Procedure: Production and Work Environment

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This procedure is based on Section 6.4 of ISO 13485 and applies to all areas where the environment is to be controlled. Control of the environment is to ensure product conformity rather than personnel comfort.

Clauses 6.4.a) and 6.4.b), require that environmental conditions be controlled where they may have an adverse effect on product quality. Similarly, requirements for health, cleanliness and clothing of personnel must be established and documented when they could adversely affect product quality. Where devices are cleaned prior to sterilisation or use, these requirements do not apply (refer ISO 13485 Clause 7.5.1.2.1).

Environmental requirements vary, depending on the nature of the product, manufacturing methods and regulations. They can vary from general housekeeping standards to high quality clean rooms where particulate and microbial control is critical.

Procedures related to environmental control can cover personnel health, cleanliness, gowning, operation and maintenance, cleaning, air and surface sampling and testing, temperature, pressure, particulates and bioburden. Add to or delete from this procedure to reflect the company’s requirements.

# Purpose

This procedure establishes a process for controlling environmental conditions in production and other appropriate work areas at [Company].

# Scope

The scope of this procedure includes areas where materials, components or medical devices may be adversely affected by environmental conditions. Similarly, it applies to the personnel who enter these areas.

# Responsibilities

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

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

# Procedure

This procedure provides an overall system and outlines the basics of environmental control. It does not provide details of a control program. For a small company, this procedure can be expanded to provide the detail required. For a larger company, or one where a more complex environmental control program is required, the detail may be provided in additional tables, plans and instructions.

This procedure takes the approach of a larger company and references the additional documents.

## General

Environmental conditions for production, and other related areas, are based on regulatory requirements and are determined in conjunction with engineering, production and QA.

The level of environmental control required is based on the type of medical device and whether it is distributed sterile or is cleaned and sterilised prior to use.

Delete and reference to sterilisation if it is not applicable.

Production staff are responsible for maintaining the required environmental conditions in production, packaging and storage areas.

## Control program

Describe the main elements of the company’s environmental control program. Delete or modify sections describing microbial/particulate limits and personnel, below, as relevant.

General operational controls for maintaining suitable environment in all relevant areas include:

* good housekeeping practices – the manufacturing facility ,must be maintained in a clean state, free of dust, rubbish, insects, rodents, etc
* clean up any spills immediately
* ensure ventilation, heating and air conditioning equipment is serviced and maintained appropriately
* develop and maintain gowning requirements

Where microbiological and/or particulate limits are important, establish a suitable program for achieving and maintaining the specified environment. This program should include:

* appropriate design and construction of the clean areas
* isolation and sealing of clean rooms
* air filtration and positive pressure regimes
* personnel requirements including entry procedures, gowning, hand washing, etc
* procedures for entry/exit of materials into/out of clean rooms
* cleaning and sanitation programs
* personnel training
* microbial and particulate monitoring programs

Personnel entering clean rooms are subject to strict hygiene requirements. This shall include:

* medical examination of staff on recruitment and periodically thereafter, as appropriate
* barring entry to personnel with open lesions or with infectious diseases
* hand washing/sanitisation before entry to clean areas
* appropriate gowning
* avoidance of direct contact with product

## Cleaning of production areas and equipment

Cleaning may vary from good general housekeeping to thorough cleaning and sanitisation of production areas. Modify this section as appropriate for the facility.

Production, packaging and storage areas, and related equipment and furniture, are designed to allow effective cleaning and maintenance.

The scope and frequency of cleaning is documented in cleaning schedules. These identify the area to which it applies, the applicable cleaning activities (what to clean, how to clean it and how often) and assign a specific frequency to each activity (daily, weekly, monthly, etc.).

Where special cleaning techniques are required, they are documented in work instructions. Cleaning personnel are specifically trained to carry out this work.

All cleaning and maintenance performed is recorded in a log (refer to Form FM603-1: Cleaning and Maintenance Log).

Modify Section 4.4 (below) to reflect the company’s practices.

## Pest Control

Control of insects and rodents is performed regularly according to a written schedule by a contracted, qualified pest control service. Chemicals used are specified in the contract and Material Safety Data Sheets are kept for all chemicals used. A plan/diagram is maintained indicating the location of baits and which areas are treated.

Generate a pest control schedule.

## Personnel requirements

This section provides a framework only for personnel requirements. It may be expanded to cover the simple requirements or, for more detailed requirements in a more complex facility, procedures may be documented in work instructions, signs, posters or training materials.

Actions of personnel directly impact on maintaining the level of environmental control required. Personnel are therefore subject to the following:

* restrictions on drinking, eating, smoking and chewing gum in controlled areas
* gowning requirements and procedures for controlled areas
* covering of all facial hair
* restrictions on wearing of watches, rings, and cosmetics
* procedures for entering and leaving controlled areas
* restrictions on items and materials allowed in controlled areas

Modify the above list for completeness and relevance.

These requirements, rules and procedures are detailed in procedures, work instructions, signs and posters. Relevant personnel are provided with training in how to use these procedures.

Entry into the clean rooms is restricted to personnel trained in gowning, entry and cleanliness procedures. These include the use of the entry room, knowledge of garments to be worn, hand washing and gowning procedures.

External contractors, consultants, auditors and other personnel who need to enter clean rooms must be trained in relevant procedures and accompanied by a trained person.

## Monitoring and measuring environmental conditions

Environmental conditions are monitored regularly to ensure they comply with requirements and that environmental control systems are effective.

The environmental monitoring program includes:

Modify as appropriate to reflect the company’s requirements. Consider also temperatures (of rooms, refrigerators and freezers), particulates, air flows, air change rates, laminar flow patterns, etc.).

* Bioburden, particulate and other contaminants including both air sampling (passive and active) and surface sampling (touch plate or swab)
* Work instructions should define:
* frequency of sampling
* operating conditions
* location and number of sample
* volume/area sample
* methods for testing
* limits
* records and data analysis.
* Monitoring of physical conditions such as temperature, pressure and RH sensors and/or chart recorders may be installed in clean areas for continuous monitoring
* Work instructions should define:
* the frequency of readings
* acceptable limits
* actions in event of deviations
* how data is recorded and analysed.

For simple systems, expand on this information here. For more complex systems, more detail should be provided in work instructions or additional procedures.

Instruments and devices used to verify environmental conditions must be calibrated and maintained in accordance with Procedure QP715: Measuring and Monitoring Equipment.

When environmental conditions deviate from specified limits, all potentially affected products should be review in accordance with Procedure QP805: Control of Non-conforming Product. When the impact on product has been determined, it may be reprocessed, released for further processing or dispatch or scrapped, as appropriate.

Records are established and maintained to demonstrate that the environment is maintained in conformity with manufacturing specifications.

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 | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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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 |
| QP715 | Measuring and Monitoring Equipment |
| QP805 | Control of Non-conforming Product |
| FM603-1 | Cleaning and Maintenance Log |

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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