Procedure: Analysis of Data

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This procedure describes collection and analysis of data already required elsewhere in the standard and that may already be collected for the company's own information.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for collection, analysis and reporting of data related to the performance of the Quality Management System (QMS) at [Company].

# Scope

The scope of this procedure includes data listed in Section 4.2: Categories, of this procedure.

# Responsibilities

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

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## General

This is a paraphrase of ISO13485:2016 (The ISO 13485 standard was updated to keep up with changes in the industry and to address changes in the underlying ISO 9001 standard. While the old ISO 13485 2003 standard was based on the old ISO 9001:2000 standard, the new one is based on ISO 9001: 2008. Since 2003, many jurisdictions had either revised or introduced new regulations for medical devices and these have been integrated with the new ISO 13485 standards.)

clause 8.4 which states that the data is to "...demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made".

Data and information recorded in quality records are compiled and analysed periodically to determine trends in the performance and effectiveness of the QMS and to identify opportunities for improvement.

QA is responsible for coordinating reviews and for reporting conclusions and trends to senior management within the framework of management reviews of the QMS (refer to Procedure *QP501: Management Review*).

## Categories

Data collection and analysis is defined in terms of the categories ISO 13485 Clause 8.4 a) to d). This ensures and demonstrates compliance with the standard.

Four categories of information and data are identified in ISO 13485 clause 8.8, a) to d). This information is recorded, collated and regularly analysed. These are described in the following four clauses.

Customer feedback is recorded and analysed by purchasing/marketing and QA:

* customer feedback and satisfaction is collected (refer to Procedure *QP801: Feedback and Customer Satisfaction*)
* customer complaints are recorded in a complaints log (refer to Procedure *QP809: Customer Complaints*)

Conformity to product requirements:

Add other data relevant to product conformity at the company.

Records are compiled and analysed by engineering, production and QA (refer to Procedure *QP805: Control of Non-conforming Product*):

* scrapped products
* reworks and repairs
* non-conformance reports

Characteristics of processes and products are compiled and evaluated by engineering, production and QA:

If other data related to this category is already collected, add it to this list.

* process performance variation recorded in SPC charts

Delete if SPC is not used.

* set-up records (refer to Procedure QP803: In-Process Inspections)
* cycle times recorded in work orders (refer to Procedure QP708: Production Work Order and History Record)
* unscheduled machine downtime recorded in equipment maintenance logs (refer to Procedure *QP602: Equipment Maintenance*)

Supplier quality performance records are compiled and evaluated by purchasing and QA:

Supplier quality performance is required in ISO 13485 Clause 7.4.

* supplier quality and on-time delivery performance recorded in sub-contractor quality performance files (refer to Procedure *QP705: Supplier Evaluation and Monitoring*)

## Reporting and use of data

Quality and operational performance data and trends are reported to the senior management for review and planning. Information is regularly communicated through distribution of charts and reports and through formal management review (refer to Procedure *QP501: Management Review*).

Quality and operational performance data and trends are used to identify opportunities for improvement and reviewing quality objectives (refer to Procedure *QP807: Continuous Improvement* and Procedure *QP501: Management Review*).

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 |
| QP501 | Management Review |
| QP602 | Equipment Maintenance |
| QP705 | Supplier Evaluation and Monitoring |
| QP708 | Production Work Order and History Record |
| QP801 | Feedback and Customer Satisfaction |
| QP803 | In-Process Inspections |
| QP805 | Control of Non-conforming Product |
| QP807 | Continuous Improvement |
| QP809 | Customer Complaints |

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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