Procedure: Production Work Order and History Record

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This procedure is based on a work order or job card. Work orders are used to initiate production, identify production and inspection operations and serve as verification and production records.

Work orders are not a specific requirement of the standard or code but they address a number of code requirements. Work orders form a production plan and schedule, a control plan and an inspection record.

Other systems that satisfy ISO 13485 and CFR 820 are acceptable.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for establishing and using work orders.

# Scope

The scope of this procedure includes internal orders for manufacturing, assembly, labelling, packaging, installation and servicing of products at [Company].

Edit the scope as appropriate to the company (i.e. delete those steps that do not apply).

# Responsibilities

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

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

# Procedure

## Development and approval of work orders

Work orders (Form FM708-1: Production Work Order) are developed jointly by Production, Engineering and Quality Assurance. They should be established in the production and quality planning phase (refer to Procedure *QP701: Production Planning and Risk Management*).

A unique work order is established for each device or group of devices:

* a single work order is sufficient for simple devices with few components
* more complex devices may require separate work orders for individual parts or sub-assemblies
* a final assembly work order may then be required for production of the finished device

Edit to reflect the company’s practices.

Work orders specify production processes and product verification activities and their sequence. They provide a means of recording results of verification activities, traceability and release of product.

Work orders are designed to fulfil the following functions:

The following functions satisfy specific requirement of ISO 13485. This work order, or any alternate system, must satisfy all of these functions.

* initiate purchasing and production activities
* communicate the production schedule to relevant personnel (key completion dates, etc)
* document the production plan
* document product verification activities (inspection and test plans)
* provide a format for recording production and verification activities and their results
* provide a record of material and process traceability data
* provide product identification and inspection status during production
* become the principal manufacturing, acceptance, traceability and release record in the Device History Record (DHR)

Work orders are reviewed and approved by Production, Engineering and QA and are subject to control in accordance with Procedure Q*P401: Control of Documents*. Approved blank work orders for each device (or group of devices) are maintained in the Device Master Record (refer to Procedure *QP402: Device Master Record*).

## Initiating production with work orders

This procedure describes a paper-based form and identifies the required information to be entered manually. Work orders are often electronic and this procedure should be modified appropriately to reflect the company’s system.

Internal instructions to manufacture products are issued to production in the form of a work order. Work orders are initiated by the Production Manager by:

* selecting the appropriate work order for the particular product or subassembly to be manufactured
* allocating a job number
* entering the number of units to be manufactured
* determining and enters a due date for completion of each operation
* printing, authorising and forwarding the work order to Production

Describe the process used by the company, i.e. identify any additional information required, such as drawings, specs, checklists, etc.

## Production management and production records

Expand this section to include recording of quality, productivity and traceability data, etc, as appropriate.

Work orders identify the job number and product particulars, including name, type, part number, etc. and assign serial or batch numbers, where applicable. Work orders also specify the quantity and required completion date.

The work orders list all operations and processes necessary to manufacture or assemble the product.

In-process inspections are specified as independent operations that are actioned immediately after the manufacturing operations that they verify.

Work orders may also reference drawings, specifications, materials, instructions, acceptance criteria or other technical documents. Unique reference documents may be enclosed with the work order.

Work orders should accompany products throughout the production phases.

Orders are retained by supervisors of the areas where the associated products are currently being processed.

When manufacturing or inspection is complete, production/inspection data is recorded, signed and dated by the operator, where appropriate.

The completed work order is closed out with a record of the final inspection and release. Work orders are retained in the DHR.

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 |
| QP402 | Device Master Record |
| QP701 | Production Planning and Risk Management |
| FM708-1 | Production Work Order |

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.

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