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Project QMS and “Quality by Design”  
Activities



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## 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



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## “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.



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## Project Structure

Each project can be divided in process sequences

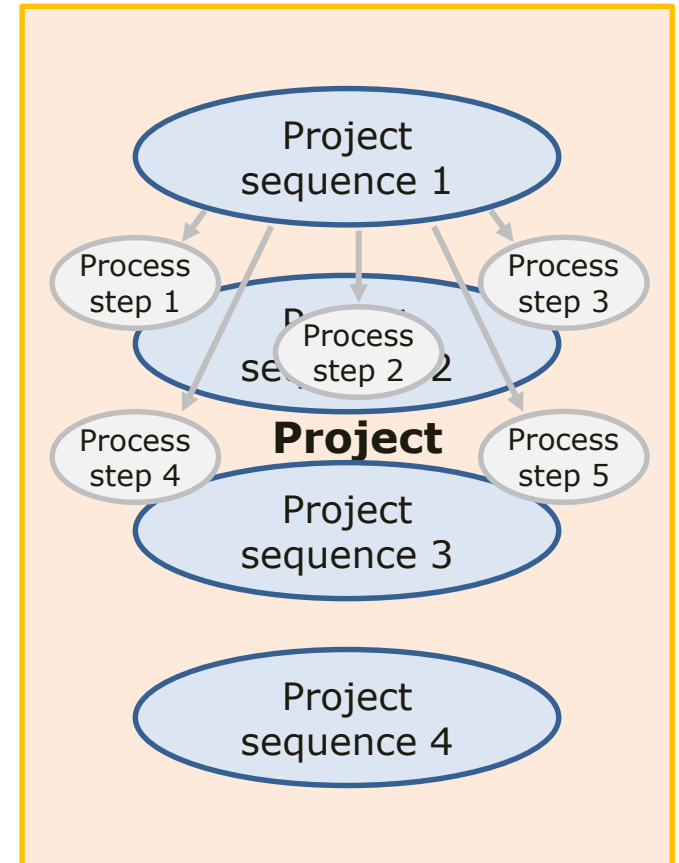
→ Each process sequence has its process steps

→ 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.





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## 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



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## Critical Control Points in the Different Process Phases



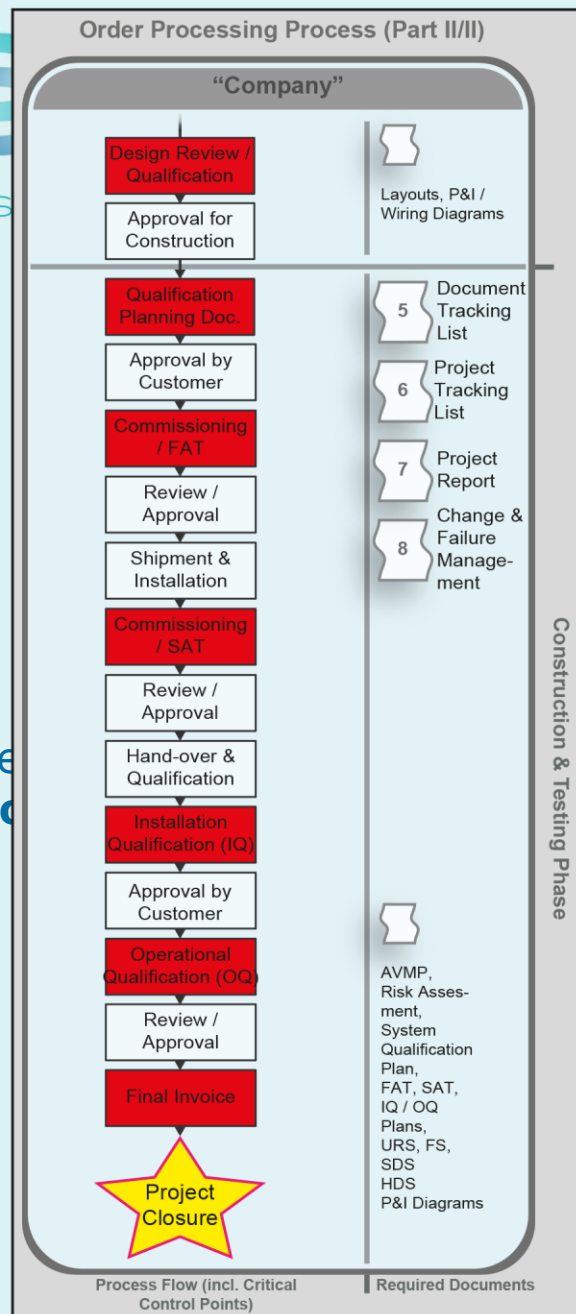
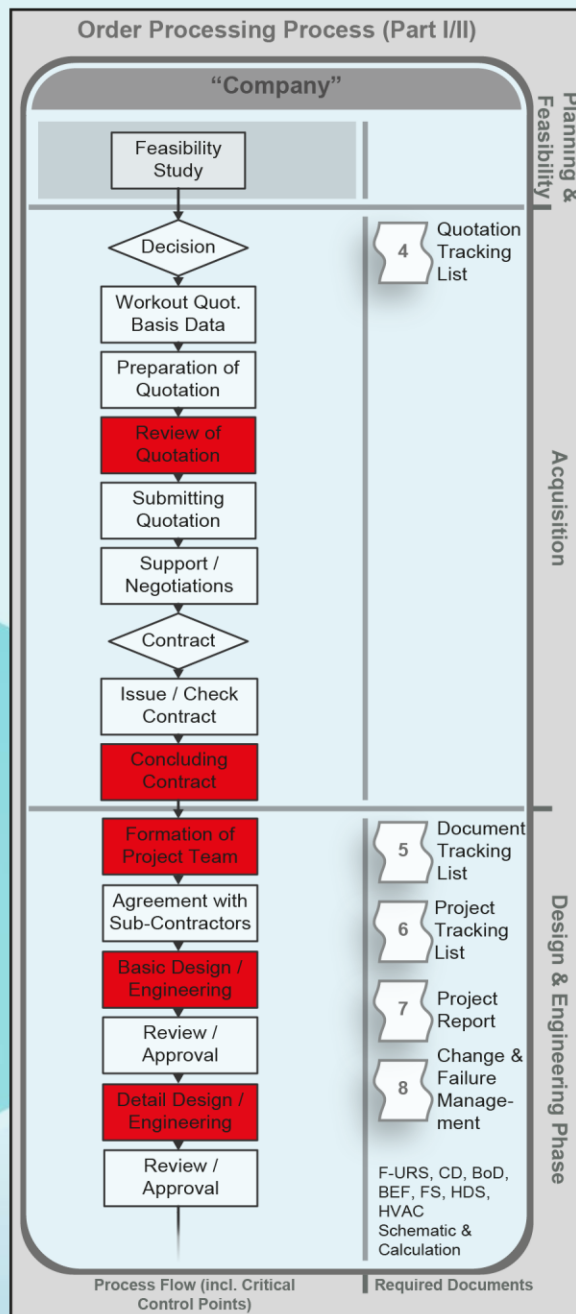
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# Critical Control Points

## 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**.



Review of the different





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# 1. Acquisition Phase

## 1.1 Review of the Quotation

### Key Factors:

- Technical & financial feasibility
- Comprehension of customer requirements and needs

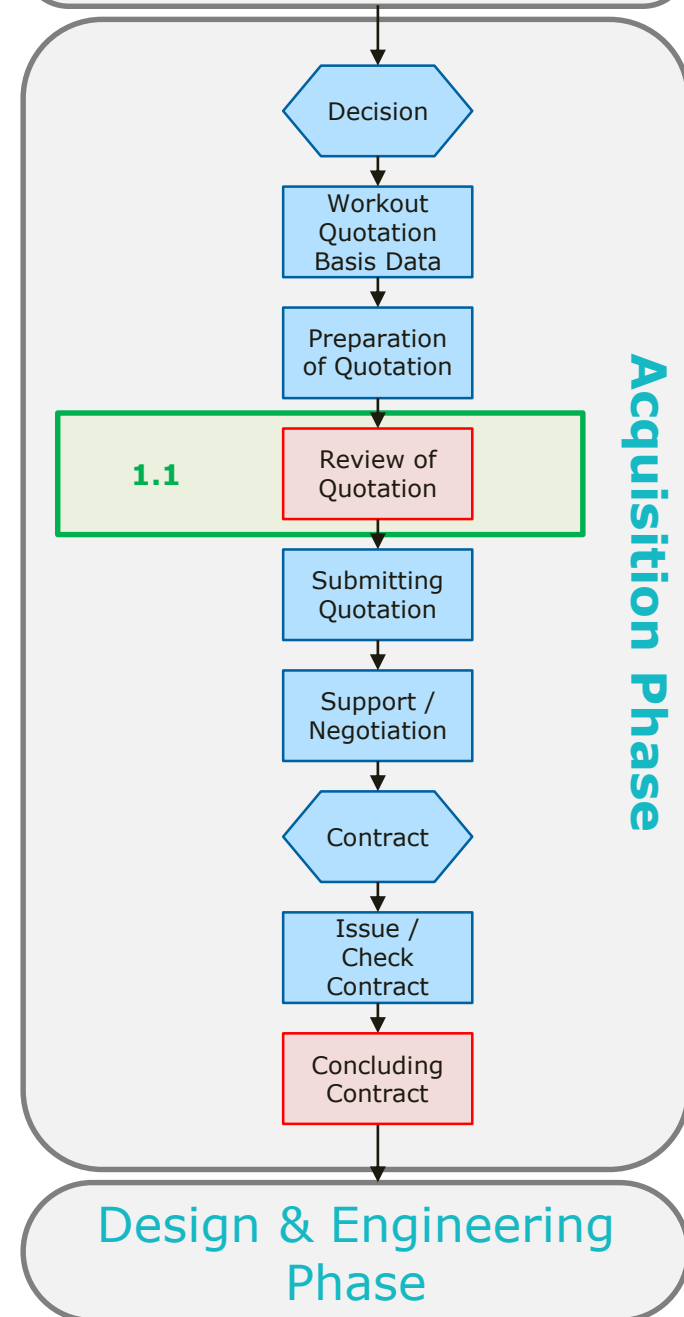
### Control procedure / responsibilities:

- Independent review of the quotation Finance / Sale Dept. Project Management
- Optional: Additional review Company Management

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!**

## Request for Quotation





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# 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



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# 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

Company Management

Finance / Sale Dept.

