**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 agnecies 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 Site 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** [**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 | | | |
| **Address:** | | | |
| Street 1 | | | |
| Street 2 | | | |
| City | State | | Zip Code |
| Country | | | |
| **Primary Point of 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 | | | |
| **PMA Site Change Summary:** | | | |
| Body Text | | | |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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:

## Current Approved Site:

**NOTE: In accordance with current regulatory requirements this site must be in compliance with 21 CFR 820 requirements.**

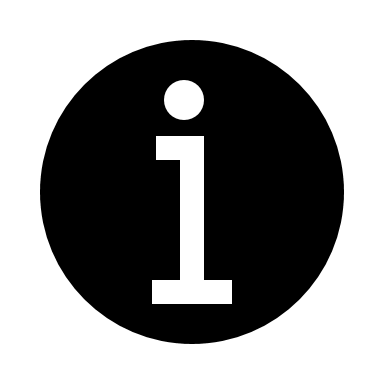
|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Facility:** | | | **Firm Establishment Identifier (FEI):** | |
| Company Name | | | Select Date | |
| Company Organizational Unit | | | | |
| **Address:** | | | | |
| Street 1 | | | | |
| Street 2 | | | City | |
| State | Zip Code | | | Country |
| City | |  | | Zip Code |

## Proposed Site:

|  |  |  |  |
| --- | --- | --- | --- |
| **Facility:** | | **Firm Establishment Identifier (FEI):** | |
| Company Name | | Select Date | |
| Company Organizational Unit | | **CMMI Appraisal Number** | |
| **Address:** | | CMMI Appraisal Number. | |
| Street 1 | | | |
| Street 2 | | City | |
| State | Zip Code | | Country |

# Submission information:

## Submissions and Product Information:

**Please provide the submission and product 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)** |
|  |  |  |

## Manufacturing Description:

|  |
| --- |
| **Manufacturing Functions:** |
| Description of the manufacturing functions that will performed at the proposed site (i.e. assembly, incoming acceptance, sterilization. Description may be included as an attachment to this document. If so, note the attachment or appendix number here.) |
| **Manufacturing Flow Diagram:** |
| A flow diagram that identifies the steps involved in the manufacture, processing, packaging, or distribution of the device(s) under review at the proposed site. The flow may be included as an attachment to this document. If so, note the attachment or appendix number here. |

## Manufacturing Process Changes:

|  |
| --- |
| **Will there be changes to the manufacturing processes because of this manufacturing site change?** |
| If the applicant will be implementing new equipment, new processes, or changing processes specifications as part of the site change, provide a description of equipment and processes that would be changed or affected by the site change. If the applicant has determined that the changes being implemented may impact safety or effectiveness, provide a summary of testing performed and results. If no equipment or processes are being changed, please note: **NO CHANGES**. |
| **NOTE: Changes to device design are not within the scope of a site change supplement, please contact CDRH for additional guidance. Additions of new sterilization methods or a change in the sterilization method (i.e. addition of Ethylene Oxide (EO) Sterilization or changing from EO to Radiation Sterilization) may be considered design changes and should be discussed with the CDRH review team.** |

## Supporting Information:

|  |
| --- |
| **Changes to Acceptance Activities:** |
| If the applicant will be implementing changes to acceptance activities (i.e. Incoming acceptance, final acceptance, in-process acceptance. Provide a description of any changes. If no changes note - **NO CHANGES**. |
| **Changes to Environmental and Contamination Controls:** |
| If environmental or contamination conditions could adversely affect the device, provide a summary description of controls established. If no changes or adverse impact note - **NO CHANGES** |
| **Changes to Supplier or Contract Manufacturer:** |
| If this submission implements a different supplier or contract manufacturer, please provide a summary description including:   * The quality controls that are established for the supplier, how those quality controls are evaluated, how the quality controls are monitored, and final acceptance activities. * The communication method for ensuring that you and the supplier or contract manufacturer fully understand all the controls that are applicable to the supplier. * The change control mechanism utilized for ensuring adequate control over design and process related changes made by both you and the supplier or contract manufacturer.   The details may be included here or as an attachment to this document. If so, note the attachment or appendix number here. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary Results Provided:** | | | |
| **Summary Details** | | **Provided** | **NA** |
| **Process validation summary results** | [See example](#bkprocessExample) |  |  |
| **Software validation summary results** | [See example](#bksoftwareExample) |  |  |
| **Sterilization process summary results** | [See example](#bksterilizationExample) | **☐** | **☐** |

The following headers for ***Template Instructions*** 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.

**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>

## 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.
* 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.**

### Current approved Site

Details for the currently approved site(s). Please note that this site must be in good compliance standing with regards 21 CFR 820.

### Proposed Site

Details of the sites being proposed for the change. Note that only those sites with a CMMI appraisal will qualify for the modification benefits.

## Submission Information:

## Submission and Product 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.**

## Manufacturing Description:

### manufacturing functions:

Provide a high-level description of the of the various manufacturing functions that are intended to be performed at the new site. Examples of these functions may be product assembly, incoming acceptance, storage, distribution, sterilization, etc. The functions listed are just examples and are not intended to be all inclusive.

### manufacturing flow diagram:

Provide a flow diagram that identifies the steps involved in the manufacture, processing, packaging, or distribution of the device(s) at the proposed site.

