Procedure: Cleanliness and Control of Product

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This procedure addresses ISO 13485 clause 7.5.1.2.1, Cleanliness of Product and Contamination Control. Delete this whole procedure if cleaning or contamination during production is not relevant. However, the quality manual should then address cleaning and contamination at a general level.

As with any manufacturing process, cleaning of product must be controlled and must be documented in process specifications and procedures. Where cleanliness is an important regulatory concern (e.g. sterile implantable devices) consider a dedicated cleaning procedure.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for ensuring cleanliness of product and control of contamination.

# Scope

The scope of this procedure includes materials, components and finished devices and to those areas and equipment that could lead to product contamination at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Production Manager |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Cleanliness of product

Establish procedures related to product cleanliness and documented when:

* product cleanliness is of significance
* product is to be cleaned for any reason or at any time prior to use

These requirements must be established in the design stages of product development.

If the product is supplied non-sterile but is subject to cleaning prior to sterilisation and/or use, these requirements must be communicated to the customer and/or end user.

Where lubricants, coolants, release agents or other manufacturing materials and processing agents may have an adverse effect on the finished product, the product is:

* cleaned to remove the contaminants or
* special procedures are developed to prevent contamination

Where applicable, process operators and maintenance personnel are trained and provided with written instructions on implementation of these methods and procedures.

The term "manufacturing materials" is used in CFR 820.70(h) and is defined in 820.3(p) as “... any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a by-product constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.”

Product cleaning processes and processes for removal of manufacturing materials are developed, documented and implemented under the same procedures and controls that generally apply to manufacturing processes.

Processes designated as a special process are validated and controlled in accordance with Procedure *QP710: Validation of Processes and Software*.

The application of cleaning processes and processes for removal of manufacturing materials (whether from product, components or the manufacturing environment) must be recorded.

These processes would normally be specified in the production work order (refer QP708) or an equivalent system. To satisfy CFR 820.70(h), cleaning activities should be recorded and the record dated and signed. It may be appropriate to design a cleaning record form.

## Contamination control

Returned devices that have been used and may be biologically contaminated, must have a BIO HAZARD label attached. They should be segregated in a dedicated decontamination area and decontaminated before examination, servicing, disposal or other processing.

The decontamination process must be described in a work instruction or SOP. Only trained, authorised personnel may handle and disinfect biologically contaminated devices.

Personnel handling contaminated devices or performing decontamination must be trained in the use of personal protective equipment, handling techniques and the decontamination process.

This applies to devices that have been used by patients or in trials or demonstrations and may be contaminated (typically with bodily fluids). Delete the first two clauses in the above sub-section if they do not apply.

However:

a) if biological contamination is a possibility, ensure appropriate facilities, equipment, written instructions and training is provided

b) where this is likely to occur frequently, dedicated procedures should be developed and containment facilities provided.

Where products may be contaminated with manufacturing materials, detergents, rodenticides, environmental microorganisms, etc, they are handled, identified and processed the same way as Non-conforming and suspect products (refer to Procedure QP805: Control of Non-conforming Product).

Where contaminated product may cause contamination of other product, the work environment or personnel, the contaminated product is removed and placed in a quarantine area.

Contaminated products must be inspected and/or analysed to identify the source and extent of the contamination. A disposition is made as to the fate of the product and whether any actions are required to prevent further contamination of other products, work areas or personnel (refer to Procedure QP805: Control of Non-conforming Product).

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP710 | Validation of Processes and Software |
| QP805 | Control of Non-conforming Product |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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