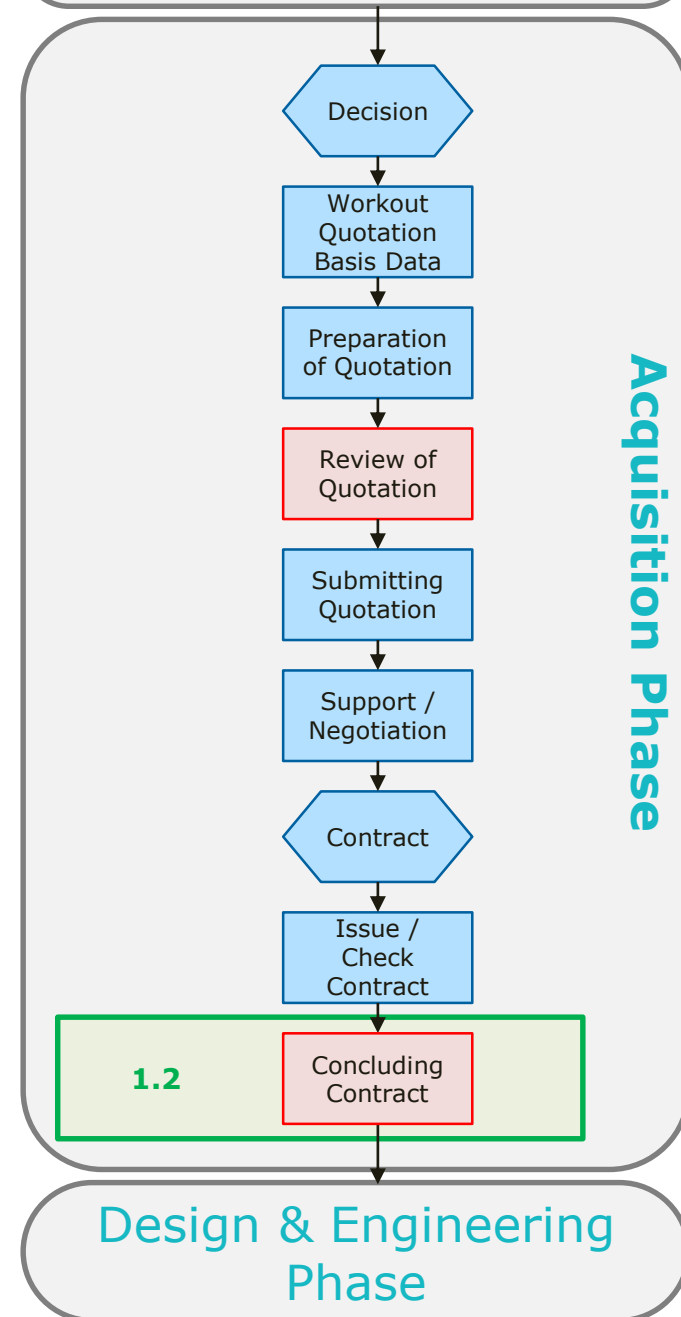
Project Management

Finance / Sale Dept.

Company Management

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

## Request for Quotation





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# 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



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## 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.**

## Acquisition Phase

2.1

Formation of  
Project  
Team

Agreement  
with Sub-  
Contractors

Basic Design  
/ Engineering

Review /  
Approval

Detail Design  
/ Engineering

Review /  
Approval

Design  
Review /  
Qualification

Approval for  
Construction

Design & Engineering Phase

## Construction & Testing Phase



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## 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



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## 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 Customer Representative Project Management
- 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

## Acquisition Phase

Formation of Project Team

Agreement with Sub-Contractors

2.2

Basic Design / Engineering

Review / Approval

Detail Design / Engineering

Review / Approval

Design Review / Qualification

Approval for Construction

Design & Engineering Phase

## Construction & Testing Phase



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## 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

2.2

Basic Design  
/ Engineering

Review /  
Approval

Detail Design  
/ Engineering

Review /  
Approval

Design  
Review /  
Qualification

Approval for  
Construction

Design & Engineering Phase

## Construction & Testing Phase





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## 2. Design & Engineering Phase

### 2.3 Detail Design / Engineering

#### Key Factors:

Correctness of the detail design / engineering documents

#### Control procedure / responsibilities:

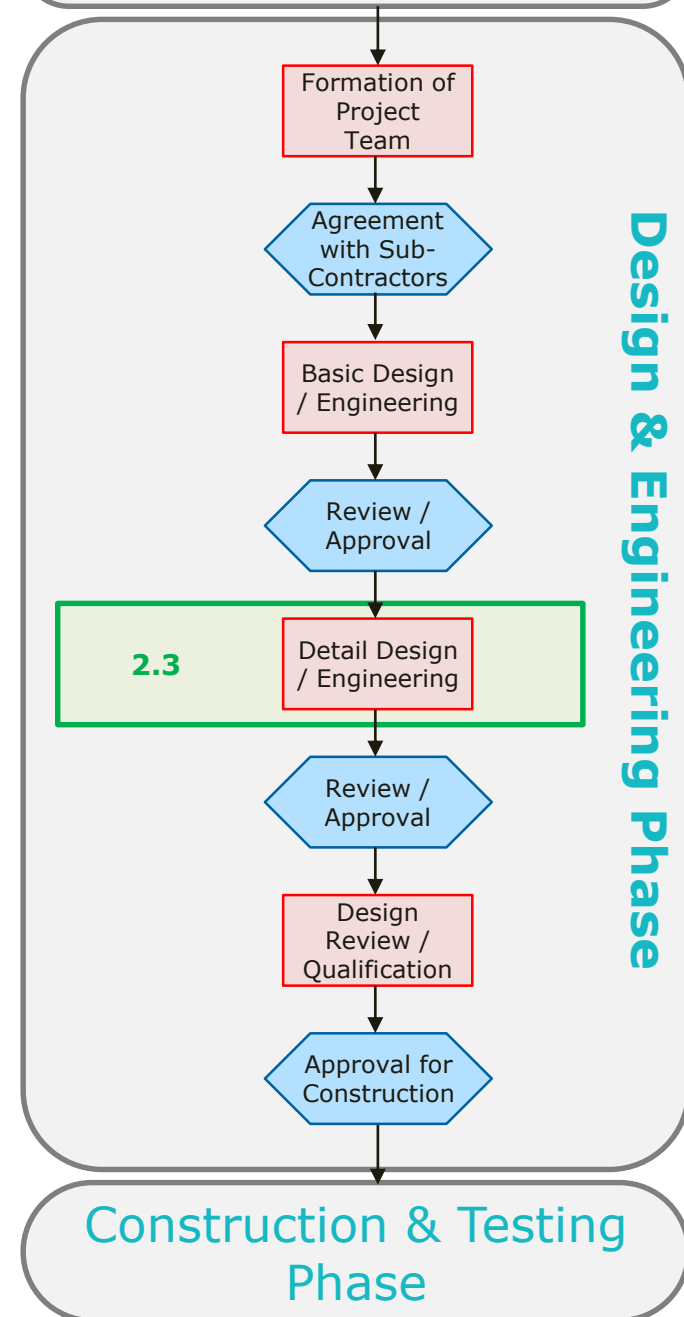
- Independent review of the documents Customer Representative Project Management
- Both parties have to formally approve the critical documents by signing

**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.

## Acquisition Phase





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## 2. Design & Engineering Phase

### 2.3 Detail Design / Engineering

Examples of relevant Documents:



Functional Specification



Hardware Design Specification



HVAC Schematic  
& Calculations

## Acquisition Phase

Formation of  
Project  
Team

Agreement  
with Sub-  
Contractors

Basic Design  
/ Engineering

Review /  
Approval

2.3

Detail Design  
/ Engineering

Review /  
Approval

Design  
Review /  
Qualification

Approval for  
Construction

Design & Engineering Phase

## Construction & Testing Phase



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## 2. Design & Engineering Phase

