Presentation 17

Corrective and preventive actions

- Corrective and preventive actions definitions
- The corrective and preventive actions process
- Information collection
- Analysis of collected information
- Development of solutions and their implementation
- Follow-up of activities
- Organizing for preventive and corrective actions

OHT 17.2

Corrective and preventive actions - definitions

Corrective actions

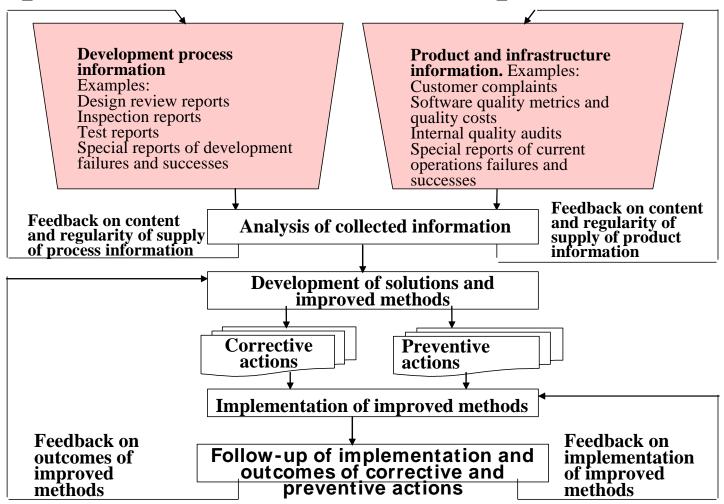
A regularly applied feedback process that includes collection of information on quality non-conformities, identification and analysis of sources of irregularities as well as development and assimilation of improved practices and procedures, together with control of their implementation and measurement of their outcomes.

Preventive actions

A regularly applied feedback process that includes collection of information on potential quality problems, identification and analysis of departures from quality standards, development and assimilation of improved practices and procedures, together with control of their implementation and measurement of their outcomes.

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The corrective and preventive action process



Sources of CAPA information

Internal information sources

Software development process

- * Software risk management reports
- * Design review reports
- * Inspection reports
- * Walkthrough reports
- * Experts opinion reports
- * Test reviews
- * Special reports on development failures and successes
- * Proposals suggested by staff members

Software maintenance

- * Customer applications statistics
- * Software change requests initiated by customer applications
- * Software change requests initiated by maintenance staff
- * Special reports on maintenance failures and successes
- * Proposals suggested by staff members

SQA infrastructure class of sources

- * Internal quality audit reports
- * External quality audit reports
- * Performance follow-up of trained and certified staff
- * Proposals suggested staff members

Software quality management procedures class of sources

- * Project progress reports
- * Software quality metrics reports
- * Software quality cost reports
- * Proposals of staff members

External information sources

- * Customer complaints
- * Customer service statistics
- * Customer-suggested proposals

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Corrective actions board (CAB) – the tasks

- * Collecting CAPA records from the various sources.
- * Screening the collected information.
- * Nominating ad hoc CAPA teams to tend to given subjects or head the teams.
- * Promoting implementation of CAPA
- * Following up information collection, data analysis, progress made by ad hoc teams, implementation as well as outcomes of improved CAPA methods.