Procedure: Continuous Improvement

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Continuous improvement is only required by ISO9001:2015. However, it is necessary to maintain the suitability of the quality system. In ISO13485:2016, continuous improvement is not a discreet element but it is a way to managing the system. This procedure defines how the six elements of a quality system are used to achieve continuous improvement. The six elements are:

|  |  |
| --- | --- |
| quality policy  quality objectives  internal audits | quality performance data  corrective and preventive actions  management reviews |

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for continuous improvement of the Quality Management System (QMS).

# Scope

The scope of this procedure includes all processes and related activities of the QMS at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| All personnel |  |
| Senior Managers |  |
| Quality Manager |  |

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

# Procedure

## General

This clause uses the six elements used in continuous improvement (see above) and refers to the quality manual where the relationship is described in more detail.

[Company] is committed to a continuous improvement philosophy. Continuous improvement opportunities are identified by management review of audit results and analysis of quality performance data.

Improvement projects are defined either as corrective and preventive actions or as quality objectives supporting the quality policy. Interaction of these quality system processes to achieve continuous improvement is defined in this procedure and in the Quality Manual Section 8.5, Continuous Improvement.

## Identification of improvement opportunities

Edit the following lists as appropriate for the company. Ensure there is a system for collecting and analysing data for each item on the list (ensure this matches QM Section 8.4, Analysis of data).

To identify opportunities for improvement, [Company] continuously monitors its quality and operational performance in the following areas:

* process data and product characteristics and their trends
* product non-conformances
* customer satisfaction/dissatisfaction and feedback
* market research and analysis of competitive products
* feedback from employees, suppliers and other interested parties
* internal and external audits of the quality system

The clause below is not explicitly required by ISO 13485 but it makes continuous improvement more comprehensive.

Additionally, special assessment projects may be initiated to identify opportunities for improvement in other areas, such as:

* machine set-up and tool changeover times
* non value-added use of floor space and other facilities
* excessive testing not justified by accumulated results
* waste of labour and materials
* cost of non-quality
* excessive handling and storage

Employee suggestions are a source of information for improving processes, procedures and work environment. All staff are encouraged to make improvement suggestions. Suggestions are submitted to, evaluated and prioritised by QA.

Opportunities for improvement may be related to specific events or problems such as changed regulatory requirements, new technology, complaints, returned products or production interruptions.

Opportunities for improvement may be:

* continuous - by departmental managers, based on daily feedback from operations, employee suggestions and in response to events or problems
* periodic - by management review, based on analysis of longer-term data and trends

## Evaluation of improvement opportunities

Opportunities for improvement are evaluated by QA and are based on daily feedback from operations. Where appropriate, they are implemented through corrective and preventive actions.

Improvements are triggered by identification of non-conformances, review of complaints, audits, etc (refer to Procedure *QP810: Corrective and Preventive Action*).

Opportunities for improvement based on longer-term data and trends are evaluated by management review. They are prioritised with respect to their relevance for enhancing customer satisfaction and achieving the quality policy. Improvement opportunities selected for implementation are defined as quality objectives and are implemented through special management projects (refer to Procedure *QP501: Management Review*).

Opportunities for improvement of products are evaluated by marketing, engineering, QA and senior management.

## Implementation of improvement projects

Improvements to address daily feedback from operations are implemented through corrective and preventive actions (refer to Procedure *QP810: Corrective and Preventive Action*).

Longer-term improvement projects to achieve quality objectives and the quality policy, improve quality performance or correct unfavourable trends are implemented through special projects (refer to Procedure *QP501: Management Review*).

Product improvement projects may be implemented through product briefs or engineering change requests.

## Review of continuous improvement

The continuous improvement system is reviewed periodically by senior management review (refer to Procedure *QP501: Management Review*).

Management review includes evaluation of current and completed corrective and preventive action projects for achieving quality objectives. These reviews assess quality performance data, to identify new opportunities for improvement and new quality objectives.

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 |
| QP501 | Management Review |
| QP810 | Corrective and Preventive Action |

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

| Associated records | |
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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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