Project QMS and “Quality by Design” Activities
Main Topics of the Presentation

• “Quality by Design”
• Project Structure
• Critical Control Points in the Different Project Phases
  1. Acquisition Phase
  2. Design and Engineering Phase
  3. Construction and Testing Phase
• QMS Platforms and Tools
“Quality by Design”

“Quality cannot be tested into products; it should be built-in or should be by design.”

The focus of this concept is that quality should be built into a product with an understanding of the product and process by which it is developed and manufactured along with a knowledge of the risks involved in manufacturing the product and how best to mitigate those risks. This is a successor to the “quality by QC” (or “quality after design”) approach that the companies have taken up until the 1990s.
Project Structure

Each project can be divided in process sequences

→ Each process sequence has its process steps

→ Some of these process steps are critical (so called critical process steps)

They are called this way because failure in these steps can create serious consequences.

→ For each critical process step, acceptance criteria are defined.

With the fulfilment of the acceptance criteria, the complete and correct implementation is entered in the project report (later explained) for confirmation.
Different Project Phases

During the following three phases, procedures and activities have to be performed at critical control points:

1. Acquisition Phase
2. Design and Engineering Phase
3. Construction and Testing Phase
Critical Control Points in the Different Process Phases
Critical Control Points

Introduction

Critical control points are the corner posts of the QMS and are the points at which the QMS process interacts with the project realization process.

All critical control procedures and activities have to be documented properly and have to be tracked in the project report.
Order Processing Schematic

The Order Processing Schematic shall serve as an overview of the order processing process and shall display the different dependencies.
1. Acquisition Phase

1.1 Review of the Quotation

Key Factors:
• Technical & financial feasibility
• Comprehension of customer requirements and needs

Control procedure / responsibilities:
• Independent review of the quotation
• Optional: Additional review

Before a quotation is prepared, it has to be checked if the customer’s requirements are technically feasible and can be fulfilled.

=> Well-prepared quotations are the basis for a successful project acquisition → Quotation Tracking List!
1. Acquisition Phase

1.1 Review of the Quotation

The following points should be considered for preparation and review of quotations:

• Offered prices for products and costs should be realistic and competitive, but should assure profitability of the project at the same time

• Prices should contain a reasonable negotiation margin

• All needs and requirements of the customer from the inquiry should be included in the quotation

• The scope of delivery, services, shipment, warranty, spare parts, etc. should clearly be described to avoid misunderstandings later

• The offered project timelines should comply with the customer’s overall project schedule, but should also be realistic and reasonable at the same time

• A fair, milestone-bound payment schedule should be proposed
1. Acquisition Phase

1.2 Negotiations and Contract Conclusion

Key Factors:
- Adjustment of the quotation with preservation of the project profitability
- Signing of the final quotation / contract

Control procedure / responsibilities:
- Independent review of the adjusted quotation and the final contract
- Optional: Additional review
- Signing of the final contract

The initial quotation is adjusted following the input of the customer. Prices are negotiated and the quotation is corrected accordingly.
1. Acquisition Phase

1.2 Negotiations and Contract Conclusion

The following points have to be considered for this procedure in addition to the points mentioned before:

• The discount given should not exceed the predefined negotiation margin, project profitability should be maintained

• All changes in the scope of delivery, services, etc. (customer input or results of the negotiations) should be included in the revised quotation and the final contract
2. Design & Engineering Phase

2.1 Formation of the Project Team

Key Factors:

- Enough resources are available for the project
- The project staff has the required qualifications and skills

Control procedure / responsibilities:

Assessment

Project Management

Enough resources have to be available to successfully handle the project.
2. Design and Engineering Phase

2.1 Formation of the Project Team

If enough resources are not available, the following options exist:

- Hiring of additional employees (to be discussed with the human resources / finance department)
- Evaluation of subcontractors which are able to handle a part of the project

If Subcontractors are required, they should be selected carefully. Subcontractors should...

- ... not impair the overall quality of the project (skilled personnel, timelines, etc.)
- ... not endanger the profitability of the project
- ... work following a QMS as well
2. Design & Engineering Phase

2.2 Basic Design / Engineering

Key Factors:
Correctness of early design and engineering documents

Control procedure / responsibilities:
- Independent review of the documents
- Both parties have to formally approve the critical documents by signing

All critical early design / engineering documents are submitted to the customer for review and approval.

