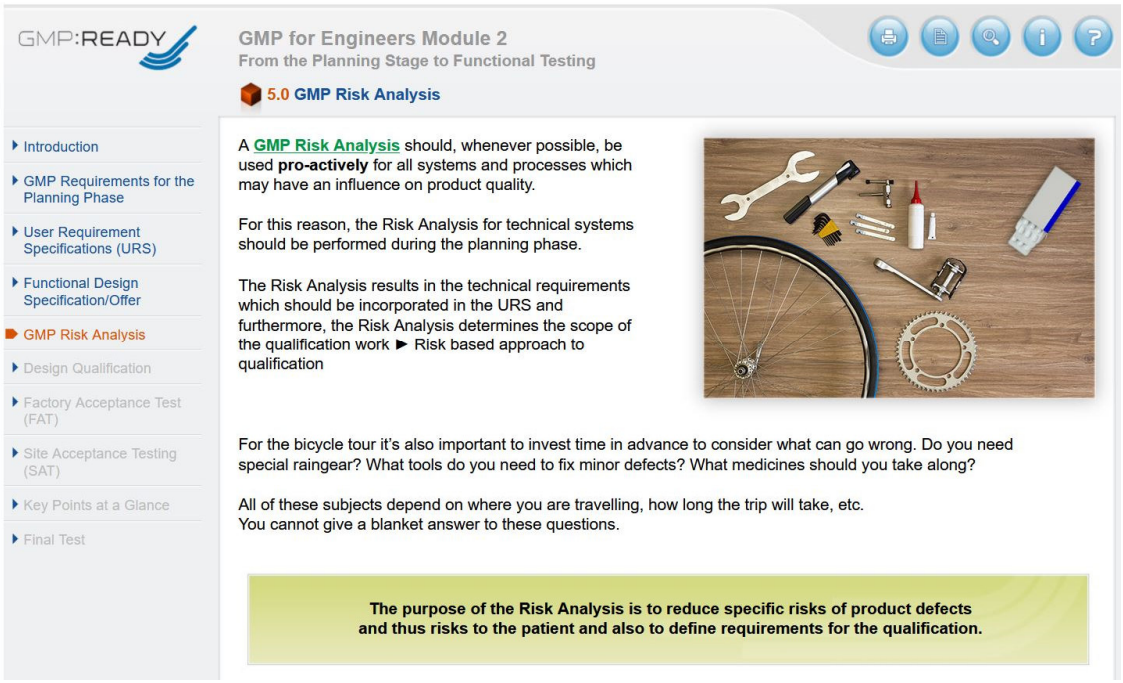
LOGFILE Feature 13/2021

GMP Risk Analysis in Qualifications

Excerpt from the E-learning GMP:READY: GMP for Engineers, 12.B, chapter 5.0 GMP Risk Analysiss



GMP:READY

GMP for Engineers Module 2
From the Planning Stage to Functional Testing

5.0 GMP Risk Analysis

- Introduction
- GMP Requirements for the Planning Phase
- User Requirement Specifications (URS)
- Functional Design Specification/Offer
- GMP Risk Analysis
- Design Qualification
- Factory Acceptance Test (FAT)
- Site Acceptance Testing (SAT)
- Key Points at a Glance
- Final Test

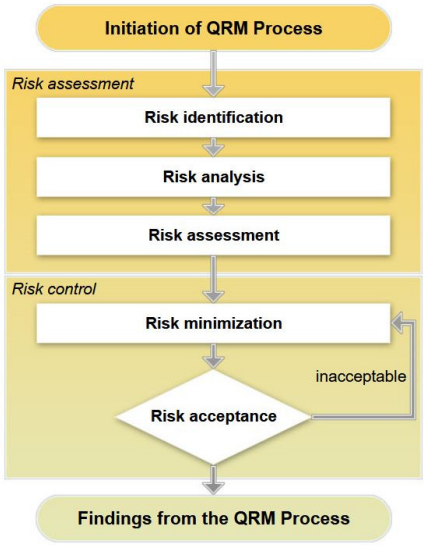
The process which is commonly referred to as a "Risk Analysis" is actually much more than that.

It can be presented based on the Quality Risk Management System as defined in ICH Q9 as follows (see figure).

The following individual steps are included:

- Risk identification– which risks may occur?
- Risk analysis – appraisal of the identified risks, e.g. what is the probability it will occur?
- Risk assessment – is the risk acceptable?

Afterwards, actions are defined meant to reduce the risk to an acceptable level.



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Depending on the planning phase and therefore also the amount of information available about the system, different types of Risk Analyses are performed.

At the start of planning it has to be figured out if the system has an influence on product quality and thus needs to be qualified. This type of Risk Analysis is also called an Impact Assessment (IA).
In most cases the result of this is recorded in the Validation Master Plan.

Once there is more information about the system available other types of Risk Analyses are performed.
At this point either an FMEA or an HACCP analysis are commonly used.

- FMEA – Failure Mode Effects Analysis
- HACCP – Hazard Analysis & Critical Control Points

In the pharmaceutical industry the FMEA analysis or related method is most commonly used.
An HACCP analysis is most often used in the food industry.

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FMEA Risk Analyses were introduced in the USA in the 1960's as part of the Apollo space program and then subsequently became popular in the automotive industry. Today it is probably the most widely accepted method in use.

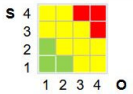
The FMEA is a quantitative method. It is used to evaluate potential failures with respect to their significance for the product and thus also for the patient. As part of the assessment the following failure characteristics are considered:

Probability of Occurrence (O), **Probability of Detection (D)**, or Probability of not being detected and **Potential Degree of Severity (S)**.
These three characteristics are used to calculate the Risk Priority Number (RPN) by multiplication of the factors:
RPN = O * D * S

The ranges for the values used for the different failure characteristics must be defined in advance. In the original version of the tool the range was from 1 - 10. But ranges from 1 - 4 are commonly used. Limit values must also be set for the RPN which define from which values actions are necessary in order to minimize the risk.
What is critical is that the risks be assessed both before and after the preventive actions are in place. Only in this way can a conclusion be made if the actions are sufficient.

Severity of Defect		Probability of Occurrence		Probability of Detection	
Very low	1	Rare event	1	Very high probability	1
Low or minor	2	Seldom occurence	2	High probability	2
Significant	3	Common occurence	3	Moderate probability	3
Critical	4	Expected event	4	Low probability	4

Limit value	
Negligible risk	7
Acceptable risk	12
Significant risk	>17



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When performing a Risk Analysis, representatives of the various fields of expertise who have the appropriate qualification should cooperate, e.g.:

- Planning (depending on impacted field),
- Operations Engineers,
- Operators,
- Qualifications Technicians,
- Quality Assurance.

Only this way is it possible to consider all the aspects, since everyone contributes his or her own individual perspective and expertise.

The same thing happens when a group of people want to go on a trip together.
Everyone makes a different contribution.

A Risk Analysis is only as good as the group of people who perform it!

Use the test to check how much you know about GMP Risk Analyses.
Click the button on the left to start the test.

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