**As part of the FDA's Case for Quality, a Voluntary Manufacturing and Product Quality Pilot was launched on December 28, 2017. Participants in the pilot are part of the agencY’s efforts to evaluate a third-party evaluation and to adjust agency practices and policies TO increase the capability to drive continous improvements within the medical device industry. Modifications to the manufacturing change submissions for participants are being piloted to support the improvements and to enable increased understanding of organizational performance and product quality.**

**These changes are being submitted as part of the Voluntary Manufacturing and Product Quality Pilot. Any questions or concerns regarding the format or processing of this submission should be directed to THE CASE FOR QUALITY TEAM AT** [**CASEforquality@FDA.HHS.GOV**](mailto:CASEforquality@FDA.HHS.GOV)**.**

**Voluntary Manufacturing and Product Quality Pilot**

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# Cover Information:

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicant:** | | **Submission Date:** | |
| Company Name | | Select Date | |
| Company Organizational Unit | | **MDUFA Payment Identification Number:** | |
| **Address:** | | Payment Identification Number | |
| Street 1 | |  | |
| Street 2 | |
| City | State | | Zip Code |
| Country | | | |
| **Contact:** | | **Contact Information:** | |
| Contact Name | | Contact Email | |
| Contact Title | | Phone Number | |
| Contact Organization | | | |
| **Alternate Contact:** | | **Alternate Contact Information:** | |
| Alt Contact Name | | Alt Contact Email | |
| Alt Contact Title | | Alt Contact Phone Number | |
| Alt Contact Organization | | | |
| **Summary:** | | | |
| Body Text | | | |
| **Statement of Conformance:** | | | |
| Changes described herein were made in accordance with the requirements of the Quality System Regulation, regarding change control, validation, and document control found in 21 CFR Part 820. | | | |
| **Responsible Party Signature:** | | **Date:** | |
|  | | Date of Signature | |

# Impacted OPEQ REVIEW TEAMS:

The following OPEQ Offices can be expanded or collapsed by clicking on the triangle icon () located at the left of the office title. Please select the teams with the product areas that will be affected by this submission.

## OFFICE OF HEALTH TECHNOLOGY 1: Ophthalmic, Anesthesia, Respiratory, Ear/Nose/Throat, & Dental Devices

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 1A**  **Ophthalmic Devices**   |  |  | | --- | --- | |  | **INTRAOCULAR LENS AND ACCESSORY DEVICES TEAM** | |  | **CONTACT LENS AND DRY EYE DEVICES TEAM** | |  | **RETINAL AND DIAGNOSTICS DEVICES TEAM** | |  | **GLAUCOMA, CORNEA, AND SURGICAL DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 1B**  **Dental Devices**   |  |  | | --- | --- | |  | **IMPLANTABLE DENTAL DEVICES TEAM** | |  | **RESTORATIVE AND SURGICAL DENTAL DEVICES TEAM** | |  |  | |  |  | | **DIVISION OF HEALTH TECHNOLOGY 1C**  **Anesthesia, Respiratory, and ENT Devices**   |  |  | | --- | --- | |  | **ANESTHISIA DEVICES TEAM** | |  | **ENT DEVICES TEAM** | |  | **RESPIRATORY DEVICES TEAM** | |  | **SLEEP DISORDERED BREATHING DEVICES TEAM** | |

## OFFICE OF HEALTH TECHNOLOGY 2: Cardiovascular Devices

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 2A**  **Cardiac Electrophysiology, Diagnostics, and Monitoring Devices**   |  |  | | --- | --- | |  | **BLOOD PRESSURE AND FLOW DEVICES TEAM** | |  | **CARDIAC ABLATION, MAPPING, AND IMAGING DEVICES TEAM** | |  | **EXTERNAL HEART RHYTHM AND RATE DEVICES TEAM** | |  | **IMPLANTABLE ELECTROPHYSIOLOGY DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 2B**  **Circulatory Support, Structural and Vascular Prostheses**   |  |  | | --- | --- | |  | **VASCULOR ANDENDOVASCULAR DEVICES TEAM** | |  | **CARDIAC OCCLUDERS AND HEMOSTASIS DEVICES TEAM** | |  | **HEART VALVE DEVICES TEAM** | |  | **CIRCULATORY SUPPORT DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 2C**  **Coronary and Peripheral Intervention Devices**   |  |  | | --- | --- | |  | **CORONARY INTERVENTIONAL DEVICES TEAM** | |  | **PERIPHERAL INTERVENTIONAL DEVICES TEAM** | |  | **PLAQUE MODIFICATION DEVICES TEAM** | |