Aim is ...
- ... to verify that “the Company” and the customer both have the same understanding of the concept for project realization.
- ... to detect, correct and prevent potential failures as early as possible in the project
2. Design & Engineering Phase

2.2 Basic Design / Engineering

Examples of relevant Documents:

- Conceptual Design
- F-URS
- Basic Engineering Files
- Basis of Design

Acquisition Phase

Formation of Project Team
Agreement with Sub-Contractors

Basic Design / Engineering

Review / Approval
Detail Design / Engineering

Review / Approval
Design Review / Qualification

Approval for Construction

Construction & Testing Phase
2. Design & Engineering Phase

2.3 Detail Design / Engineering

Key Factors:
Correctness of the detail design / engineering documents

Control procedure / responsibilities:
- Independent review of the documents
- Both parties have to formally approve the critical documents by signing

All critical detail design / engineering documents are submitted to the customer for review and approval.

Aim is ...
- ... to verify that “the Company” and the customer both have the same understanding regarding the details of the project realization.
2. Design & Engineering Phase

2.3 Detail Design / Engineering

Examples of relevant Documents:
- Functional Specification
- Hardware Design Specification
- HVAC Schematic & Calculations
2. Design & Engineering Phase

2.4 Design Review / Qualification

Key Factors:
Correctness of all critical construction documents → Including critical documents from sub-suppliers / subcontractors

Control procedure / responsibilities:
• Independent review of the documents
• Both parties have to formally approve the critical documents by signing
• The review and approval procedure is documented in a DR / DQ report

=> At the end of this report, the formal approval for construction is given
2. Design & Engineering Phase

2.4 Design Review / Qualification

Examples of relevant Documents:
- P&I Diagrams
- Layouts
- Wiring Diagrams
2. Design and Engineering Phase

2.4 Design Review / Qualification
(Approval for Construction)

At the end of the design review / qualification, the project management and the competent customer representatives have to agree on the approval for construction.

The design review / qualification is the last chance to detect potential failures before construction is started. Undetected potential failures are likely implemented during construction then and may cause high consequential costs therefore.
3. Construction & Testing Phase

3.1 Qualification Planning Documents

**Key Factors:**
Before the testing phase is started and the test plans are approved, the qualification planning documents have to be approved by the customer.

**Control procedure / responsibilities:**
Since GMP qualification is ultimately the responsibility of the system user, the final qualification planning documents have to be approved by the customer.
3. Construction & Testing Phase

3.1 Qualification Planning Documents

Examples of relevant Documents:
- AVMP
- Risk Assessment
- System Qualification Plan
3. Construction & Testing Phase

3.2 Commissioning / Factory Acceptance Test (FAT)

Key Factors:
Before shipment, the equipment should work as expected and specified and should be free of defects.

Control procedure / responsibilities:
- FAT plans and reports are reviewed and approved.
- If factory acceptance tests are used for qualification as well (IQ / OQ, test leveraging), the FAT plans and report have to be reviewed and approved.

If defects or failures are detected during FAT, it is less expensive to remedy these defects / failures in the factory, before shipment.
3. Construction & Testing Phase

3.2 Commissioning / Factory Acceptance Test (FAT)

Examples of relevant Documents:

- FAT Plans
3. Construction & Testing Phase

3.3 Commissioning / Site Acceptance Test (SAT)

Key Factors:
- After the installation at site, the equipment should work as expected and specified and should be free of defects

Control procedure / responsibilities:
- SAT plans and reports are reviewed and approved
- If site acceptance tests are used for qualification as well (IQ / OQ, test leveraging), the SAT plans and report have to be reviewed and approved

Equipment ready for hand-over? ☑️ or ❌

=> After SAT has successfully been finished, the equipment / system can be handed over to the customer and qualification can be started
3. Construction & Testing Phase

3.3 Commissioning / Site Acceptance Test (SAT)

Examples of relevant Documents:

- SAT Plans
3. Construction & Testing Phase

3.4 Installation Qualification (IQ)

Key Factors:
- GMP documented evidence that the installed equipment / system comply with the user requirements and the agreed design

Control procedure / responsibilities:
- The IQ plan and report can be written and reviewed
- ...but must be reviewed and approved by the customer’s qualification department in the end

If properly organized, FAT / SAT tests can be used for IQ.

