraisal evaluates the participating site's capability to support, manage, sustain, and improve its established processes. As such, FDA intends to offer VIP participants the opportunity to use a modified submission format which does not recommend:

    - *A summary of the procedures established for the identification, documentation, validation, review, and approval of the manufacturing changes submitted in the 30- day notice.*
    - *A description of how you will monitor and control any manufacturing process you intend to change.*
    - *Within the summary of the completed validation study that demonstrates that the manufacturing change can be made without significantly changing the operation of the final device, an explanation of how change control procedures were implemented, including whether the submitter modified the manufacturing or quality control instructions, or the manufacturing specifications.*
    - *A summary of how purchasing control procedures were implemented to evaluate any new supplier or contractor, if the manufacturing change involves changes in*

[15] FDA defines "least burdensome" to be the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time. See also The Least Burdensome Provisions: Concept and Principles, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.

[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/30-day-notices-135-day-premarket-approval-pma-supplements-and-75-day-humanitarian-device-exemption

suppliers of components or raw materials that are critical to the performance of the device, or the use of a new contractor for a manufacturing process or quality control testing.
- *A description of the type and extent of control to be exercised over the component or raw material, including specifications for the incoming material and a description of in-coming acceptance activities. Also, a description of any testing that was completed to evaluate the use of the component or material and include a summary of the data.*

- During the course of the VIP, the appraisal is expected to evaluate sampling methods. As such, FDA intends to offer VIP participants the opportunity to use a modified submission format which does not recommend:

    - *the statistical rationale for the sampling method, if the submitter plans to verify the changed processes by routine sampling and independent measurement.*

- Other FDA recommendations from the guidance may also be addressed as follows:

    - A *description of the device* may be replaced by the Device Identifier (DI), as applicable.
    - An *identification of the manufacturing facilities where the change will be implemented* may be captured through the FEI and CMMI Appraisal Numbers.

PMA/HDE Manufacturing Site Change Supplement

Recommendations for content to be included in a PMA or HDE Manufacturing Site Change Supplement are listed in FDA's guidance titled "Manufacturing Site Change Supplements: Content and Submission."[17] FDA anticipates that, during the course of the VIP, participants may provide FDA with information that will likely address some FDA recommendations regarding Manufacturing Site Change Supplements. The results of the appraisal and the VIP performance metrics may provide FDA with an understanding of the participating site's control capabilities and sufficient assurances to make a knowledgeable judgment about the quality control used in the manufacture of the device. FDA has created a modified submission format available to VIP participants for addressing the remainder of those recommendations.

- The VIP appraisal evaluates the participating site's capability to support, manage, sustain, and improve their established processes. As such, FDA intends to offer VIP participants the opportunity to use a modified submission format which does not recommend:

    - *If the manufacturing site change results in the use of a different supplier or contract manufacturer, within the current purchasing control procedures detailing the supplier evaluation process:*

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacturing-site-change-supplements-content-and-submission

How the submitter maintains records of acceptable suppliers and how the submitter addresses the purchasing data approval process.

- *How the submitter balances purchasing assessment and receiving acceptance to ensure that products conform to specified requirements.*

Additionally, based upon review of control capabilities as part of the VIP appraisal, FDA intends to offer VIP participants the opportunity to use a modified submission format which does not recommend the following for processes that are consistent across manufacturing sites:

- *A description of the equipment and processes that would be affected by the site change.*
- *A list of any standards used in the new manufacturing processes, if applicable*
- *The process validation or revalidation procedures (and reports, if applicable)*
- *The procedures for environmental and contamination controls if such conditions could adversely affect the device (21 CFR 820.70).*
- *If different from the original PMA, any procedures that explain how inspection, measuring, and test equipment are routinely calibrated, inspected, checked, and maintained (21 CFR 820.72). If this involves a large number of procedures, a sample of the most relevant procedures would be sufficient. If procedures are the same as those contained and approved in the original PMA, the submitter should provide a statement indicating this.*
- *The procedures for the incoming acceptance activities at the subject manufacturing site, if different from the procedures contained and approved in the original PMA. If procedures are the same as those contained and approved in the original PMA, the submitter should provide a statement indicating this.*
- *The procedures for the final acceptance activities at the subject manufacturing site, if applicable and different from the procedures contained and approved in the original PMA. If procedures are the same as those contained and approved in the original PMA, the submitter should provide a statement indicating this.*

However, if processes differ from the original manufacturing site, FDA may continue to recommend one or more of the previously listed elements.

