Procedure: Device Master Record

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| Document information, authorship and approvals | | | |
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| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
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ISO 13485 clause 4.2.1 f) requires that “For each type or model of medical device, the organisation shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements. These documents shall define the complete manufacturing process and, if applicable, installation and servicing.”

CFR 820.181 requires that “Each manufacturer shall maintain device master records (DMRs)” and specifies similar documentation to ISO 13485.

# Purpose

This procedure describes the requirements for a Device Master Record (DMR), its establishment and maintenance, and the persons responsible.

# Scope

The scope of this procedure includes technical and engineering documents and specifications for each type or model of medical device produced by [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
|  |  |
| Quality Manager |  |

Add roles and responsibilities as applicable for your Company structure.

# Procedure

## General

Each DMR contains or references the documents that precisely describe a device and its manufacture. It includes the device specifications, process specifications, QA procedures, packaging and labelling specifications and, if applicable, installation, maintenance and servicing procedures.

The DMR may be either a file containing these documents (e.g. for a simple device) or an index listing the documents and their location (preferable for more complex devices).

DMR means a compilation of records containing the procedures and specifications for a finished device. A DMR is a current record of the physical configuration of the device.

A unique DMR is set up for each type or group of medical device manufactured by the company.

A DMR will include the following:

* 1. Device specifications
  2. Manufacturing process specifications
  3. Quality assurance procedures and specifications
  4. Packaging and labelling specifications
  5. Installation, maintenance and servicing procedures and methods

## Documents included in DMR

For each type or group of medical device, the DMR includes the following types of documents:

This list is based on 21 CFR Part 820.181, Device Master Record, but is applicable to ISO 13485 also. Modify this list to reflect the company’s actual procedures.

|  |  |
| --- | --- |
| DMR Documents | Description |
| Device specifications | Product name  Intended use(s)  Performance characteristics and operation  Physical specifications  Environmental limitations  Product stability and storage requirements  User safety characteristics  Component, subassembly and assembly drawings and specifications  Bills of materials  Compositions  Formulation  Wiring and piping diagrams  Software specifications |
| Manufacturing process specifications | Process flow charts  Process/assembly line diagrams  Equipment, tools and moulds  Manufacturing environment specifications  Setup procedures  Operator instructions  Equipment maintenance procedures  Validation reports  Sterilisation specifications, procedures and validation  Blank work orders  Nonconforming product/process forms  Other reporting forms |
| Device specific QA procedures and specifications | Quality manual  Quality system procedures and forms  Process control specifications/charts  Control plans, instructions and acceptance criteria for incoming, in-process and Finished device inspection and testing  Procedures and acceptance criteria for verification of packaging, labelling  Installation and servicing procedures  Blank work order forms for recording inspection/testing activities  Traceability and other data for device history records  Device review/evaluation and release checklists |
| Packaging and labelling specifications | Package drawings and specifications  Filling/packaging procedures  Label/labelling drawings  Instruction manuals |
| Installation, maintenance and servicing specifications | Installation specifications and instructions  Maintenance instructions  Servicing specifications and manuals |

Not every document in this section is relevant for each type or group of device. For any particular device, the Engineering, Production and QA Managers decide jointly which documents are to be included in a DMR.

Edit to reflect the responsibilities for determining the contents of the DMR in the company.

## Format of the DMR Index

The content of each DMR is recorded on Form FM402-1: Device Master Record Index. The actual specifications may be kept in a DMR file or they may be referenced in a DMR Index.

Documents in the DMR or referenced from within a DMR Index are identified by:

* code/number
* title or description
* releasing/approval authority
* location of the original/master document

To prevent the need for frequent updates of multiple documents, the DMR does not specify the effective date or revision of each document. This information is maintained in the Document Master List (refer to QP401 and FM401-1) which identifies the revision and distribution status for all documents.

The effective date, revision level and distribution of all documents in the DMR (Index) are maintained in Form FM401-1: Controlled Document Master List (refer also to Procedure QP401: Control of Documents).

## Review, approval and change control

Changes to the DMR contents or to the DMR Index, such as additions, deletions or revisions, are reviewed and approved by the QA Manager.

Review of the DMR (Index) is for completeness for regulatory requirements and not for the correctness of individual documents.

Review and approval of the DMR (Index) is to ensure completeness and relevance rather than for correctness of individual documents. Individual documents in the index are independently reviewed and approved by their issuing authority, in accordance with Procedure QP401: Control of Documents.

A DMR is subject to the same document control requirements as other controlled documents.

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 |
| QP401 | Control of Documents |
| FM401-1 | Controlled Document Master List |
| FM402-1 | Device Master Record Index |

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

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

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.

DOCUMENT END