IQ tests can be executed by “the Company”, but have to be witnessed by the customer in this case.
3. Construction & Testing Phase

3.4 Installation Qualification (IQ)

Examples of relevant Documents:

- IQ Plans
- URS
- HDS
- P&I Diagrams
3. Construction & Testing Phase

3.5 Operational Qualification (OQ)

Key Factors:
- GMP documented evidence that the installed equipment / system comply with the user requirements and the agreed functionality

Control procedure / responsibilities:
- The OQ plan and report can be written and reviewed
- ...but must be reviewed and approved by the customer’s qualification department in the end

If properly organized, FAT / SAT tests can be used for OQ.

OQ tests can be executed by “the Company”, but have to be witnessed by the customer in this case.
3. Construction & Testing Phase

3.5 Operational Qualification (OQ)

Examples of relevant Documents:
- FS
- URS
- SDS
- OQ Plans

Flowchart:
1. Installation Qualification (IQ)
2. Approval by Customer
3. Review / Approval
4. Final Invoice
3. Construction & Testing Phase

3.6 Final Invoice

**Key Factors:**
- All invoices and the final invoice have to be balanced

**Control procedure / responsibilities:**
- The finance / sales department tracks all invoices and informs the project management once the final invoice is balanced

Once all invoices within a project are balanced, the project can formally be closed!
The QMS Schematic shall serve as a brief overview of the QMS and shall display the different dependencies.

The project phases described above are shown and now follows the QMS platforms (number 1-3) and the QMS tools (number 4-8) which are used.

Each QMS platform produces different QMS tools (documents) which are used in the different project phases.
Example of a Control Loop to guarantee Product Quality in a Company

- **In:** Customer requirements
- **Out:** Customer satisfaction
- **Between:** Internal processes (QMS Platforms and tools)
- **Goal:** Continuous improvement of product quality and thus customer satisfaction
Quality Management System (QMS): Platforms and Tools

How can QMS issues be discussed?
How can QMS decisions be taken?
Which kind of tools exist to document QMS procedures?
1. Project Leader Meeting
2. Management Meeting
3. Team Meeting
4. Quotation Tracking List
5. Document Tracking List
6. Project Tracking List
7. Project Report
8. Change & Failure Management Procedure
QMS Platforms
People who are involved in the Project Leader Meeting

Who is involved?

- Project Leader 1
- Project Leader 2
- Project Leader 3
- Project Leader 4
- Project Leader 5

*Before* the meeting each project leader has to fill out the project report for his project.
Exchanged Information during Project Leader Meeting

1. Project Leader Meeting

- Discussion of project deadlines, customer requirements, infrastructure, etc.
- Discussion of process mistakes (determining, improvement)
- Checking the provisions of critical process steps
- Presentation of changes by the company management for previous process mistakes
- Discussion of technical measures
2. Management Meeting

QMS relevant Departments which are involved in the Management Meetings

Company Management

Quality Representatives

Human Resources Department

Project Management

Finance / Sales Department

Who is involved?
Exchanged Information during Management Meetings

- Company Management
- Human Resources Department
- Finance / Sales Department
- Project Management
- Quality Representatives

Process mistakes and their cause are evaluated.
Suggestions for improvement are discussed.
Have all critical process steps been done?

Evaluation of the QMS
Development and maintenance

2. Management Meeting
QMS relevant Departments which are involved in the Team Meetings

Who is involved?

- Company Management (CM)
- Quality Representatives
- Project Management
- Project Staff
- Human Resources Department
- Finance / Sales Department

Send one or more representatives
Example of Exchanged Information during Team Meetings

- **Company Management (CM)**
  - Proclamation of new and changed quality policies and quality objectives
  - Financial review
  - Feedback on projects from the project staff
  - Communication of CM change decisions
  - Implementation of the measures
  - Communication of regulation changes

