# Risk Analysis in the Equipment Life Cycle

**An excerpt from the GMP Focus PDF Download Principles of Equipment Qualification**

5 min reading time

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## Significance of risk analysis for a qualification

A risk analysis is a fundamental element of a qualification because the content and extent of the qualification tasks are determined therein. Furthermore, it is via the risk analysis that the effectiveness of the aligned measures is verified. It presents the basis for the identification of quality-relevant metering points and the resulting calibration strategy. Additionally, the risk analysis is the basis for the quality-relevant preventive maintenance strategy.

The purpose of the risk analysis is to systematically evaluate potential impacts from the equipment, its design and the process. It should be generated during the design qualification phase to counteract potential risks in time by ensuring appropriate equipment designs and specifications.

This is more difficult to address for equipment which is prototype-like compared to equipment bought "off the shelf". In any case it is recommended to invest significant effort at an early stage in the subject of risk analysis. The quality of the initial equipment design can be improved significantly by working closely with the supplier, and the increase in the initial time investment in the planning phase quickly pays off during the execution phases.

It is common to apply the FMEA Method during qualification. An FMEA risk analysis supports the systematic evaluation of the equipment including its hardware and software components. Using this method the potential risks to product quality and patient safety or the usability of the equipment are determined and assessed. The FMEA method forces the user to identify preventive actions which help to avoid or minimize the identified risks by reducing the probability of the occurring or increasing its probability of being detected.

Important steps in risk analysis include:

- Design review
- Determination and assessment of quality-relevant metering points (e.g. to set the re-calibration strategy, range of measurement)
- Assembly of critical process influences, if not already available
- Determination of maintenance items (maintenance schedule and contents)
- Assessment of functional scheme of automation and controls system
- Determination of test plan contents for qualification plans and assessment of critical items in the operating SOPs
- Check whether defects and defect root causes can be adequately identified
- Reduction of extent of testing, as applicable



 

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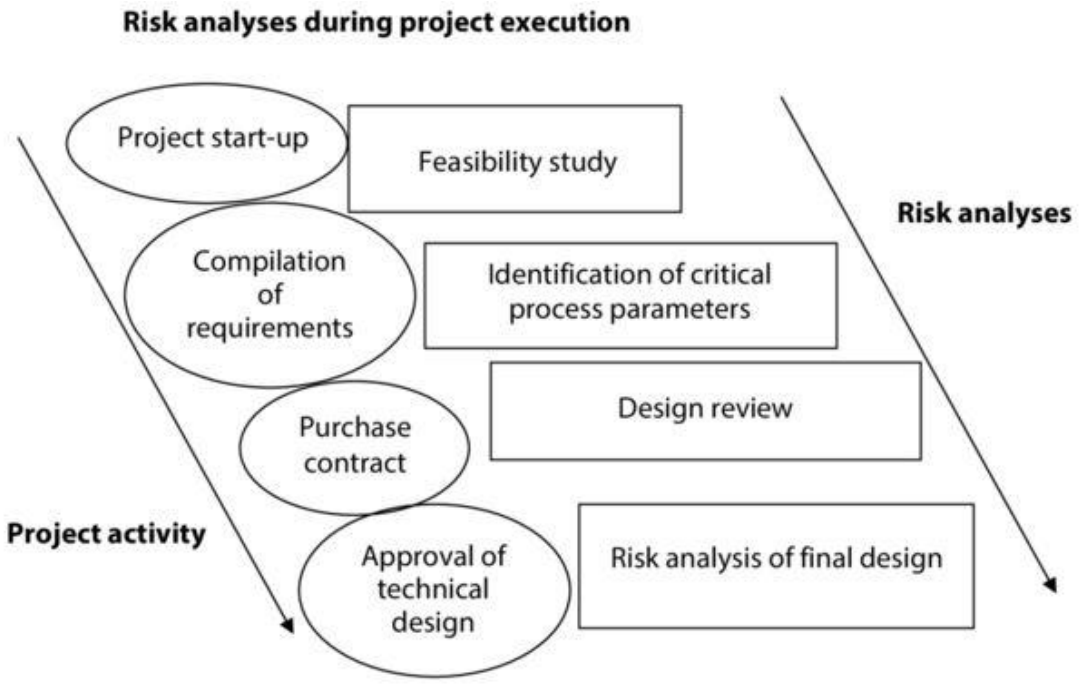


A project begins with a feasibility study which is also a form of risk analysis.

Critical process parameters are identified during the next step. In this risk analysis it should be documented what risks to the product may be caused by the equipment. This risk assessment is to be performed as part of the user requirements to support the determination of critical process parameters (CPP) and the critical quality attributes (CQA). The risks identified here can receive particular attention during project execution and during initial production trials.

The assessment of the equipment and its influence on the process can be categorized according to the following criteria:

- Critical (C): A failure can lead to a violation of GMP requirements with an influence on product quality and patient safety.
- Major (Ma): A failure can lead to a direct, undetected violation of GMP requirements without impact to patient safety.
- Minor (Mi): A failure can lead to a detectable violation of GMP requirements without influence on patient safety.
- not applicable when no GMP requirements are in effect.

During the design phase a further risk analysis is performed to identify potential risks as a result of process changes, design changes, piping changes (arrangement of valves, slope of pipes, etc.) as well as the arrangement of sensors. This way it is possible to influence the design, the equipment and the control systems.

Once the final execution plan is available the risk analysis can be used to verify the extent of the qualification. Based on the engineering drawings (P&ID, equipment design drawings) and other specifications (functional description, hardware specifications) the assessment of the equipment and process is performed and the team determines the actions to minimize the identified risks

The following risk reduction actions are possible:

- Change in function, program steps or design of equipment
- Testing during IQ, OQ, PQ, Validation
- Execution of studies and experiments in advance
- Additional monitoring



 

- Regular calibration
- Preventive maintenance activities
- Administrative measures/regulation by SOPs

It is necessary to follow up on all the measures and steps during qualification as a documented proof of completeness (Traceability-Matrix). This can be done using reference numbers provided in the risk analysis in the test protocol numbers, SOP numbers, maintenance plans, etc. A statement should be included in the qualification report that all the actions taken to minimize the risks have been implemented.

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