## Manufacturing Process Changes:

New equipment, new processes, or changes to the manufacturing process specifications may be submitted as part of the site change submission. For these activities, provide a description of the equipment and processes that are changing or affected by this site change. For these changes, the applicant should determine if the changes being implemented may impact safety or effectiveness, provide a summary of testing performed and results.

## Supporting Information:

### Changes to acceptance activities

For changes to acceptance activities (i.e. Incoming acceptance, final acceptance, in-process acceptance) that will be implemented as part of this site change. Provide a description of any changes.

### Changes to environmental and contamination controls

For environmental or contamination conditions that could impact the safety or effectiveness of the device, identify and provide a summary description of controls established.

### changes to supplier or contract manufacturers

For new suppliers or contract manufacturers please provide a summary description that includes:

* The quality controls that are established for the supplier, how those quality controls are evaluated, how the quality controls are monitored, and final acceptance activities.
* The communication method for ensuring that you and the supplier or contract manufacturer fully understand all the controls that are applicable to the supplier.
* The change control mechanism utilized for ensuring adequate control over design and process related changes made by both you and the supplier or contract manufacturer.

### Summary results Provided:

**Process validation summary results**

For manufacturing and process activities the summary of results should include the following information.

* Process
* Process Description
* Associated Equipment/Tools
* Process validation summary and acceptance determination. For example:
  + Installation Qualification (IQ) results summary and acceptance determination
  + Operational Qualification (OQ) results summary and acceptance determination

**NOTE: If the process specifications or details are not changing from the original operational qualification window or no new process is being implemented, OQ may not be required. If the process validation did require OQ, include results in the summary.**

* + Performance Qualification (PQ) results summary and acceptance determination
* Deviations identified, disposition, and rationale

## Process Validation Example

An example is provided below. The summary may be in this format or may be submitted in a report that includes the information noted above.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **Validation Summary** | | | **Deviation Summary** | | |
| **Process** | **Process Description** | **Equipment/ Tools** | **Validation Activity** | **Results** | **Acceptance** | **Deviation** | **Disposition** | **Rationale** |
|  |  |  |  |  |  |  |  |  |

## Software Validation Example

An example is provided below. The summary may be in this format or may be submitted in a report that includes the information noted above.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **Validation Summary** | | | **Deviation Summary** | | |
| **Software Change** | **Process Impacted** | **Equipment/ Tools Impacted** | **Validation Activity** | **Results** | **Acceptance** | **Deviation** | **Disposition** | **Rationale** |
|  |  |  |  |  |  |  |  |  |

## Sterilization Process Changes Example

The samples below vary depending on the sterilization process. Apply the format that corresponds to the sterilization method(s) used for the devices in this submission. **NOTE: A site change supplement can only be used for changes in the process or process specifications for methods already approved in the PMA. Adding a new sterilization method or changing from one method to another may require a different submission.**

### Ethylene oxide

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assessment** | **Summary Information** | **Results** | **Deviations** | **Disposition/Rationale** |
| Bioburden | Bioburden validation summary including the validation method, extraction method, extraction time/temperature, speacies used for enumeration method, culture media and time, and recovery efficiency and correction factor; action/alert limits, and the monitoring frequency |  |  |  |
| Sterilization Process validation | Summary of validation activities performed (i.e. IQ, OQ, PQ, MPQ, PPQ) |  |  |  |
| Bacteriostasis/ Fungistasis | Summary of activities performed |  |  |  |
| EO Residual Testing | Summary of methods used for testing and the allowable limits |  |  |  |
| Bacterial Endotoxin Testing | Summary of testing methods, batch testing method (number tested per batch, frequency of batch, allowable limits. |  |  |  |

### Radiation sterilization

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assessment** | **Summary Information** | **Results** | **Deviations** | **Disposition/Rationale** |
| Bioburden | Bioburden validation summary including the validation method, extraction method, extraction time/temperature, speacies used for enumeration method, culture media and time, and recovery efficiency and correction factor; action/alert limits, and the monitoring frequency |  |  |  |
| Sterilization Process validation | Summary of validation activities performed (i.e. IQ, OQ, PQ, MPQ, PPQ), dose map, dose verification, and sterility testing method |  |  |  |
| Bacteriostasis/ Fungistasis | Summary of activities performed |  |  |  |
| Bacterial Endotoxin Testing | Summary of testing methods, batch testing method (number tested per batch, frequency of batch, allowable limits. |  |  |  |

### Chemical Sterilization

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assessment** | **Summary Information** | **Results** | **Deviations** | **Disposition/Rationale** |
| Bioburden | Bioburden validation summary including the validation method, extraction method, extraction time/temperature, species used for enumeration method, culture media and time, and recovery efficiency and correction factor; action/alert limits, and the monitoring frequency |  |  |  |
| Viral Inactivation | Summary of methods to demonstrate viral inactivation, viral inactivation risk assessment, include future monitoring of risk |  |  |  |
| Bacteriostasis/ Fungistasis | Summary of activities performed |  |  |  |
| Bacterial Endotoxin Testing | Summary of testing methods, batch testing method (number tested per batch, frequency of batch, allowable limits. |  |  |  |

# Document Change History:

|  |  |  |
| --- | --- | --- |
| **Version** | **Description of Changes** | **Date Released** |
| v.1.0 | v.1.0 Initial Release | 04/19/2019 |
| v.1.1 | v.1.1 Updated contact information on the cover page to include Case for Quality mailbox. | 7/24/2019 |