- **Human Resources Department**

- **Project Staff**

- **Finance / Sales Department**

- **Project Management**

- **Quality Representatives**
QMS Tools
1. Project Leader Meeting

2. Management Meeting

3. Team Meeting

4. Quotation Tracking List

5. Document Tracking List

6. Project Tracking List

7. Project Report

8. Change & Failure Management Procedure
What has to be included / considered in the quotation tracking document?

1. Tracked with a reference to the customer inquiry
2. Tracked with a quotation number
3. Completion of the review / approval before submission to the customer must be documented → QMS critical control point
4. Summarize customer’s feedback → leads to either direct refusal, refusal after negotiation or acceptance after negotiation
5. After acceptance, the contract will be elaborated

→ enter the contract reference into the tracking list, followed by the review / approval of the contract before submission to the customer (QMS critical control point)

=> After conclusion of the contract → assignment of a project number and the formal opening of the project itself
### Example of a Quotation Tracking List

<table>
<thead>
<tr>
<th>Quotation</th>
<th>Quotationname</th>
<th>Review Quotation</th>
<th>Contract completion</th>
<th>Refusal</th>
<th>Quotation status</th>
</tr>
</thead>
<tbody>
<tr>
<td>5000-A</td>
<td>XXX1</td>
<td>Oct 15</td>
<td>Dec 15</td>
<td></td>
<td>Contract completion</td>
</tr>
<tr>
<td>5001-A</td>
<td>XXX2</td>
<td></td>
<td></td>
<td></td>
<td>open</td>
</tr>
<tr>
<td>5220-A</td>
<td>XXX3</td>
<td>Nov 15</td>
<td></td>
<td>Dec 15</td>
<td>Refusal</td>
</tr>
<tr>
<td>5223-A</td>
<td>XXX4</td>
<td>Feb 16</td>
<td></td>
<td></td>
<td>open</td>
</tr>
</tbody>
</table>

**Critical process steps**

- Review Quotation
- Contract completion
- Refusal
- Quotation status
1. Project Leader Meeting

2. Management Meeting

3. Team Meeting

4. Quotation Tracking List

5. Document Tracking List

6. Project Tracking List

7. Project Report

8. Change & Failure Management Procedure
What has to be included / considered in the document tracking list?

1. Issued for engineering, design and qualification documents

2. Purposes are:
   - Overview of documents required within project
   - Definition of responsibility for document issuing
   - Tracking of the progress of document issuing, review and approval
   - Indirect tracking of the project progress

3. Providing of information for the project tracking list and the project report
Template of a Qualification, an Engineering or a Design Document List

<table>
<thead>
<tr>
<th>Document</th>
<th>Document No.</th>
<th>Issued by</th>
<th>Review and Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Company</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Customer</td>
</tr>
</tbody>
</table>

n/a: not applicable (customer approval not required)

**TO BE ADAPTED AND COMPLETED FOR EACH PROJECT INDIVIDUALLY**
What has to be included / considered in the project tracking list?

1. All project are tracked in this list
2. Provide an overview of the project status from start to the end
3. The list can include project number, reviews, agreements, approval of all documents and the final approval
### Template of a Project Tracking List

<table>
<thead>
<tr>
<th>Passed Critical Control Points (QMS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project No.</td>
</tr>
<tr>
<td>------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

The list gives an overview about in which status are the project by checking which critical control points have been passed.
### Simple Example of a Project Tracking List

<table>
<thead>
<tr>
<th>Quotation</th>
<th>Project number</th>
<th>Projectname</th>
<th>Project leader</th>
<th>Project status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1310-A</td>
<td>XXX1</td>
<td></td>
<td>Name 1</td>
<td>ongoing</td>
</tr>
<tr>
<td>1320-A</td>
<td>XXX2</td>
<td></td>
<td>Name 2</td>
<td>ongoing</td>
</tr>
<tr>
<td>5000-A</td>
<td>1308-A</td>
<td>XXX3</td>
<td>Name 3</td>
<td>ongoing</td>
</tr>
<tr>
<td>5242-A</td>
<td>1361-A</td>
<td>XXX4</td>
<td>Name 4</td>
<td>close</td>
</tr>
</tbody>
</table>
What has to be included / considered in the project report?