## OFFICE OF HEALTH TECHNOLOGY 3: Reproductive, Gastro-Renal, Urological, General Hospital Devices, & Human Factors

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 3A**  **Gastroenterology, Renal, Endoscopy, Transplant, and Obesity Devices**   |  |  | | --- | --- | |  | **RENAL AND TRANSPLANTATION DEVICES TEAM** | |  | **GASTROENTEROLOGY AND ENDOSCOPY DEVICES TEAM** | |  | **OBESITY AND HEPATOBILIARY DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 3B**  **Reproductive and Urological Devices**   |  |  | | --- | --- | |  | **OBSTETRICAL AND REPRODUCTIVE HEALTH DEVICES TEAM** | |  | **GYNECOLOGICAL AND SURGICAL DEVICES TEAM** | |  | **UROLOGICAL DEVICES TEAM** | |  | **INCONTINENCE AND FEMALE UROLOGICAL DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 3C**  **Drug Delivery and General Hospital Devices and Human Factors**   |  |  | | --- | --- | |  | **INJECTION DEVICES TEAM** | |  | **INFUSION DEVICES TEAM** | |  | **GENERAL HOSPITAL DEVICES TEAM** | |  | **HUMAN FACTORS AND RELIABILITY ENGINEERING** | |

## OFFICE OF HEALTH TECHNOLOGY 4: Surgical & Infection Control Devices

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 4A**  **General Surgery Devices**   |  |  | | --- | --- | |  | **ROBOTIC ASSISTED SURGERY DEVICES TEAM** | |  | **NON-LIGHT-BASED ENERGY DEVICES TEAM** | |  | **LIGHT BASED ENERGY DEVICES TEAM** | |  | **CANCER DIAGNOSIS AND TREATMENT DEVICES TEAM** | | |  |  | | --- | --- | |  |  | |  |  | | **DIVISION OF HEALTH TECHNOLOGY 4B**  **Infection Control and Plastic & Reconstructive Surgery Devices**   |  |  | | --- | --- | |  | **STERILITY DEVICES TEAM** | |  | **PERSONAL PROTECTIVE EQUIPMENT, REPROCESSING, & DISINFECTION DEVICES TEAM** | |  | **PLASTIC SURGERY IMPLANT DEVICES TEAM** | |  | **PLASTIC SURGERY SKIN AND WOUND DEVICES TEAM** | |

## OFFICE OF HEALTH TECHNOLOGY 5: Neurological & Physical Medicine Devices

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 5A**  **Neurosurgical, Neurointerventional, and Neurodiagnostics Devices**   |  |  | | --- | --- | |  | **NEUROSURGICAL DEVICES TEAM** | |  | **NEUROINTERVENTIONAL DEVICES TEAM** | |  | **NEURODIAGNOSTICS DEVICES TEAM** | | |  |  | | --- | --- | |  |  | |  |  | | **DIVISION OF HEALTH TECHNOLOGY 5B**  **Neuromodulation & Rehabilitation Devices**   |  |  | | --- | --- | |  | **NEUROSTIMULATION-NEUROLOGY DEVICES TEAM** | |  | **NEUROMODULATION-PSYCHIATRY DEVICES TEAM** | |  | **ACUTE INJURY DEVICES TEAM** | |  | **NEURODEGENERATIVE DEVICES TEAM** | |

## OFFICE OF HEALTH TECHNOLOGY 6: Orthopedic Devices

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **DIVISION OF HEALTH TECHNOLOGY 6A**  **Joint Arthroplasty Devices**   |  |  | | --- | --- | |  | **KNEE ARTHROPLASTY DEVICES TEAM** | |  | **HIP ARTHROPLASTY DEVICES TEAM** | |  | **SHOULDER ARTHROPLASTY DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 6B**  **Spinal Devices**   |  |  | | --- | --- | |  | **INTRACOLUMNAR DEVICES TEAM** | |  | **EXTRACOLUMNAR DEVICES TEAM** | |  |  | |  |  | | **DIVISION OF HEALTH TECHNOLOGY 6C**  **Restorative, Repair, and Trauma Devices**   |  |  | | --- | --- | |  | **RESTORATIVE, REPAIR, TRAUMA, AND FRACTURE FIXATION DEVICES TEAM** | |  | **STEREOTAXIC, BONE GROWTH STIMULATORS, AND FRACTURE FIXATION DEVICES TEAM** | |