### 2.4 Design Review / Qualification

#### Key Factors:

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

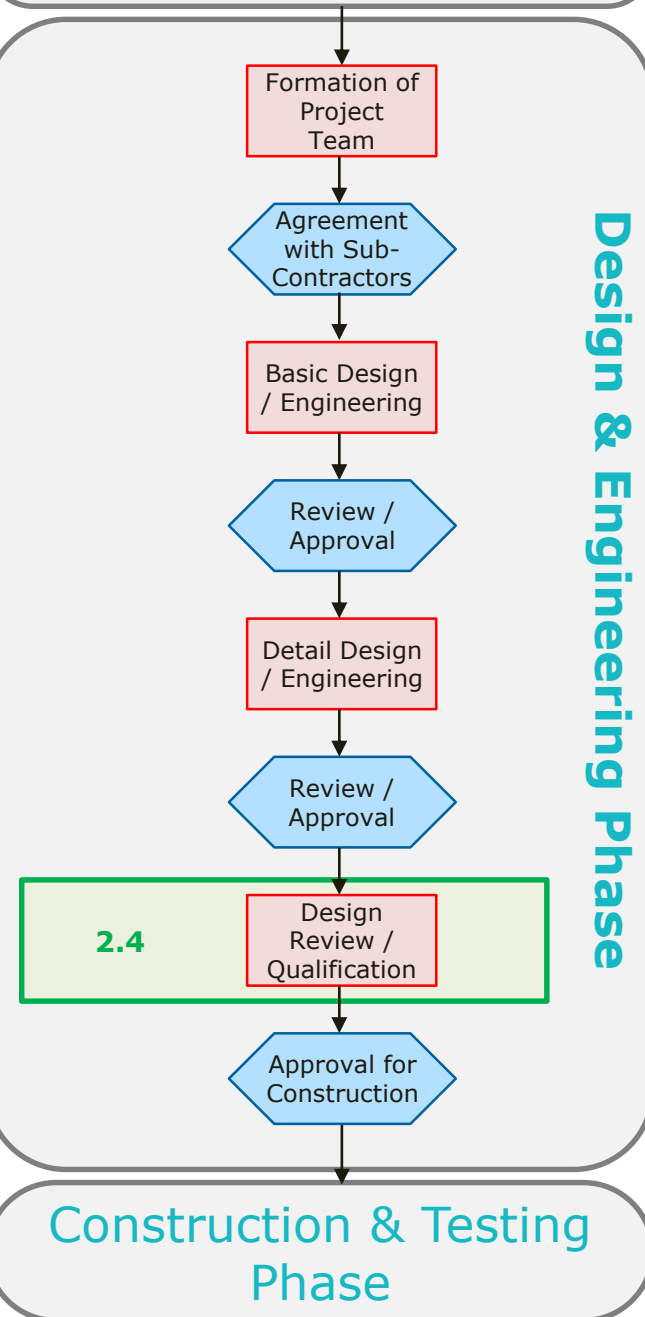
#### Control procedure / responsibilities:

- Independent review of the documents Customer Representative Project Management
- 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**

## Acquisition Phase

## Design & Engineering Phase





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## 2. Design & Engineering Phase

### 2.4 Design Review / Qualification

Examples of relevant Documents:



P&I Diagrams

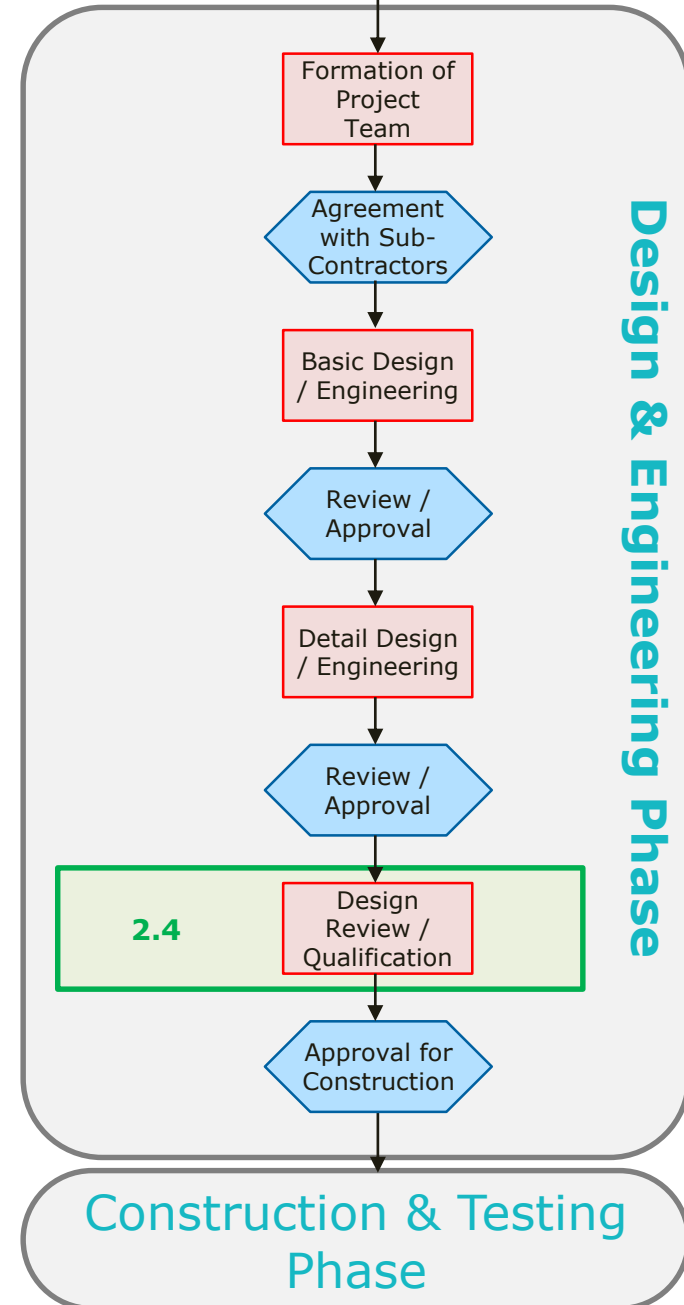


Layouts



Wiring Diagrams

## Acquisition Phase





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## 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.



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## 3. Construction & Testing Phase

### 3.1 Qualification Planning Documents

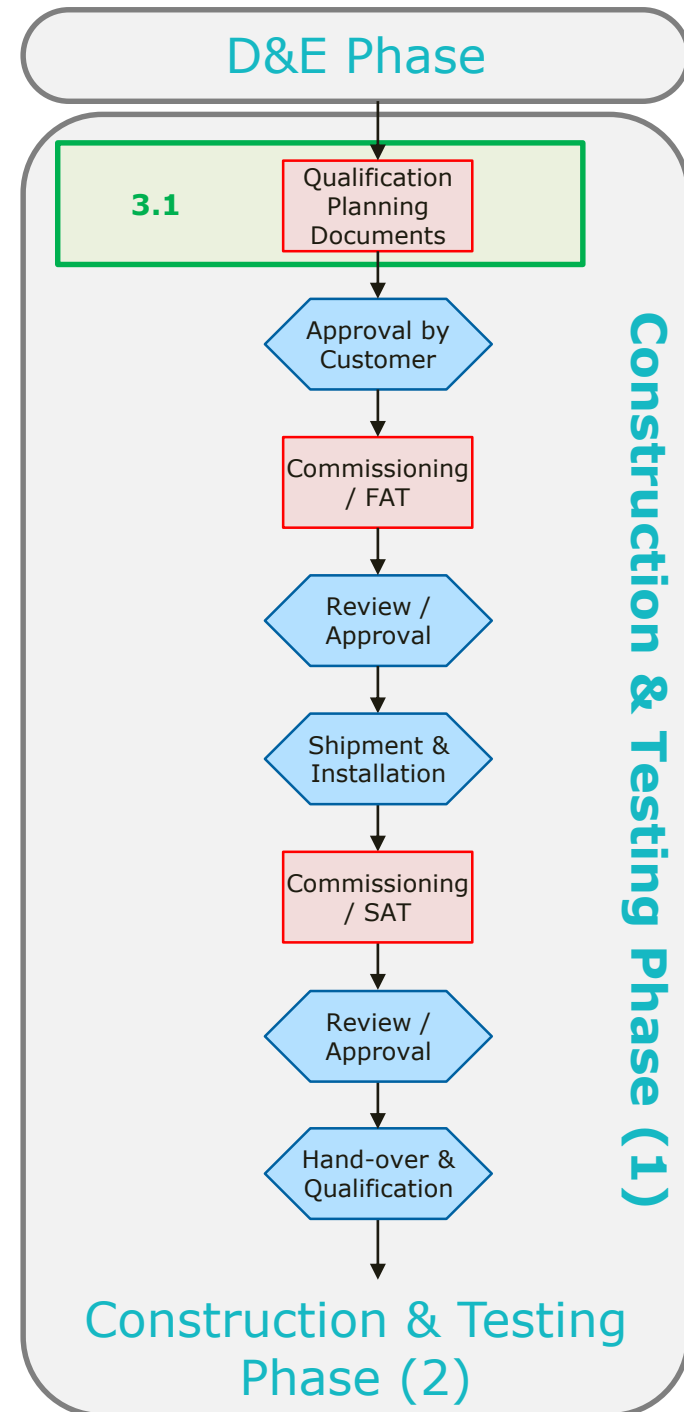
#### Key Factors:

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

Customer





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## 3. Construction & Testing Phase

### 3.1 Qualification Planning Documents

Examples of relevant Documents:



AVMP



Risk Assessment



System Qualification  
Plan

## D&E Phase

3.1

Qualification  
Planning  
Documents

Approval by  
Customer

Commissioning  
/ FAT

Review /  
Approval

Shipment &  
Installation

Commissioning  
/ SAT

Review /  
Approval

Hand-over &  
Qualification

Construction & Testing Phase (1)

Construction & Testing  
Phase (2)



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## 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

Project Staff

Project Management

Customer Representative



Equipment

ready for ?



or



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

## D&E Phase

Qualification  
Planning  
Documents

Approval by  
Customer

3.2

Commissioning  
/ FAT

Review /  
Approval

Shipment &  
Installation

Commissioning  
/ SAT

Review /  
Approval

Hand-over &  
Qualification

Construction & Testing Phase (1)

Construction & Testing  
Phase (2)