1. Project management is responsible for completing
2. List that includes the feedback (summarized and collected)
3. Project quality relevant parameters & critical process steps are assessed and evaluated (regularly during project execution)
   • Work quality (all involved parties)
   • Adherence to project schedule
   • Compliance with customer requirements
   • Cost control
   • Project resources (personnel and infrastructure)
   • Internal and external communication
   • Successful passing of critical control points
   • Customer satisfaction

=> Measurement for the overall project quality (in planning and realization phase)
If the rating of one or more quality relevant parameters or critical process steps decreases, actions can be discussed, decided and documented in the project report to improve the overall quality of the project again!
# 7. Project Report

## Template of a Project Report

<table>
<thead>
<tr>
<th>Date</th>
<th>Work Quality</th>
<th>Adherence to Project Schedule</th>
<th>Compliance with Customer Requirements</th>
<th>Cost Control</th>
<th>Project Resources (Personnel)</th>
<th>Project Resources (Infrastructure)</th>
<th>Internal Communication</th>
<th>External Communication</th>
<th>Successful Passing of Critical Control Points</th>
<th>Customer Satisfaction</th>
<th>Comments, Decisions, Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Rate for the project report:

- **good**
- **average**
- **bad**
Work Quality

Question:
How is the work quality of the company, the sub-contractors and the sub-suppliers?

Rating:

- **good**: The work was done properly, organised and correct. No failure were done and deadlines were fulfilled. External documents have been done properly.

- **average**: The work was done okay. Failure could have been done, but they were eliminated as soon as possible. No consequence appeared for the project.

- **bad**: Failure have been done which have severe consequence to the project. Project deadlines have been missed because of missing organisation.
Adherence to Project Schedule

**Question:**
Is the work done until the deadline which is written in the project schedule?

**Rating:**
- **good**
  - The work was done on schedule.
- **average**
  - The work was done with delay, but there is no consequence for milestone deadlines.
- **bad**
  - Milestone deadline for the work has passed and the work is not done yet.

=> Repetition can be avoided if more resources are available!
Compliance with Customer Requirements

**Question:**
Have the customer requirements been implemented in the project?

**Rating:**

- **good**
  All customer requirements have been implemented without problems. They are verified regularly by the project leaders.

- **average**
  All customer requirements have been implemented, but one/some of them were only implemented after consultation with the customer because realisation couldn’t be done 100%.

- **bad**
  Implementation of one or more customer requirements couldn’t be done because of impossibility and no alternative have been found.
Cost Control

**Question:**
Are the real costs of the project corresponding to the assumed costs which were calculated at the beginning?

**Rating:**

- **good**
  The real costs coincide with the assumed costs or are lower than them.

- **average**
  The real costs correspond more or less to the assumed costs. In few cases the real costs are higher than expected, but still in a prescribed range.

- **bad**
  The real costs don’t coincide at all with the assumed costs. The real costs are much higher than expected and are out of the prescribed range. Consultation with the customer has to be done.

  => Compensation may be possible in other part of the project later
Project Resources (Personnel)

Question:
Are enough and competent personnel available?

Rating:

- **good**: Enough and competent personnel is available for the work which has to be done. This is controlled regularly by the project leaders.

- **average**: Personnel is available but either the amount of personnel could be higher or for special work more competent personnel is needed.

- **bad**: The work can’t be done because not enough and no competent personnel is available.

=> Options for remediation: Allocation of additional company-internal resources, contracting of sub-suppliers or hiring new employees
Project Resources (Infrastructure)

**Question:**
Are enough and good infrastructure available for satisfactory performance of the personnel?

**Rating:**

- **good**: Enough and good infrastructure is available for personnel to comply with the required work. The availability and state of the infrastructure is controlled regularly.

- **average**: In some cases more infrastructure is needed. The availability and state of the infrastructure is not checked regularly. No influence on the project itself.

- **bad**: Less infrastructure than needed is available. The availability and state of the infrastructure is never controlled. Bad influence on the project.
Internal Communication

**Question:**
How is the communication in the company itself?

**Rating:**

- **good**
  The project-related internal communication works and is proofed by project leader.

- **average**
  The project-related internal communication doesn’t work 100%. Some misunderstandings appeared which caused small delays in the project. The project leader only controls the communication occasionally.

- **bad**
  Some severe mistakes have been done in the project because of missing project-related internal communication.
External Communication

**Question:**
How is the communication between the parties (company, customer, sub-contractors, sub-suppliers, etc.)?

**Rating:**

- **good**
  The project-related external communication between all parties works and is proofed by the compliance of all requirements and process deadlines.