## OFFICE OF HEALTH TECHNOLOGY 7: Invitro Diagnostics and Radiological Health

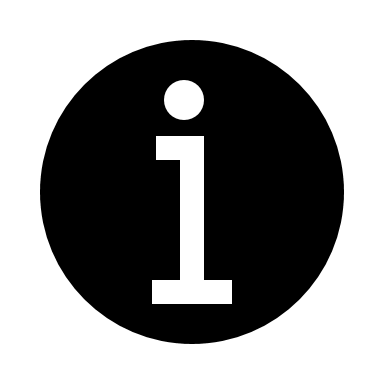
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **DIVISION OF HEALTH TECHNOLOGY 7A**  **Immunology and Hematology Devices**   |  |  | | --- | --- | |  | **HEMATOLOGY DEVICES TEAM** | |  | **IMMUNOLOGY AND FLOW CYTOMETRY DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 7B**  **Chemistry and Toxicology Devices**   |  |  | | --- | --- | |  | **CHEMISTRY DEVICES TEAM** | |  | **DIABETES DEVICES TEAM** | |  | **TOXICOLOGY DEVICES TEAM** | |  | **CARDIO-RENAL DIAGNOSTICS DEVICES TEAM** | |
| **DIVISION OF HEALTH TECHNOLOGY 7C**  **Microbiology Devices**   |  |  | | --- | --- | |  | **VIRAL RESIRATORY AND HPV DEVICES TEAM** | |  | **GENERAL VIRAL AND HEPATITIS DEVICES TEAM** | |  | **GENERAL BACTERIAL AND ANTIMICROBIAL SUSCEPTIBILITY DEVICES TEAM** | |  | **BACTERIAL RESPIRATORY AND MEDICAL COUNTERMEASURES DEVICES TEAM** | | **DIVISION OF HEALTH TECHNOLOGY 7D**  **Radiological Health Devices**   |  |  | | --- | --- | |  | **MAGNETIC RESONANCE AND ELECTRONIC PRODUCTS BRANCH** | |  | **DIAGNOSTIC X-RAY SYSTEMS DEVICES TEAM** | |  | **NUCLEAR MEDICINE AND RADIATION THERAPY DEVICES TEAM** | |  | **MAMMOGRAPHY, ULTRASOUND, AND IMAGING SOFTWARE DEVICES TEAM** | |
| **DIVISION OF HEALTH TECHNOLOGY 7E**  **Molecular Genetics and Pathology**   |  |  | | --- | --- | |  | **MOLECULAR PATHOLOGY AND CYTOLOGY DEVICES TEAM** | |  | **MOLECULAR GENETICS DEVICES TEAM** | | |  |  | | --- | --- | |  |  | |

# Affected Sites:

|  |  |
| --- | --- |
| **Firm Establishment Identifier** | **CMMI Appraisal Number** |
| FEI Number | CMMI Appraisal Number. |

# Submission information:

## Submissions and Product Information:

**Please provide the submission details in this table or include them in an attachment/appendix to this document with the following information: [](#bkSubInfo)**

|  |  |  |
| --- | --- | --- |
| **PMA Number** | **Associated product Name/Make/Model** | **Device Identifier (If available)** |
|  |  |  |

# Summary of changes:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Change Control Number: [Information](#bkCCNum)** | | |  | |
| Enter number(s) that provide traceability to the change activities | | | | |
| **Type of Change: [Information](#bkType)** | | | | |
| Select the type(s) of change | | | | |
| **Reason for Change: [Information](#bkReason)** | | | | |
| Select the reason(s) for the change | | | | |
| **Is the change related to:** | | | | |
| **Field Action/ Recall** | **Adverse Event** | **Device Malfunction/Field Event** | | **Corrective Action** |
| Please Indicate | Please Indicate. | Please Indicate. | | Please Indicate. |

If the submission is intended for devices reviewed by OHT click on the triangle icon () located at the left of the following header and check if the change impacts any of the topics shown.