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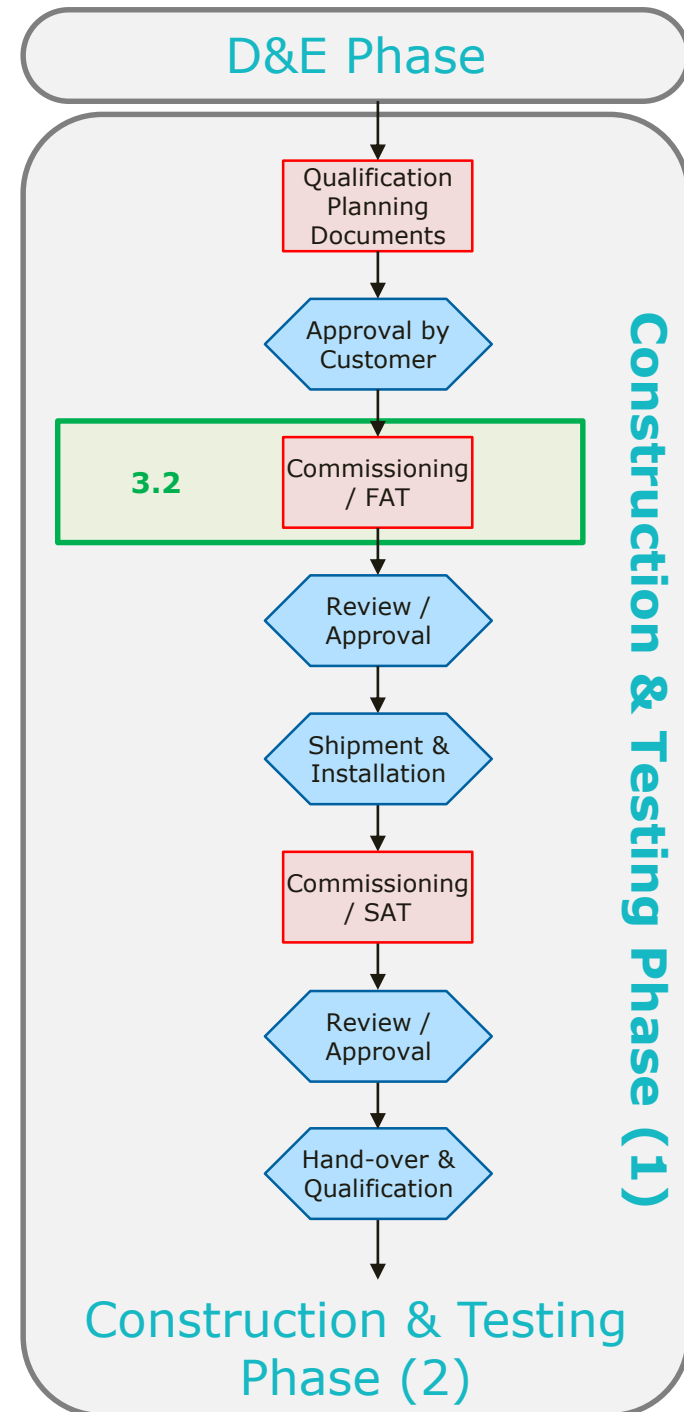
## 3. Construction & Testing Phase

### 3.2 Commissioning / Factory Acceptance Test (FAT)

Examples of relevant Documents:



FAT Plans





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## 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

Project Staff

Project Management

Customer Representative



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

## D&E Phase

Qualification Planning Documents

Approval by Customer

Commissioning / FAT

Review / Approval

Shipment & Installation

3.3

Commissioning / SAT

Review / Approval

Hand-over & Qualification

Construction & Testing Phase (1)

Construction & Testing Phase (2)



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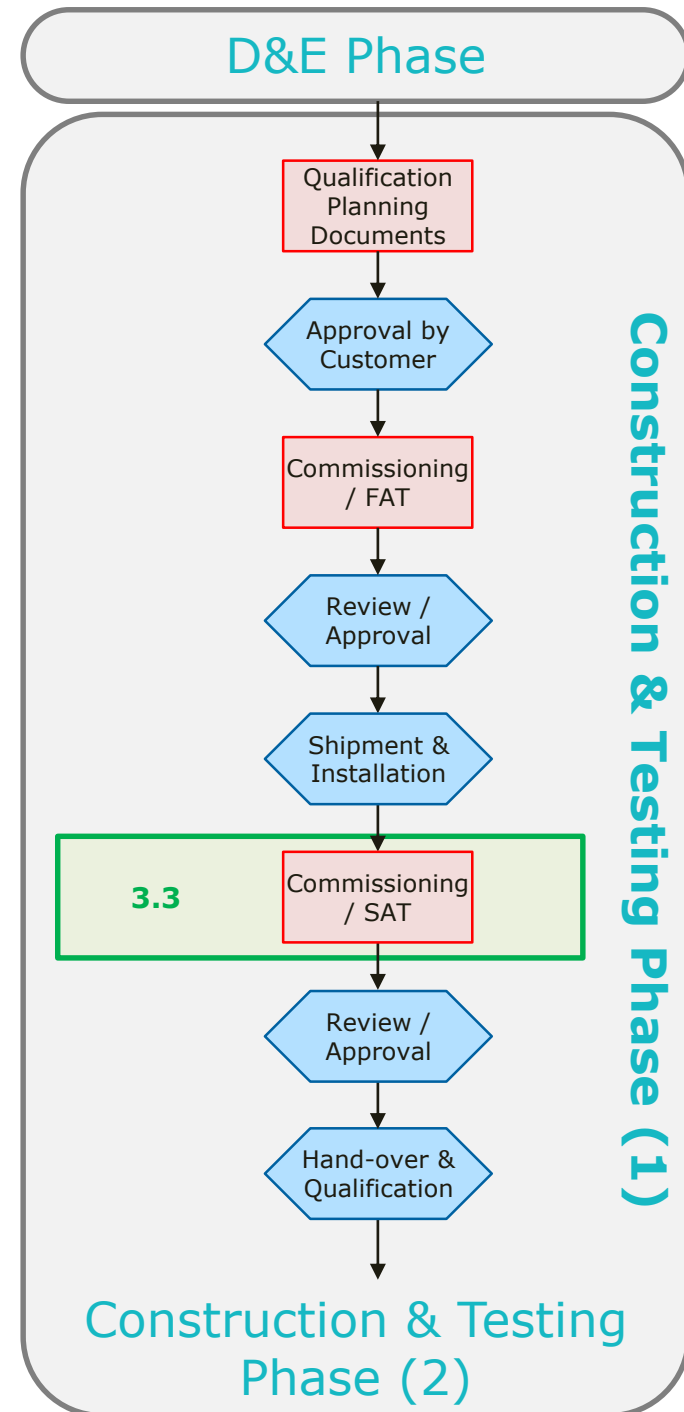
## 3. Construction & Testing Phase

### 3.3 Commissioning / Site Acceptance Test (SAT)

Examples of relevant Documents:



SAT Plans





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## 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

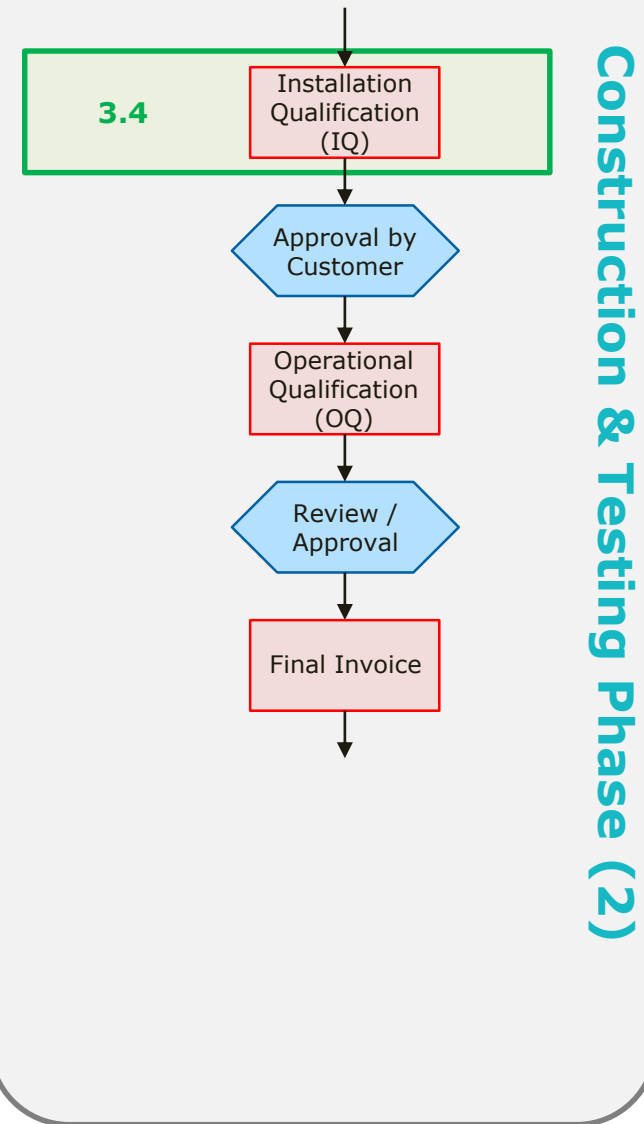
Project Staff

Project Management

**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.

## Construction & Testing Phase (1)





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## 3. Construction & Testing Phase

### 3.4 Installation Qualification (IQ)

Examples of relevant Documents:



IQ Plans



URS

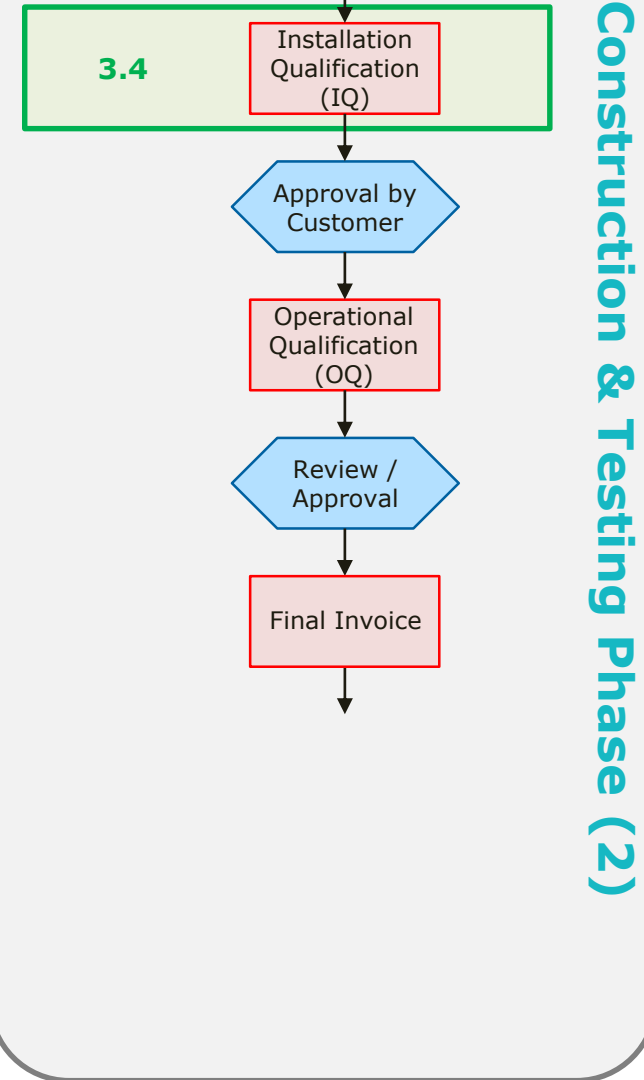


HDS



P&I Diagrams

## Construction & Testing Phase (1)





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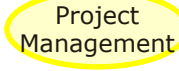
## 3. Construction & Testing Phase

### 3.5 Operational Qualification (OQ)

#### Key Factors:

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

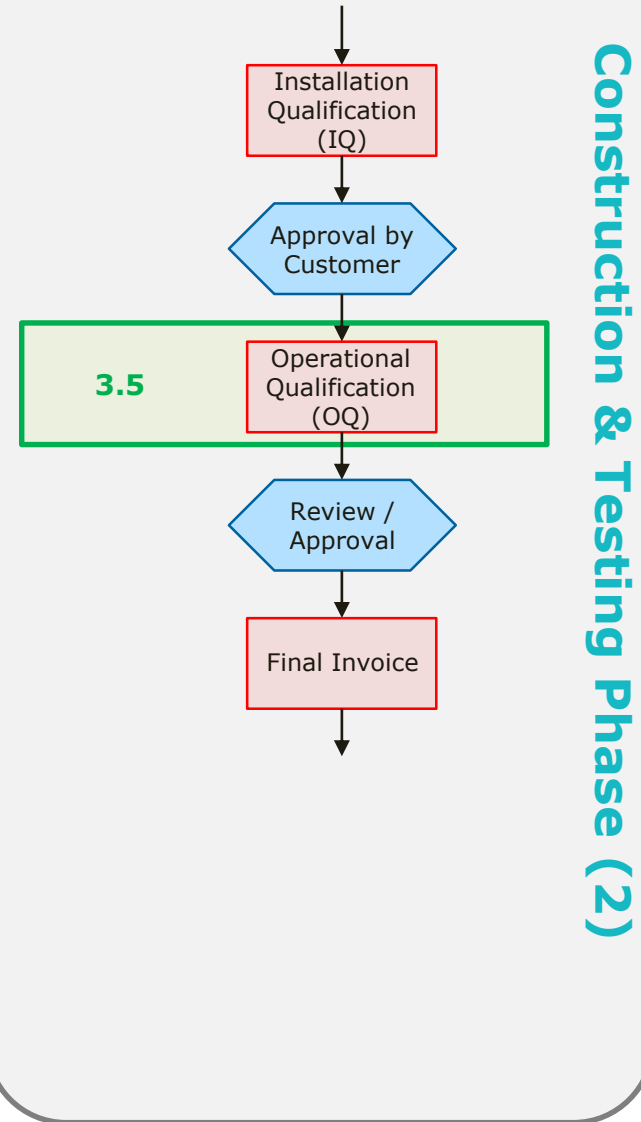
#### Control procedure / responsibilities:

- 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.

## Construction & Testing Phase (1)





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## 3. Construction & Testing Phase

### 3.5 Operational Qualification (OQ)

Examples of relevant Documents:



FS



URS

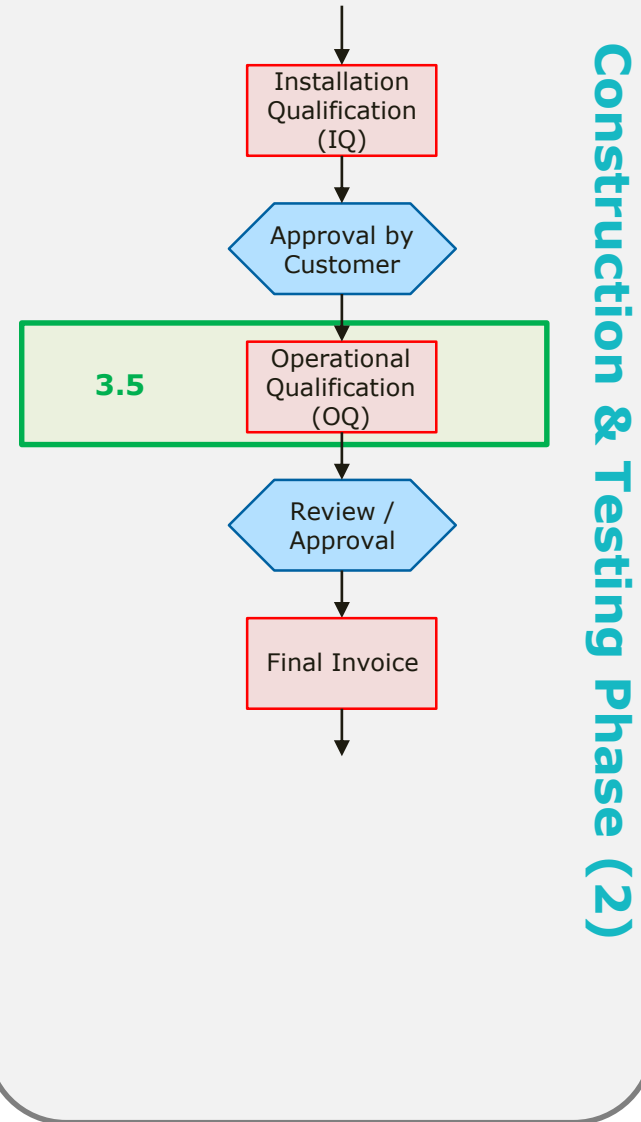


SDS



OQ Plans

## Construction & Testing Phase (1)





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## 3. Construction & Testing Phase

### 3.6 Final Invoice

#### Key Factors:

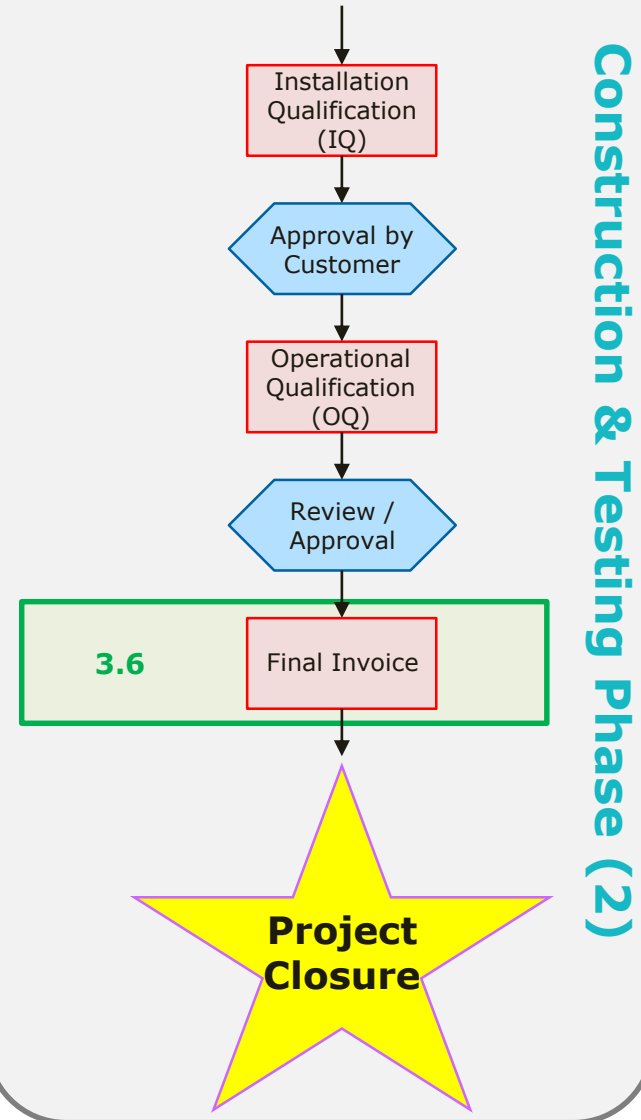
- All invoices and the final invoice have to be balanced