- **average**
  The project-related external communication doesn’t work 100%. Some misunderstandings appeared which caused small delays in the project.

- **bad**
  Some sever mistakes have been done in the project because of missing project-related external communication.
Successful Passing of Critical Control Points

**Question:**
Have all critical control points been passed successfully?

**Rating:**
- **good**: Yes, without doing any modification before acceptance.
- **average**: Yes, but some modifications had to be done before acceptance.
- **bad**: One critical control point couldn’t have been passed successfully which leads to a significant delay in the project.
Customers Satisfaction

Question:
Is the customer satisfied?

Attention! Assessment is done subjectively by the project leader!

Rating:
- good
  Yes, the customer is highly satisfied. The quality of the services is high because of professionalism and kindness towards the customer. This reflects the reality.

- average
  Yes, but some small inconveniences appeared during the project for the customer which doesn’t have an influence at the end.

- bad
  Customer is not satisfied at all, because of delay, incompetence by the company, or termination of the cooperation.
What has to be included / considered in the change / failure management procedure?

Defines a formal procedure for the handling of project changes and failures.

The document are tracked in the document tracking list for change / failure
Change & Failure Management

Introduction

A formal handling procedure for changes and failures is required as part of the QMS.

For each change or failure, the following points shall formally be documented:

1. **Description** of the initiated change / detected failure
2. **Classification** of the change / failure and description of its impact
3. **Analysis** of the change / failure and definition of actions for its implementation / correction
4. **Tracking** of defined actions and formal closure of the procedure once all actions have been completed
The change / failure is described with sufficient details to allow for a proper analysis of the change / failure and for definition of appropriate actions later.

**Responsibility:** Anyone who detects a failure or would like to initiate a change (project staff, project management, quality representative, etc.)
2. Impact Classification

<table>
<thead>
<tr>
<th>Impact Classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Quality impact (products / services)</td>
<td></td>
</tr>
<tr>
<td>□ Safety impact</td>
<td></td>
</tr>
<tr>
<td>□ Cost impact</td>
<td></td>
</tr>
<tr>
<td>□ Impact on the timelines</td>
<td></td>
</tr>
</tbody>
</table>

Impact Description: (improvement)

Date / signature (project management / quality representative):

<table>
<thead>
<tr>
<th>Impact Classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Quality impact (products / services)</td>
<td></td>
</tr>
<tr>
<td>□ Safety impact</td>
<td></td>
</tr>
<tr>
<td>□ Cost impact</td>
<td></td>
</tr>
<tr>
<td>□ Impact on the timelines</td>
<td></td>
</tr>
</tbody>
</table>

Impact Description: (negative influence)

Date / signature (project management / quality representative):

Failure tracking list updated

Changes / failures are classified according their main impact. This shall help to understand the change / failure and to define appropriate actions later

Responsibility: Project management or quality representative (for QMS)
Change & Failure Management

3. Definition of Actions

Proposed actions must be reviewed and approved by a second person / department, for example:

- By the finance / sales department for changes/failures that affect the costs
- By the project management for changes/failures that affect the quality or the timelines
- By the quality representative or company management for changes/failures that have an impact on the QMS

Responsibility: Depending on the nature of the change / failure, actions should either be proposed by the project management or by the quality representative
### 4. Tracking of Actions / Report

At the end of the change / failure procedure, a short report is written to confirm that all actions have been worked off.

With this report, the change / failure handling procedure is formally closed.

<table>
<thead>
<tr>
<th>Tracking of actions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action 1</td>
</tr>
<tr>
<td>☐ completed</td>
</tr>
<tr>
<td>(reference: _____________)</td>
</tr>
<tr>
<td>Action 2</td>
</tr>
<tr>
<td>☐ completed</td>
</tr>
<tr>
<td>(reference: _____________)</td>
</tr>
<tr>
<td>Action 3</td>
</tr>
<tr>
<td>☐ completed</td>
</tr>
<tr>
<td>(reference: _____________)</td>
</tr>
<tr>
<td>Action 4</td>
</tr>
<tr>
<td>☐ completed</td>
</tr>
<tr>
<td>(reference: _____________)</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

All actions have been completed and the change procedure is formally closed:
☐ Change track list updated

Date / signature (project management or quality representative):

---

**Responsibility:**  Project management or quality representative
Further Questions?