- FDA anticipates reviewing a VIP participant's master plan as a part of a manufacturing site change supplement. As such, FDA intends to offer VIP participants the opportunity to use a modified submission format which does not recommend:

  - *A list of processes at the new site that the submitter does not plan to validate but will verify by inspection and test.*

- Other FDA recommendations may also be addressed as follows:

- *A description of the device […]* may be replaced by the Device Identifier (DI), as applicable.
- The FEI and CMMI Appraisal Numbers may also be useful to identify the site.

PMA/HDE Original Manufacturing Module

Recommendations for content to be included in a PMA or HDE Original Manufacturing Module are listed in FDA's guidance titled "Quality System Information for Certain Premarket Application Reviews."[18] FDA anticipates that, during the course of the VIP, participants may provide FDA with information that will likely address some FDA recommendations regarding PMA/HDE Original Manufacturing Modules. Because participation in the VIP depends upon FDA's verification that the manufacturer complies with the FD&C Act and its implementing regulations, FDA anticipates that the recommendations regarding information to provide about the design control process (i.e., recommendations under 21 CFR 820.30) will likely have already been verified and reviewed accordingly. Additionally, the results of the appraisal and the VIP performance metrics may provide FDA with an understanding of the participating site's control capabilities and sufficient assurances to make a knowledgeable judgment about the quality control used in the manufacture of the device. FDA has created a modified submission format available to VIP participants for addressing the remainder of those recommendations.

- FDA anticipates that the following recommendation from the guidance will likely be addressed for VIP participants based upon their inspection/audit history:
    - *You should provide a copy of your basic quality system procedure(s).*
- Several items may only continue to be recommended from VIP participants if the processes or procedures for controls have changed since last FDA review. This includes information regarding:
    - *Production and Process Controls, 21 CFR 820.70*
    - *Inspection, Measuring, and Test Equipment, 21 CFR 820.72*
    - *Receiving Acceptance Activities, 21 CFR 820.80(b)*
    - *Final Acceptance Activities, 21 CFR 820.80(d)*
    - *Nonconforming Products, 21 CFR 820.90*
    - *Complaint Files, 21 CFR 820.198*
    - *Servicing, 21 CFR 820.200*

The Device Identifier (DI), as applicable, and FEI and CMMI Appraisal Numbers may also be useful to describe the device and identify the site, respectively.

[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-system-information-certain-premarket-application-reviews

Appendix B: Performance Measures Example

The following table is an example of how a participant may define its performance measures. VIP expects that participants will provide appraisers, who will then in turn provide FDA, with these, or other, definitions, and provide FDA with data quarterly, as described above in Section IV.C.

Performance Measure Information	**Quality Domain**			
	Safety *(Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.)*	**Reliability** *(Device system or component is able to function under stated conditions for a specified period of time.)*	**Availability** *(Device is available to fill first request orders.)*	**Effectiveness** *(Device produces the effect intended by the manufacturer relative to the medical condition(s).)*
Quality	Reduce Field Actions	Product is serviced correctly, the first time it is serviced	Demonstrate ability to operate in a full state of control	Continuously improve the safety and reliability of our products
Business	Improved patient safety and customer experience	Develop, test, and maintain products that consistently meet customer and business expectations	Customers orders are filled completely and on time, every time.	Improve patient health and contribute to better quality of life
Title	Number of Field Actions	First Pass Yield	Backorder On Time and In Full (OTIF)	Complaint Rate (CRR) (as reported) Compliant Incidents per Million (CIPM)
Level	Product	Aggregate across all products at site	Aggregate across all products for entire site	Aggregate across all products at site
How Calculated	Count of actions taken on products outside of distribution control	Percentage of passing final serviced units compared to total units serviced	Backorder Over (BO) Days of Sales = (90 Days Average) Order w/o BO, w/o complaints / Shipped = 30 Days Average	Sum of the quantity of complaint incidents Incidents as related to units released
Indication of good performance	The value decreases with target of 0	The value increases	Backorder: Decreasing from target OTIF: Increasing from target	The value decreases
Limitations or blind spots	None identified	None identified	None identified	None identified
Why the measure matters/How is it used	Helps identify necessary product changes/reviewed quarterly in our Management Review process	Helps identify necessary product changes/ Results are used as part of our trending process and also reviewed in Management Review	Ensure our customers are receiving what they expect and when they expect it.	Helps identify necessary product changes/ Results are used as part of our trending process and also reviewed in Management Review
Capture Frequency	Monthly	Monthly	Weekly	Daily
Organization Reporting Frequency	Quarterly	Quarterly	Quarterly	Quarterly