Procedure: Validation of Processes and Software

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This procedure addresses the requirements of ISO 13485 Clauses 7.5.1.3, 7.5.2.1, 7.5.2.2 and the last paragraph of 7.6. It also complies with CFR 820.75 and 820.70(i).

More company specific detail is required in this procedure. Where possible, substitute the general terminology with specific instructions on how activities are actually performed.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for validation and control of production processes and validation of computer software used in production and in quality control.

# Scope

Edit the following scope as appropriate for the company.

The scope of this procedure includes all special processes used in manufacturing, assembly, labelling, packaging, installation and servicing of medical devices and to processes using computer software at [Company].

# Responsibilities

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

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

# Procedure

## General validation requirements

All processes where the resulting output cannot be verified by subsequent monitoring or measurement, must be validated. Validation must demonstrate that the process is capable of consistently achieving planned results.

Validation must include:

* defined criteria for review and approval of processes
* approval of equipment and qualification of personnel
* use of specific methods and procedures
* clear documentation and record keeping
* revalidation.

## Identification of special processes

Quality Assurance (QA) is responsible for reviewing all manufacturing processes to identify those that need to be designated as special processes and that will require validation. Production and Engineering may be called upon to assist with the review.

The following types of processes are designated special processes unless a proven method of inspection or testing can be implemented to demonstrate their effectiveness:

* sterilisation, disinfection and cleaning
* joining of materials by welding, soldering, splicing or gluing
* moulding and casting of metals, plastics or cements;
* coating with paints, epoxies, metals, plastics or other materials
* heat, radiation or chemical treatment of materials

Add to or delete from this list to include any additional types of processes used by the company and that meet the above definition of special processes. Delete those that are not relevant.

In addition to processes not falling under the definition of a special process, QA may designate any manufacturing process to be a special process on the basis of the importance of the process and/or a history of problems with controlling the process.

Special processes are identified in a process flowchart (refer to Procedure QP701: Production Planning and Risk Management).

If process flowcharts are not used, describe how special processes are identified and documented (revise procedure QP701 to match).

## Validation of special processes

Each special process is validated to demonstrate its ability to achieve planned results. QA is responsible for selecting an appropriate validation method, performing the validation and documenting its results. Production and Engineering may be called upon to assist with these activities.

Process validation and its results are documented in a validation report. As a minimum, the report includes the following information:

* identification of the validated process and/or equipment
* characteristics of the process and/or the processed product to be validated
* validation methodology
* defined criteria for review and approval of the process
* validation results
* required revalidation frequency
* signature and date of the persons approving the validation report

Process and/or equipment validation reports are reviewed and, when satisfactory, are approved by the QA Manager. The approval is documented by the QA Manager signing and dating the report.

When material changes that could impact process performance are made to a special process, the process must be revalidated and re-approved.

Revalidation should also be considered when processes deviations (non-conformities) occur.

## Control of special processes

In addition to validation, special processes are controlled and monitored to ensure that the specified conditions continue to be met. The process control and monitoring program includes, as appropriate:

* use of specific methods and procedures
* training and qualification of process operators
* monitoring and recording of process parameters

Process parameters may be such things as temperature, pressure, speed, tool wear, etc. Typically, values of selected important parameters would be checked and recorded in a log or trend chart at prescribed intervals (e.g. SPC).

Records of process monitoring and control for special processes include documentation of the monitoring method, data, date performed and identification of the person(s) performing the process or operating the monitored equipment. These records are maintained in the DHR (Device History Record).

Operators and process parameters may be recorded in the work order (refer to QP708). The monitoring method would be documented in process operator instructions.

## Sterilisation process

Sterilisation process is considered special process. Special processes are validated and qualified using a documented validation protocol. A validation report will typically contain all the parameters of the sterilisation process and will be maintained in the Device Master Record (DMR).

All control parameters of the sterilisation process are recorded and are traceable to each production batch. These records are maintained in the DHR.

Where sterilisation is subcontracted, the subcontractor is required to validate the process, submit the validation report and to maintain records of process parameters.

## Computer software

Where a software malfunction could result in product non-conformity, the computer software controlling the production process must be validated prior to initial use. This includes software used in Quality Control (QC) inspection equipment (or otherwise in monitoring and measurement of specified requirements).

QA and Information Technology (IT) are responsible for validation of production process software and QC inspection software. This includes preparation of validation protocols, performance of the validation and documenting the results.

Software validation and its results are documented in a validation report. At a minimum, the report includes the following information:

* identification of software including the revision level and the processes or equipment controlled by the software
* functions, modules, peripherals, sensors, alarms, etc. to be validated
* validation methods, simulation techniques, etc. that were used
* definition of criteria for approval of the software
* results
* signature(s) and date of person(s) approving the validation report

Software validation reports are reviewed and approved by the QA Manager. The approval is documented by the QA Manager signing and dating the validation report.

When validated software is changed, the QA Manager evaluates the need for revalidation. If validation is required, QA and IT evaluate the extent and scope of the revalidation.

After revalidation, the QA Manager reviews and approves the validation report.

If revalidation is not deemed to be necessary (i.e. changes do not pose an increased risk to the function of the software), the QA Manager retrieves the previous validation report and extends approval to cover the new revision.

Where possible, production software developed and supplied under contract is validated by the contractor, in accordance with acceptance procedures which should be specified in the contract. The QA and IT Managers are responsible for reviewing software development contracts to ensure the software validation program meets requirements of this procedure.

Software validation reports established by the contractor are reviewed and approved by the QA Manager. Only approved software may be used in production. Validation records should be supplied with the software.

Standard off-the-shelf software for use in production processes and software that is included with standard manufacturing equipment is only purchased from approved suppliers and in accordance with Procedure QP705: Supplier Evaluation and Monitoring and Procedure QP706: Purchasing.

Supplier approval includes gathering and evaluating information regarding the supplier's software validation program. Only suppliers who validate their software before release may be placed on the Approved Supplier List.

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. |
| Special process | A manufacturing or servicing process which cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become apparent only after the product is in use or the service has been delivered. |
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ISO 13485 defines processes requiring validation and this has been adapted for the above definition. (CFR 820.75 includes only the first sentence.)

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 |
| QP701 | Production Planning and Risk Management |
| QP705 | Supplier Evaluation and Monitoring |
| QP706 | Purchasing |

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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