INDEX

FIGURES

1 SCOPE

The document scope is the introduction to the Quality by Design and Risk Management approaches, with references and their utilities.

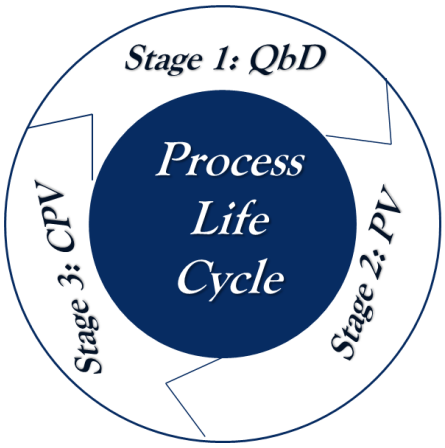
1.1 Application

The Quality by Design and Risk Management are approaches used for the pharmaceutical processes but should be helpful also for different manufacturing processes.

1.1.1 Quality by Design

It is a systemic approach aim to process and product knowledge in order to control the process, it is based on scientific rationale and risk management. It is the Stage 1 of the product lifecycle, followed by the Process Validation (Stage 2) and the Continued Process Verification CPV / On going process verification (Stage 3). It provides you with the instruments to evaluate the process failure opportunities, the process improvements and considers the quality as a requirement to be Assured instead to be Tested.

Figure 1: Process Lifecycle Approach



For the Pharmaceutical Company it is regulated by the ICH Q8.

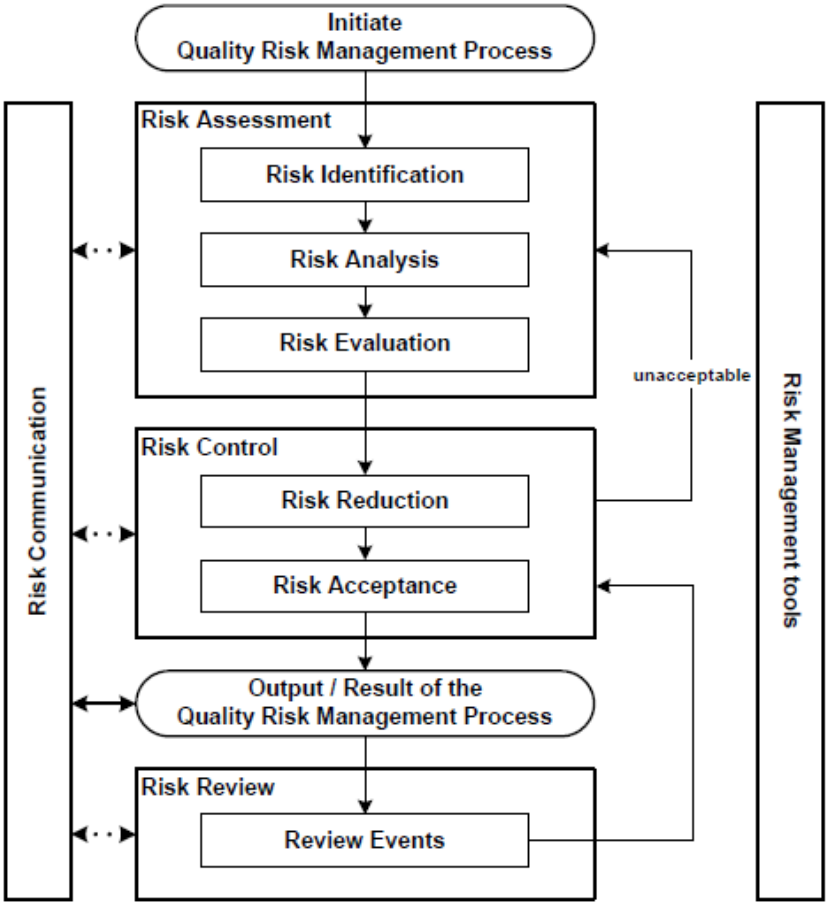
1.1.2 Risk Management

It is a systemic approach aim to evaluate, control, communicate and review the risk for the product quality during the product lifecycle. It is a multidisciplinary activity, every SME has to contribute as per his knowledge and responsibility, under Quality Assurance Coordination.

