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Example Procedure

CORRECTIVE & PREVENTATIVE ACTION

1. PURPOSE

Purpose of this process description is the permanent improvement of the quality of products and processes through systematic elimination of potential and already occurred causes of nonconformities, including customer complaints, internal audit reports and non-conformance events.

The aim of this procedure is the elimination of the cause of nonconformities as well as the prevention of reoccurrence.

2. SCOPE

This process description is valid for all sections and products of [Insert Company Name].

All staff are responsible for abiding by this SOP and ensuring all non-conformance events are reported to senior management at the earliest available time and to follow all corrective and preventative actions initiated.

The [insert relevant positions] are directly responsible for this procedure.

3. TERMS & DEFINITIONS

Complaint: An expression of dissatisfaction, made either verbally or written, about the quality of product, the standard of service or lack of action taken by staff, affecting an individual customer or a group of customers.

Continuous Improvement: Regular review of the management and quality system to permanently improve quality, service and value offered to the customer

Corrective Action: Action to eliminate the cause of a detected non-conformity or other desirable situation. Corrective action is taken to prevent or eliminate the recurrence of non-conformity.

FMEA: Failure Mode Effects Analysis, a method to identify potential problems and their subsequent effect

Non-Conformance: Any non-fulfilment of required specification. Any defect, imperfection or failing against specifications, procedures and/or processes.

Preventative Action: Action to eliminate the cause of a potential non-conformity or other undesirable outcome. Preventative action is taken to prevent the occurrence whereas corrective action is taken to prevent recurrence.

Non-conforming goods:-Nonconforming goods are goods or products, which do not conform to COMPANY or customer expectations or determinations.

Returned goods: Returned goods are goods, which return from storages and customers. A delivery note of returned goods has to be added to the goods (incl. reasons). Reasons for returned goods are:

- Goods have expired from recommended shelf-life.

- Goods are not as per Product Specification.

Urgent actions: Urgent actions are preventive actions to eliminate the causes of nonconformities.

4. PROCESS

Corrective action
Corrective actions are reactive – a process, product, service or management has gone wrong and these are the actions taken to deal with this issue/problem.

Non-conformance is resolved through corrective actions.

Corrective actions can be identified through:
- Conducting internal audits and general inspections
- Testing and monitoring
- Consulting with staff
- Customer feedback and complaints
- Hazard reporting
- Non-conformance
- System failures
- Regulatory requirements

Steps to be taken with corrective action:
- Review and document the issue/problem
- Contain or temporarily resolve the problem. This may include removing and isolating the affected product or replacing the service.
- Investigate the cause of the problem. The Company shall use a root cause analysis process to identify the cause of a problem.
- Propose an appropriate and suitable solution that will prevent the issue/problem from re-occurring. This may include a change to the process.
- Report actions taken in the Corrective Actions report

Corrective Actions shall be reviewed at Management Reviews or on an immediate basis if urgent in nature.
The Management Committee is responsible for close out of corrective actions and ensuring that effectiveness has been resolved appropriately.

Urgent actions
At the appearance of a (potential) source of defect with high risks the responsible department manager has to initiate urgent actions to eliminate the causes irrespective of the following rules.

Cause analyses of nonconformities.
The Company shall use root cause analysis to review issues/problems and to identify appropriate solutions.

Root cause analysis involves:
- Defining the problem
- Asking:
  - What is the problem?
  - When does the problem occur?
  - Where does the problem occur?
  - Significance of the problem?

Create a cause-and-effect chart
For each primary effect, ask why?
Look for causes in Actions and Conditions

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Connect causes with a "Caused By"
Support causes with Evidence
Identify effective solution
Challenge the causes and offer solutions
Identify the best solutions;
That prevent recurrence
Are within control
Meet goals and objectives
Implement the best solution

Implementation of eliminating actions
Corrective actions may include:

- Behaviour of employees
- Process conditions
- Manufacturing process
- Formulation or product design
- Process management
- Packaging
- Distribution conditions
- Implementation of the QM-system
- Monitoring of the effectiveness

Once a corrective action is completed the Management Committee shall review the effectiveness in resolving and removing the issue/problem.

The corrective action shall not be closed out until the Management Committee can confirm its effectiveness. Where the effectiveness is considered to be insufficient it will remain active

Recording and documentation
All corrective action activities shall be recorded in the CAPA. Register.

Preventive actions
Preventative actions are proactive – something could go wrong and actions are taken to stop it happening or to reduce its severity.

In contrast if something has gone wrong, then it is a non-conformance and is addressed as corrective action, Preventative actions are identified through the continual monitoring and verification of the management and quality system.

Preventative actions provide the evidence that an effective quality system is established and is able to anticipate, identify and eliminate potential issues/problems before they cause harm to product quality and safety, or affect customer satisfaction.

Preventative actions can be identified in the following manner:

- Management review process
- Process monitoring
- Trend analysis
- Process analysis
- FMEA analysis
- Risk assessment
- Staff suggestions for improvement
- Contingency planning
- Marketplace trends
- Regulatory or legislation changes

- New technology
- Internal and external audits
- Observation

Preventative actions shall be identified in the CAPA Register. This register shall include:

- Identification of potential problem
- Suggested investigation
- Action decided to be taken
- Effectiveness of action taken
- Close out.

The Management Committee will review and manage all preventative actions.

Continuous Improvement

The idea of a permanent improvement is a main topic within the comprehensive quality management. All staff support the process of continuous improvement.

Continuous improvement is included in Management Review and all staff are encouraged to submit ideas and innovations to improve efficiency, effectiveness and customer satisfaction

5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program was conducted according to the Quality Policy.

- Non-Conformance Reports
- Non- Conformance Register
- Corrective Action Request Form
- Corrective Action Register
- Management Review

6. DOCUMENT HISTORY

Version No.:			
Last saved by:		Date:	
Original Author:		Date:	
Approved by:		Date:	