#### Control procedure / responsibilities:

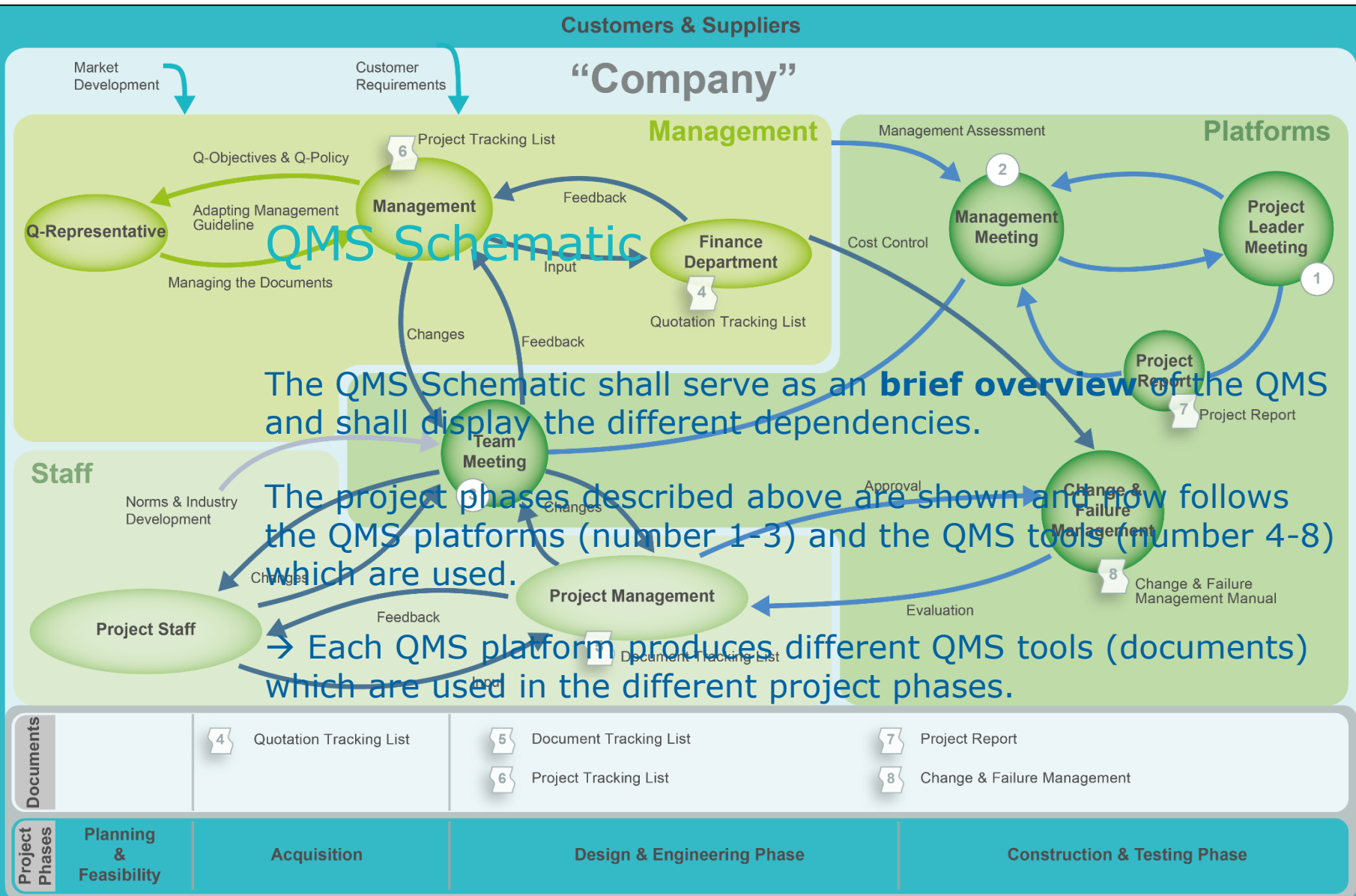
- The finance / sales department tracks all invoices and informs the project management once the final invoice is balanced

**Once all invoices within a project are balanced, the project can formally be closed!**

## Construction & Testing Phase (1)





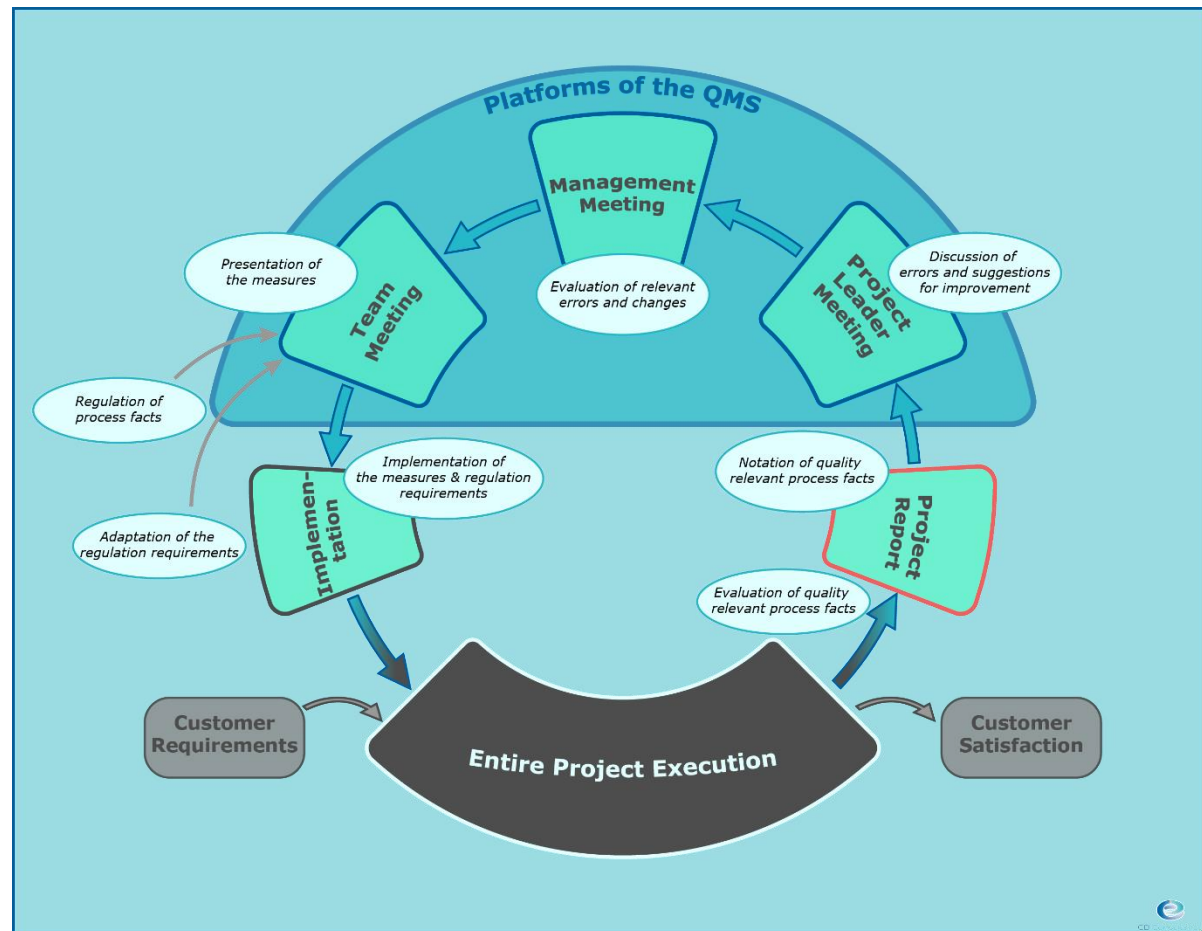




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## Example of a Control Loop to guarantee Product Quality in a Company

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





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## 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?



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QMS Platforms

QMS Tools

**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



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## QMS Platforms



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



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## 1. Project Leader Meeting

### People who are involved in the Project Leader Meeting

**Before** the meeting each project leader has to fill out the project report for his project.

Who is involved?

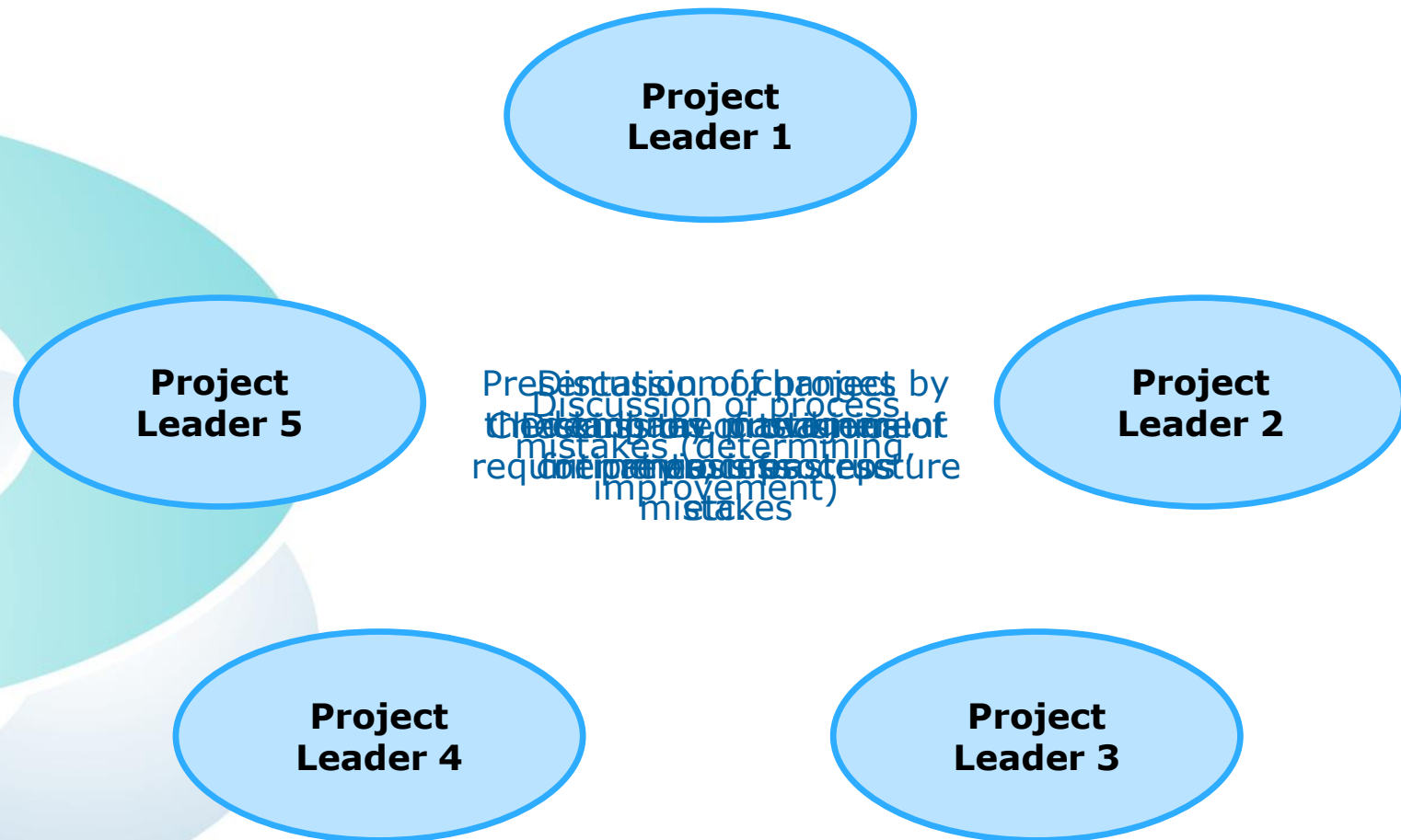




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## 1. Project Leader Meeting