## FOR OHT 2 SUBMISSIONS ONLY - Indicate if the change is impacting one of the following categories

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | |  | **Pulse generator battery** | |  | **Pulse generator HV capacitor** | |  | **Pulse generator firmware** | |  | **Pulse generator communication/telemetry** | |  | **Pulse generator header/connector block** | |  | **Pulse generator feedthrough** | | |  |  | | --- | --- | |  | **Lead insulation** | |  | **Lead fixation** | |  | **Lead connector** | |  | **Lead conductors** | |  | **Lead shock coils** | |  | **Lead pace/sense electrodes** | |  | **Lead implant handling/delivery tool compatibility** | | |  |  | | --- | --- | |  | **Coating** | |  | **Nitinol processing** | |  | **Crimping** | |  | **Tissue process changes** | |  | **Valve processing** | |  | **Atherectomy devices** | |  | **Sterilization parametric release** | |

## Supporting Details

|  |
| --- |
| **Description of Change: [Information](#bkDescription)** [***See Example***](#bkDescExample) |
| Provide a brief description of the change |
| **Rationale/Supporting Justification for Change: [Information](#bkRationale)** [***See Example***](#bkRatExample) |
| Provide a brief description of the rationale and justification of the change |

The following headers for ***Template Instructions***, ***Data Definitions***, and ***Document Change History*** can be expanded or collapsed by clicking on the triangle icon () located at the left of the header.

# Template Instructions:

This form template is applicable only for those facilities and sites that have been enrolled in the Voluntary Manufacturing and Product Quality Pilot and have completed a CMMI Medical Device Discovery Appraisal. To leverage this format for changes that impact multiple sites, each site would need to be a participant enrolled in the pilot. An appraisal number associated with each site will be provided for reference.

A single 30-Day Submission form can be used to bundle all change notifications applicable to the same PMA(s), please note that when bundling changes and PMA submission number(s), The bundled PMA(s) must be impacted by all changes submitted on this form. If a PMA number is not impacted by all changes, a separate form must be used.

**Please include an electronic copy of this word document into the submission. Follow the eCopy Guidance for Medical Device Submissions** <https://www.fda.gov/MedicalDevices/ucm370895.htm> **for appropriate instructions and naming conventions.**

**Links to additional submission forms:**

* **Medical Device User Fee Cover Sheet:** <https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp>
* **CDRH Premarket Review Submission Cover Sheet:** <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf>

**Some fields will allow for additional rows to be added. Those fields and rows will have blue plus icon (****) located at the lower right-hand corner of the row or table if you click into the table.**

## Cover Information:

* Company Name – The name of the company on the submission.
* Company Organizational Unit – The name of the business unit of the company if appropriate.
* Submission Date – The date of submission to the FDA.
* MDUFA Payment Identification Number *–* Reference PIN generated by the online submission system providing traceability to your payment
* Address – Address of the applicant submitting the form.
* Contact Number – Phone number of individuals submitting the form.
* Contact Information – Contact details and Email information for applicant or primary contact
* Alternate Contact Number – Name and information of an alternate contact if applicable.
* Summary – This area is provided for any relevant summary or background material for this submission
* Statement of Conformance – Statement of compliance to the appropriate regulations
* Responsible Party Signature – Signature of the one who will testify that the changes implemented and summarized within the form have been made under the requirements of 520(f) of the FDCA and 21 CFR, Part 820.
* Date – The date of signature

## Affected Sites:

**For additional sites, please click on the blue plus icon located at the lower right hand of the affected site table to add more change sites.**

* Firm Establishment Identifier **-** Unique identifier issued by the FDA to track site inspections or information.
* Appraisal Number – Unique number issued by the institute to track and identify the site’s maturity appraisal

## Submission Information:

**Please provide the PMA submission number, the associated name/make/model of the device, and the device identifier if applicable. Additional PMA information can be added to the table by clicking on the *plus* sign located at the lower right-hand corner of the row when submitting a bundle. Alternatively, the information may be exported in a tabular format and added as in appendix to this document.**

## Summary of Change:

**For additional changes, please click on the blue plus icon located at the lower right hand of the change summary table to add more change sections.**

