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

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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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

Preface

Additional Copies

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

Draft Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

The FDA's Center for Devices and Radiological Health (CDRH) is issuing this draft guidance to describe its policy regarding FDA's participation in the Voluntary Improvement Program (VIP).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] This voluntary program is currently 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).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended

[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.

only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

As part of 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.

In an effort to elevate and enhance manufacturing practices and behaviors through which quality and safety of medical devices can be improved, FDA has 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).

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. VIP uses a version of the CMMI appraisal appropriate for the medical device industry.[4] This appraisal tool is referred to as the Medical Device Discovery Appraisal Program (MDDAP) model.[5] The baseline appraisal using the MDDAP model covers 11 practices areas, including Estimating, Planning, and Configuration Management. As part of the VIP, and as in the CfQ Pilot Program, the VIP provides firms and FDA with information about the firm's capability and performance for activities covered in the third-party appraisal.

Details and results from the 2018 CfQ Pilot Program are outlined in MDIC's Case for Quality Pilot Report.[6]

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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] The CMMI system is available at: http://cmmiinstitute.com/.

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

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

III. Program Features

The VIP is a third-party quality maturity appraisal and continuous improvement program, which was developed to improve medical device production and quality. The VIP is a voluntary program, not a regulatory requirement. It reviews a participating manufacturer's capability and performance in key business processes by having qualified, third-party appraisers visit participant firms to observe the 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 de-identified, aggregate information from this 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. Appraisers do not collect evidence during their site visit, and 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 sustained capability and performance, or improvements in the appraisal results, 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 the results and data from these 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 expects 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 proposed content of the modified submission format. FDA intends to review changes related to quality improvements within 14 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."[7]

- ***Opportunity to Utilize a Modified Submission Format for PMA and HDE Manufacturing Site Change Supplements*** – FDA expects 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 proposed content of the modified submission format. FDA intends to review such supplements as resources permit within 25 calendar days. To be eligible for use of the modified submission format, the site change should be to a site already accepted into the VIP. When necessary, 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."[8]

- ***Opportunity to Utilize a Modified Submission Format for PMA or HDE - Manufacturing Modules*** – FDA expects 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 proposed content of the modified submission format. For more information generally regarding the submission format for PMA or HDE manufacturing modules please refer to FDA's guidance titled "Quality System Information for Certain Premarket Application Reviews."[9]

[7] 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

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

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

FDA aims to remain agile and continue to actively engage with MDIC to improve processes and features of 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 VIP.

IV. Voluntary Improvement Program Operations

The VIP uses the CMMI Maturity Model for Development Version 2.0 and the Medical Device Discovery Appraisal Program (MDDAP) to perform an appraisal of capabilities and performance of the medical device manufacturer's current business processes for achieving quality objectives against the best practices outlined by the maturity model. The MDDAP program is administered by the CMMI Institute[10], which also certifies and coordinates third-party appraisers, maintains the detailed results of the appraisals, and evaluates the collected data. To establish the scope of the appraisal, the appraisal team[11] 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 for meeting quality objectives 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 a rich dataset 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 firm's results and aggregated results across all participating manufacturers. Additional details of the process for MDDAP appraisals can be found at https://cmmiinstitute.com/medicaldeviceapplication.

A. VIP Eligibility

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://cmmiinstitute.com/products/mddap/program-requirements#enrollment.
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).

[10] Information regarding the CMMI Medical Device Discovery Appraisal Program is available at: https://cmmiinstitute.com/medicaldevice.

[11] 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.

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

If you have questions regarding enrollment, contact the 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. 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 proposed appraisal process.
    - 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 or involve FDA.
- Perform a quarterly progress check-in with lead appraisers. The Agency may consider recommendations from recognized third-party appraisal programs regarding frequency of check-ins as participants demonstrate increased performance or capability in their business process.
- Submit quality performance measures according to the criteria set forth in the CMMI system and appraisal method. These measures fall into the quality domains of 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 good 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 https://cmmiinstitute.com/medicaldeviceapplication.

- The participating manufacturing site's application information is provided to FDA by the recognized third-party appraisal program. FDA intends to review manufacturing site application(s) within 5 calendar days and provide confirmation to the manufacturing site and the recognized third-party appraisal program of eligibility for participation in 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.

- 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 appraisals on an annual basis and notify FDA of new focus areas, maturity practices, or progress planned for the appraisal.

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, improve FDA resource allocations, improve review efficiency, and 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).

- 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. 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 or 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 VIP After Acceptance

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 VIP may affect the opportunities provided by FDA (as identified in Sections III and IV of this guidance). Participants who withdraw from 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 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.

Participating manufacturing site(s) in 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 VIP determines that the participant is progressing sufficiently towards resolving these issues. If participants 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 VIP. Typically, participants who have been removed from VIP may not be eligible to enroll in the program again until any outstanding issues have been resolved and verified by FDA.

VI. 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[12] 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." [13] 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 anticipates creating 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.*

[12] 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.

[13] 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

- *A summary of how purchasing control procedures were implemented to evaluate any new supplier or contractor, if the manufacturing change involves changes in 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."[14] 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 anticipates creating 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:

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

- *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:*
    - *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." [15] 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 VIP depends upon FDA's verification that the manufacturer is in compliance 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 anticipates creating 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.

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

VII. 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 Objective	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 Objective	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
Measure 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 of Measure	Product	Aggregate across all products at site	Aggregate across all products for entire site	Aggregate across all products at site
How Measure is 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