### Exchanged Information during Project Leader Meeting







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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

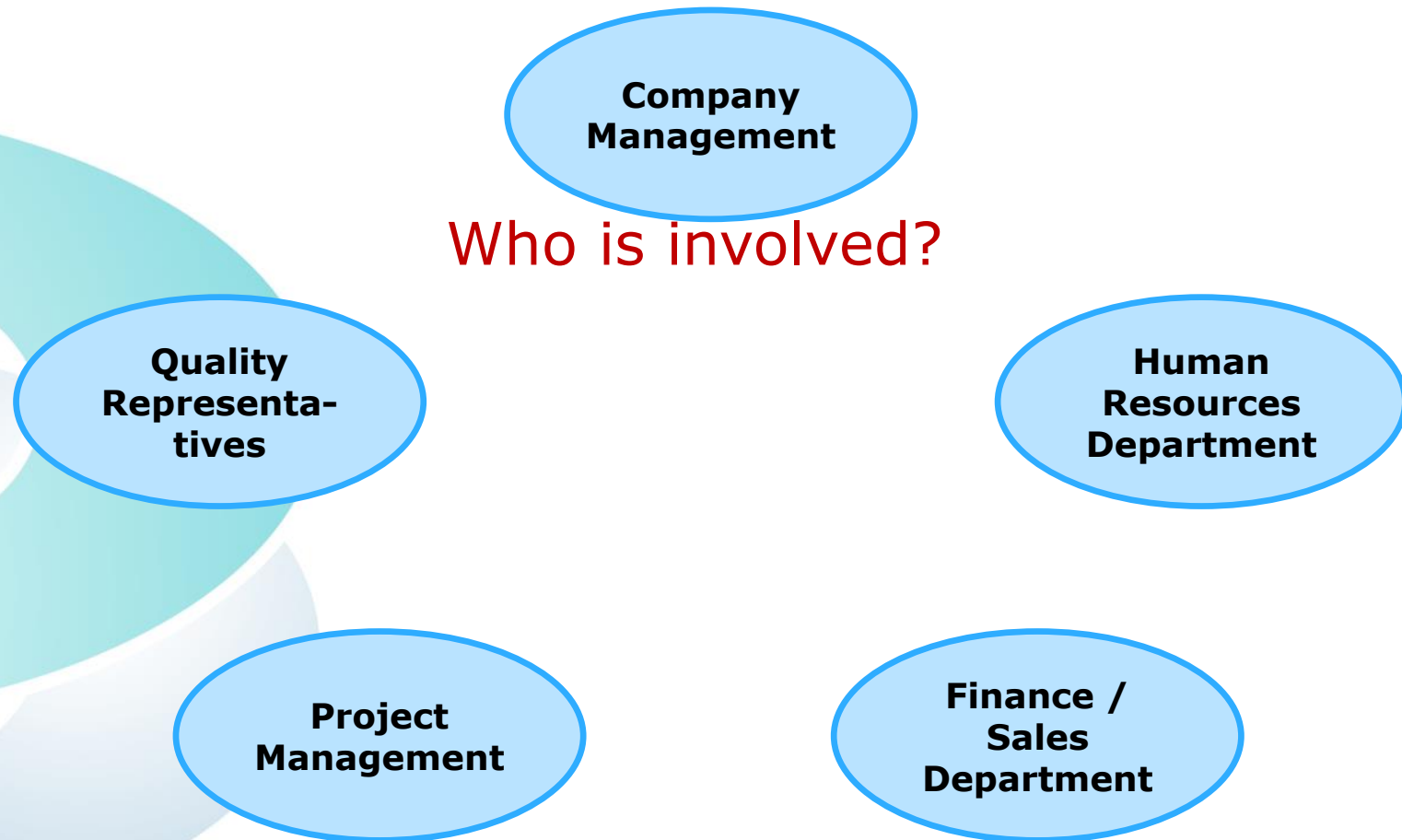
**7. Project Report**



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## 2. Management Meeting

QMS relevant Departments which are involved in the Management Meetings

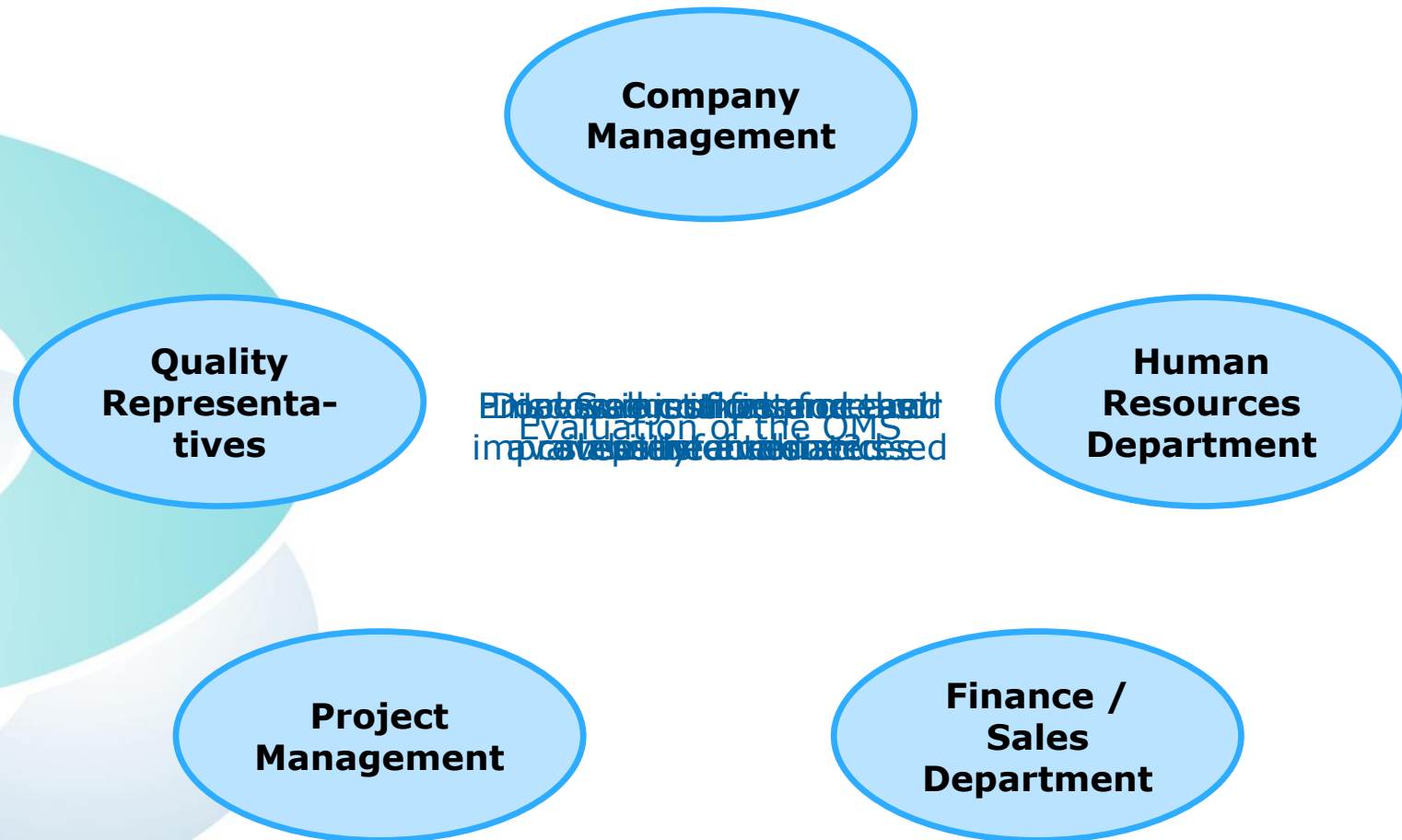




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## 2. Management Meeting

### Exchanged Information during Management Meetings





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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