* Change Control # – Unique tracking number providing traceability to the data supporting the specific change; as defined by 520(f) and 21 CFR Part 820.
* Type of Change – This is structured data field with a pull down. Definitions for each element are provided in the Data definitions tab. Please note that a some of the change types may require additional discussion for clarity. This is a pilot program and is open to feedback, clarity, and adjustment as appropriate. The change may fall into multiple categories. If there are more types associated with the change click on the blue plus sign at the lower right corner of the table row to add more.
* Reason for Change – This is structured data field with a pull down. Definitions for each element are provided in the definitions tab. This is a pilot program and is open to feedback, clarity, and adjustment as appropriate. The change may fall into multiple reason categories. If there are more types associated with the change click on the blue plus sign at the lower right corner of the table row to add more.
* Description of Change – Brief description of the submitted change. The description should provide a brief overview of the change being implemented, the product/component affected, and what the change is addressing. Although a succinct description is preferred, this field allows for tables, bullets, and images if necessary.  ***If “Other” was selected in the either the Type of Change or Reason for Change fields, please include additional detail here.***

*Example:*

FDAMED is submitting this change notice for the use of the new ink hardener component (P/NXXX-XX-XXX) mixed in ink used for the pad printing of graphics onto the injection molded components of the FDAMax Deploy System. The currently approved supplier of the injection molded components is discontinuing use of the current ink hardener (P/N XX-XXX) and replacing it with the new hardener. Both are manufactured by WeMakeInk, Inc.

* Rationale/Supporting Justification for Change – Brief high-level summary of the data and rational supporting the change. Additional rationale and data supporting the change must be available via the Change Order # for provision upon request by the FDA. The rationale and supporting data should include a summary of each test/qualification activity completed (please summarize rationale, results, deviations, and conclusions), a summary of the risk assessment performed, and conclusion regarding the change. This field allows for the use of lists, tables, charts, and images as needed.

*Example:*

The new ink hardener was identified as an equivalent replacement for the ink for marking the components. No changes have been made to other additives and pigment components of the ink. The amount of hardener component in the ink mixture remains the same (12.5%) and the acceptance requirements for receiving and handling of raw material are not changing.

|  |  |
| --- | --- |
| **Test** | **Summary and Conclusion** |
| Visual and Integrity Study | Test components were manufactured, and pad printed by the supplier per established procedures. The supplier performed visual and integrity tests on 90 nonsterile samples (30 per part number). All samples passed the visual acceptance criteria and integrity test. Based on the results the supplier determined that the performance of the new hardener is equivalent to the previously used component and has no negative impact on manufacturing process or the affected components. |
| DSC Study | Thirty test components (P/N XXXXXX, used as a worst-case test sample) were manufactured by the supplier per established procedures.  Testing was performed using differential scanning calorimetry (DSC) governed by ISO 11357-5, Plastics – Differential scanning calorimetry (DSC) – Part 5: Determination of characteristic reaction-curve temperatures and times, enthalpy of reaction and degree of conversion. This testing was done to assure that the hardener in the samples is completely reacted and will not be altered by exposure to ethylene oxide (EO) sterilization and compromise its integrity. The testing showed that the ink adhesion will not be altered or compromised when subjected to EO sterilization. |
| Microbiology  FDAMED-000001 | The hardener change was evaluated for impact on the qualified bioburden, endotoxin mitigation levels, and sterility assurance. The bioburden impact on the final device is minimal to none and the qualified sterilization level of 10-6 remains the same. This change does not affect the assembly process or the established endotoxin mitigations. |
| Toxicology  FDAMED 00014-002  Cytotoxicity Study  FDAMED-00003-002 | The overall risk assessment of the components in the new hardener relative to their worst-case exposure scenario concluded that the only risk of significance could come from acute exposure to the diethylene glycol component of the polymer in the hardener. Mitigation of this risk was evaluated through cytotoxicity assessment.  Cytotoxicity evaluation was conducted using Medium Eluate Method was performed on extracts of the parts containing printed ink. The results showed that the extracts were non-cytotoxic. |
| Chemistry  FDAMED-00007 | Chemistry was evaluated by reviewing the overall risk assessment of the components, the manufacturer’s technical data sheets and MSDS. No new chemical risks were identified therefore no chemical testing was required. |

A risk management review was performed regarding the product and change described. The review determined that there is not a change in the hazard or new failure mode associated with this change. The printed pad components do not come into direct contact with the patients and the change does not affect the design, functionality, or intended use of the affected components or the finished product.

