Procedure: Production Planning and Risk Management

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This procedure describes production and quality planning activities and provides a framework for developing a risk analysis. ISO 13485 is not specific about production planning requirements therefore, if a more structured approach is required, QP703 provides a more detailed example.

# Purpose

This procedure describes the system, provides instructions and assigns responsibilities for planning of production processes and product/process verification.

# Scope

The scope of this procedure includes manufacturing, assembly, labelling, packaging, installation and servicing processes and product and process verification and validation at [Company].

# Responsibilities

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

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

# Procedure

## General

Production and quality planning are carried out by a multidisciplinary team composed of the Production Engineer, Production Manager, QA Manager and Chief Engineer. In the production planning phase the team is led by the Production Engineer who is responsible for design transfer to Production. In the quality planning phase, the QA Manager takes the lead and responsibility for establishing the quality plan.

This team may vary in a small company but appropriate knowledge and experience should be utilised in this planning process.

## Production planning

Modify this section to describe how production plans are developed and documented in the company (e.g. flowcharts, process sheets, operator instructions). Ensure this procedure matches procedure QP708.

The Production Engineer is responsible for product design transfer to production and for planning and specifying production processes.

Production processes include manufacturing, labelling, packaging, installation and servicing. Their sequence and interrelation are defined in process flowcharts.

Each process is identified in a flowchart with the following:

* its name and/or reference code,
* its sequence and interrelation in the overall production system,
* the main processing equipment used,
* any special process designation (i.e. when results of the process cannot be verified by subsequent inspection or testing)

Production process flowcharts are not explicitly required by ISO 13485 and ISO 9001 but they are usually a clear way to demonstrate compliance with production planning requirements to an auditor. Ensure the flowchart documents are controlled by QA.

The Production Engineer and Production Manager must evaluate each process to determine the studies, documentation, controls and training required. This evaluation should address:

* and training of process operators
* operating the need for a process risk assessment
* documentation of process specifications
* environmental requirements
* qualifications procedures/instructions
* validation requirements
* process monitoring and controls

The following should be considered:

* previous experience with the process or similar processes
* complexity of the process and the equipment
* intricacy of the operator/process interface
* acceptance criteria and tolerances
* ability to detect process failures and/or non-conformances
* the severity of harm that may be caused by a failure

When the preliminary planning phase is complete, the actual studies, documentation and training are developed in accordance with relevant procedures and work instructions.

Many documents prepared in this planning and development phase are required for the Device Master Record (DMR) file. Refer to the list of documents included in the DMR in Procedure QP402: Device Master Record.

## Planning of product verification, inspection and testing activities

QA is responsible for planning verification, validation, monitoring, inspection and testing activities and for product acceptance criteria.

Product verification activities are planned in three phases:

### Verification of purchased product

This includes evaluation, approval and monitoring of suppliers, evidence of product conformity provided by suppliers and incoming goods inspections (refer to Procedure QP707: Verification of Purchased Product).

### In-process inspections

This includes inspection and testing of components and intermediates during manufacture (refer to Procedure QP803: In-process Inspections).

### Final Acceptance Inspection

This includes inspections and testing of finished product; release of product (refer to Procedure QP804: Final Acceptance Inspection).

For each product or family of products, the QA Manager determines:

* which components and characteristics require verification
* when and what inspection or testing is required (e.g. method, equipment, location, production stage, timing, frequency)
* what procedures are needed to perform the testing
* the acceptance criteria for release of components or products
* records required to provide evidence of conformity

To determine inspection and testing requirements, the QA Manager and planning team must consider:

* the criticality to product safety of the component and characteristic
* past failure rates
* supplier performance and evidence of conformity
* process performance, capability and stability and process controls
* acceptance criteria and their tolerances
* detect ability of process failures/product nonconformities
* process risk analysis

When preliminary planning is complete, QA finalises inspection and testing procedures, sampling plans, acceptance criteria, forms for recording results and any other documents required to define and record these activities.

Documents established during planning and development may be included in the DMR (refer to Procedure QP402: Device Master Record).

## Production work order

Work orders document production, inspection and testing operations (refer QP708 for more detail). If work orders are not used, describe how results of production and quality planning are recorded. Records could be in detailed production flowcharts or in control plans that list and specify all inspections.

Results of production and quality planning are documented in Form FM708-1: Production Work Order. The Work Order forms are developed for each product or group of products. There may also be Work Orders for manufacturing subassemblies. Development and establishment of Work Orders is documented in Procedure QP708: Production Work Order and History Record.

## Risk management

Clause 7.1 of ISO 13485 (refer also to ISO 14971) requires that risk management be used throughout product realisation. However, these standards do not provide details so more specific risk assessment texts or methodologies should be referenced.

This section assigns responsibility for risk analysis, defines the criteria for selection of processes to be analysed and outlines a generic method for carrying out the risk analysis.

In manufacturing, risk management and other product realisation activities are focused on quality system controls on processes with highest risk. Risk is defined as a combination of the probability of process failure and the severity of the harm caused by that failure, if undetected.

The Production Engineer and Production Manager are responsible for selecting manufacturing and other product realisation processes for formal risk analysis studies. In deciding which processes are selected, the following must be considered:

* process and equipment complexity
* the nature of the operator/process interface
* tolerances on acceptance criteria
* experience with the process or similar processes
* detect ability of process failures and/or nonconformities
* severity of harm that could be caused by a process failure

These are qualitative considerations to help prioritise risk analysis studies on processes likely to have high risk factors.

The Production Engineer is responsible for selecting an appropriate risk assessment technique for each process. The common techniques used include Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis (FTA), Hazard Analysis Critical Control Point (HACCP) and Hazard and Operability Study (HAZOP).

The following sequence of steps is used to assess risk for all techniques.

1. Identify the potential failure modes and associated mechanisms of failure. Failure mode is the type of defect that the process failure will produce. The failure mechanism is the event that causes the failure, e.g. power loss or low temperature.
2. Determine for each mechanism of failure the probability of occurrence and the probability of failure/defect not being detected. The probability should be ranked 1 to 5 with 5 being the highest risk of failure.

Several numbering systems are used with rankings varying from 1 to 10 through to a simple High, Medium and Low. In general, the simpler the system the better. There is no value in creating a scoring system that results in a larger range of outcomes than there are actions that can be taken.

To help determine the probability, it is useful to identify what process control measures are currently implemented to prevent the failure and what controls (inspection, testing, etc.) are implemented to detect the failure.

1. Determine the degree of harm or loss to the customer, user or patient that could potentially result from each mode of failure (product defect) and how severe it would be. This can be done by ranking the severity on a scale of 1 to 5, with 1 for "No discernible effect" and 5 for "Serious injury or death".

Again, use as simple a numbering system as possible while achieving a suitable degree of differentiation.

1. Combine the probability of process failure and the severity of the harm that could be caused by that failure, using suitable formulas and techniques, to calculate a risk factor.

If the risk factor is too high, additional process controls and/or failure detection measures may be implemented to decrease the probability of an undetected failure. Alternatively, the process may be redesigned to eliminate or reduce the probability of the failure.

Risk analysis studies and their results, as well as any actions taken to reduce risk factors, are documented in process risk management files. These files are maintained by the Production Engineer.

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 |
| 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 |
| QP402 | Device Master Record |
| QP707 | Verification of Purchased Product |
| QP708 | Production Work Order and History Record |
| QP803 | In-process Inspections |
| QP804 | Final Acceptance Inspection |
| 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 |
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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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