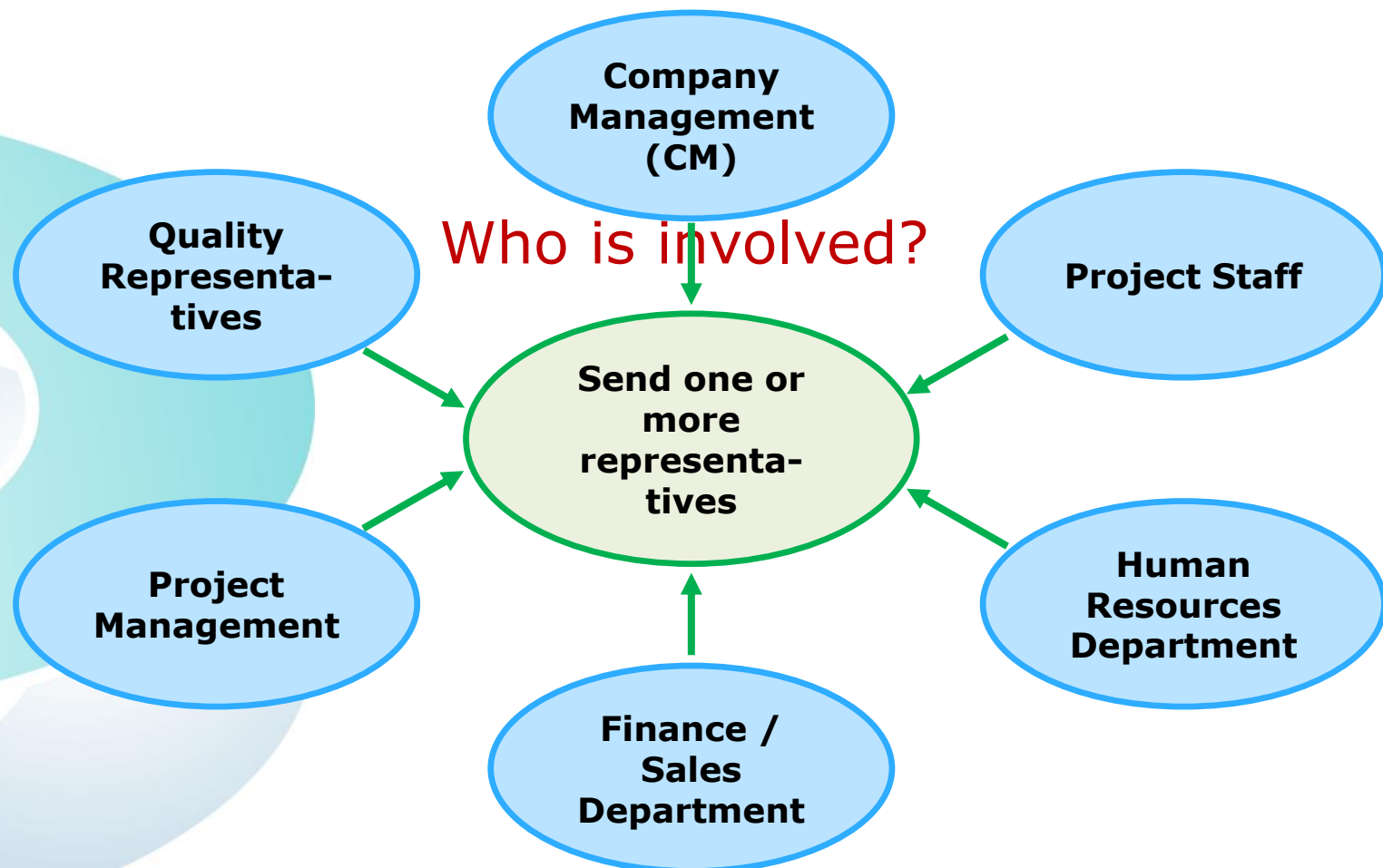
**7. Project Report**



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### 3. Team Meeting

QMS relevant Departments which are involved in the Team Meetings

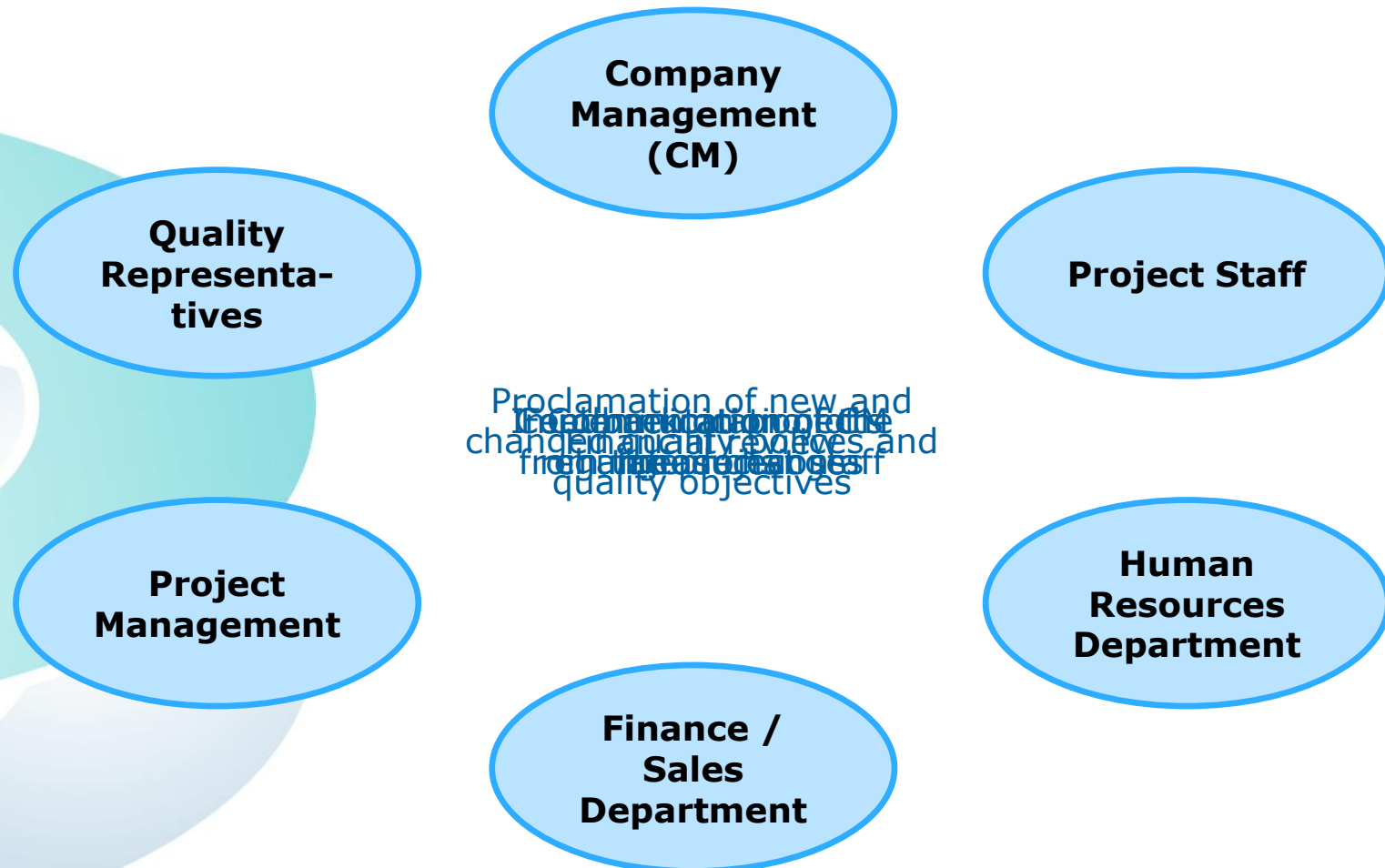




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### 3. Team Meeting

## Example of Exchanged Information during Team Meetings





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## QMS Tools



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



### 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

#### Quotation administration

Quotation	Quotationname	critical process steps		Refusal	Quotation status
		Review Quotation	Contract completion		
5000-A	XXX1	Oct 15	Dec 15		Contract completion
5001-A	XXX2				open
5220-A	XXX3	Nov 15		Dec 15	Refusal
5223-A	XXX4	Feb 16			open



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



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## 5. Document Tracking List

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

Qualification / Engineering or Design Document List				
Document	Document No.	Issued by	Review and Approval	
			Company	Customer

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

**TO BE ADAPTED AND COMPLETED FOR EACH PROJECT INDIVIDUALLY**



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



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## **6. Project Tracking List**

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

## 6. Project Tracking List

### Template of a Project Tracking List

Passed Critical Control Points (QMS)													
Project No.	Review of Quotation	Concluding the Contract	Determining the Project Team	Agreement on Test Responsibilities	Approval of FS	Approval of HDS	Approval of SDS	Approval of C&I Inspection	Approval of HW Tests	Approval of SW Module Tests	Approval of FAT	Approval of SAT	Final Approval

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

#### Project Administration

Quotation	Project number	Projectname	Project leader	Project status
	1310-A	XXX1	Name 1	ongoing
	1320-A	XXX2	Name 2	ongoing
5000-A	1308-A	XXX3	Name 3	ongoing
5242-A	1361-A	XXX4	Name 4	close



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**



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## 7. Project Report

### 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)**



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## 7. Project Report

**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!**

### Template of a Project Report

Date	Work Quality	Adherence to Project Schedule	Compliance with Customer Requirements	Cost Control	Project Resources (Personnel)	Project Resources (Infrastructure)	Internal Communication	External Communication	Successful Passing of Critical Control Points	Customer Satisfaction	Comments, Decisions, Actions

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 to personnel to comply 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 sever 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.



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## 7. Project Report

# 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.



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**1. Project Leader Meeting**

**2. Management Meeting**

**3. Team Meeting**

**4. Quotation Tracking List**

**5. Document Tracking List**

**6. Project Tracking List**

**8. Change & Failure Management Procedure**

**7. Project Report**





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## **8. Change & Failure Management Procedure**

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



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# 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



## 1. Change / failure description

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.

Anyone who detects a failure or would like to initiate a change  
(project staff, project management, quality representative, etc.)



## 2. Impact Classification

<p><b>Impact Classification</b></p>  <p><b>Impact Description:</b> (negative influence)</p>   <p><input type="checkbox"/> Failure tracking list updated</p> <p>Date / signature (project management / quality representative):</p> <hr/>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Quality impact (products / services)</li> <li><input type="checkbox"/> Safety impact</li> <li><input type="checkbox"/> Cost impact</li> <li><input type="checkbox"/> Impact on the timelines</li> <li><input type="checkbox"/> _____</li> </ul>
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**Responsibility:** Project management or quality representative (for QMS)



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# Change & Failure Management

## 3. Definition of Actions

Definition of actions:	
1	
2	
3	
4	
<b>Comments:</b>	
Date / signature (definition of actions by process management or quality representative): _____	
Date / signature _____	
Date / signature _____	
(review and approval of defined 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.

## Project management or quality representative



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Further Questions?