The testing and evaluation of the change have shown that the new ink hardener is acceptable and does not affect device safety or efficacy

# Data Definitions:

## Type of Change:

### Component Specification

This data element applies to modifications to the specifications applied to a component. This includes tightening of specifications, clarity on existing specifications, component inspection or acceptance criteria within validated or established specifications. ***Modification or expansion of the specifications may require a Real-Time Review or additional supplement based on the change, risk, and patient impact. For these changes, contact the ODE review branch for guidance on the submission needs and if the 30-Day is appropriate.***

### Cleanroom environment

This data element applies to changes in the environmental conditions or specifications of any cleanroom

### Equipment

This data element applies to the addition or removal of equipment used in manufacturing of the product.

### Facility/ Infrastructure

This data element applies for changes within the same facility, such as additions of rooms, movement to new space at the same facility, or clean room changes.

### Inspection addition

This data element applies for changes that include the addition of an inspection method during processing, final, or incoming material.

### Inspection method

This data element applies to changes in the inspection method, process, or specifications.

### inspection removal

This data element applies to the removal of inspection activities in processing, final, or incoming material. When using this element, provide additional summary information regarding the downstream quality checks or validation results that provide assurance of control for what the inspection was verifying.

### Manufacturing environment

This data element applies to changes in the manufacturing environment or operating specifications

### Manufactruing line Change

This data element applies to changes or additions of a manufacturing line within the same location.

### process aids

This data element applies to addition or removal of tools, directions, or visual aids used to aid in the manufacturing or inspection process

### Process change

This data element applies to changes that impact the manufacturing process referenced in the change. Including changing operating parameters, process types/technology, operating steps, or instructions.

### quality system

This data element applies to changes that impact the quality system elements, controls, or records. Including documentation, QS systems/technology, or quality records.

### Software

This data element is used for changes that are made to the existing automation or software used in production

### Sterilization

This data element applies to changes that impact the sterilization activities, such as parameter changes, process changes, or equipment changes

### supplier change

This data element references additions, removals, qualifications, or changes to the supplier criteria.

### Tooling

This data element includes the addition or modifications to tooling or fixtures used in the manufacturing of the devices indicated.

### other (please specify)

Use for change types not in the list. Please specify in the Description of Change field for potential addition.

## Reason for Change:

### audit response

Include if the change is in response to an audit, internal or external. Designate if it was internal or external in the description.

### automation

Use for the addition of new automated technologies or processing.

### business continuity

Include if the change is intended to improve or provide business continuity.

### corrective action

Use if the change is part of addressing an ongoing corrective action. Provide the associated CAPA number in the Description of the Change.

### Cost improvement

Use if the change provides a cost improvement or business value.

### error proofing

Use if the change is part of proactive quality improvement efforts that will eliminate the occurrence of identified issues or non-conformances

### error reduction

Use if the change is part of proactive quality improvement efforts reducing occurrences of non-conformances

### field action

Use if the change is being implemented as part of addressing a known field issue

### operational improvement

Use if the change is intended to improve operations, workforce performance/experience, or streamline operations

### preventive action

Use if the change is part of a preventive action strategy to eliminate the systemic occurrence of an identified issue. Provide the associated CAPA number in the Description of the Change.

### post-market surveillance

Use if the change is in response to post-market surveillance activities and help address signals received through customer feedback, complaints, field representatives, social media, or other sources.

### supplier notice

Use if the change is being performed in response to changes or issues identified or communicated by your supplier.

### other (please specify)

Use for reasons not in the list. Please specify in the Description of Change field for potential addition.

# Document Change History:

|  |  |  |
| --- | --- | --- |
| **Version** | **Description of Changes** | **Date Released** |
| v.1.0 | V1.0 Incorporates feedback from pilot participants and new OPEQ structure. Removed macros and added links for instructions. | 04/19/2019 |
| v.1.1 | Updated Coversheet to include Case for Quality mailbox to ensure responsiveness from them team. | 07/23/2019 |