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Risk assessment

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Abstract

Risk assessment purpose: There is a double purpose; by one hand protecting to the patient (avoiding risk and giving their more quality in their treatment) and the other hand with and economy purpose. This activity will identify the potential risks of the elements available in a plant (i.e., facilities, equipment, utilities, and working environment) that are expected to be involved in specific or general manufacturing process and can have an effect on the quality attributes of the product. This activity must be done by a multidisciplinary human team, that's important for covering different points of view for the same situation or issue. Everyone develop their mind according to the area where they are working and each one develop their knowledge in a different way, so that with a multidisciplinary team you can obtain many different possibility of solution for the same question. The thing is find the number of variable optimum to obtain the best result (statically).

Different Objectives Aimed:

• To be aligned with the risk based approach to GMP compliance, encouraged by the regulatory authorities

• To identify how process parameters impact to the quality of the product, so that, helping to take decision in committed situations

• To increase the flexibility of the process and opportunities for improvement

• To verify that the equipment to be used in manufacture facilities is capable of operating correctly within both (1) the

established process parameters as defined in the current batch records and (2) the stated performance range of the equipment

• To verify that the current control mechanisms available in the plant to support the manufacturing of the API will be evaluated and additional controls will be defined when necessary

Risk Assessment

Methodology and Tools:

1. FMEA (failure mode effects and analysis) (Resume)

2. FMECA (failure mode effects and critically analysis) (Resume)

3. FTA (Fault Tree analysis) (Resume)

4. HACCP (Hazard analysis and critically point) (Resume)

5. HAZOP (Hazard operability analysis) (Resume)

6. PHA (Preliminary Hazard analysis) (Resume)

7. RRF (Risk Ranking Filtering) (Resume)

To sum up:

The risk assessment is a good tool to improve a quality system and to defense come decisions, but it's not a fast process, you need more information, and time to evaluate all the consequences before start the punctuation and take some conclusions, mainly when you are in front of a new problem and you need to be sure the decision is good for the company and good for the quality. Also, it is important to know that not everything can be explained by a risk assessment; the result can be relative depending on the context.

Examples:

1. Example _ FMECA
2. Example _ FTA
3. Example _ HACCP
4. Example _ RRF
5. Example _ bad interpretation of statically result, dangerous conclusions.