1. It starts with a problem description o risk question**.**
2. Four questions are an help to clearly define the risk:
    - **What can go wrong/How the process can faile?**
    - **What is the probability of this failure?**
    - **What is the severity of this failure?**
    - **How can I detect this failure?**

For the Pharmaceutical Company it is regulated by the ICH Q9, the flowchart is in the following figure.

Figure 2: Modello di Flusso per il Risk Management



2 ADVANTAGES

2.1.1 Quality by Design

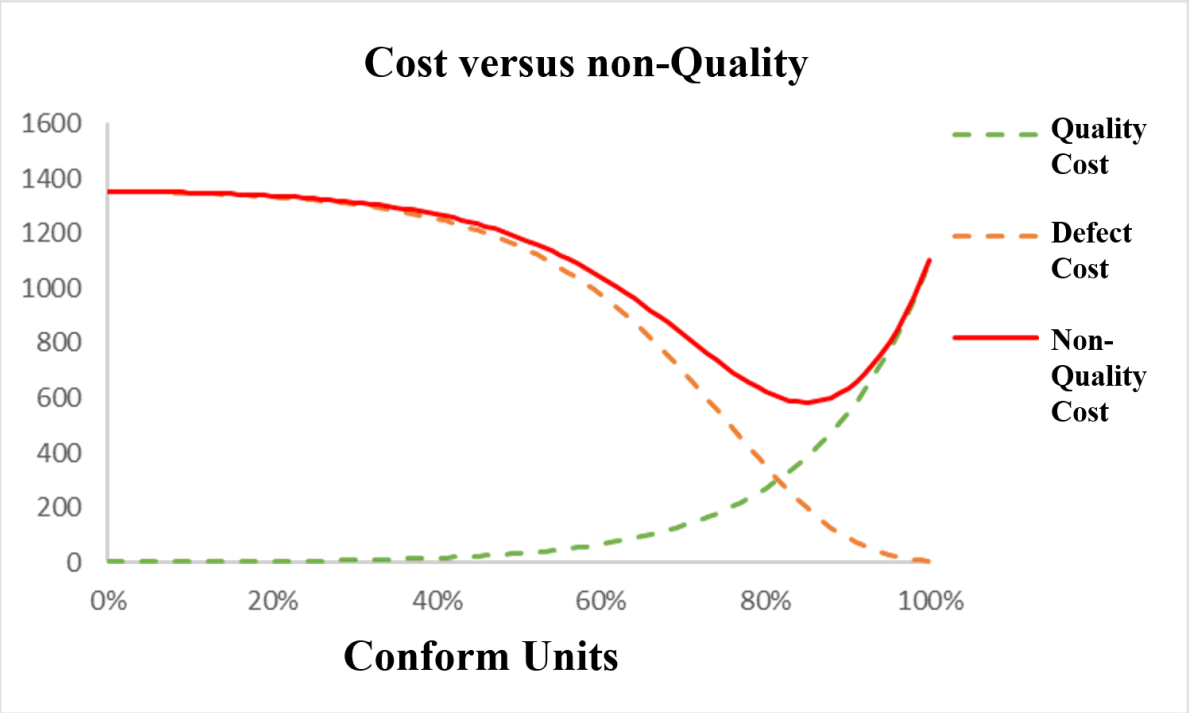
The process developed with the QbD the Process Validation can be substituted with the Continuous Process Verification (Annex 15- EU GMP), which should not be confused with the Continued Process Verification (CPV) named in Europe as Ongoing Process Verification.

It is not a Regulatory Requirement, but a kind of Quality System, but fundamental because:

1. A good process and product knowledge are fundamental to design a **ROBUST PROCESS;**
2. A robust process is fundamental to have a **LOW PROCESS VARIABILITY;**
3. A low process variability is fundamental to have **FEW DEVIATIONS, FEW BATCHES REJECTED.**

Therefore, it is not only a kind of Quality System but also a *Saving* opportunity:

Figure 3: Cost versus non-Quality

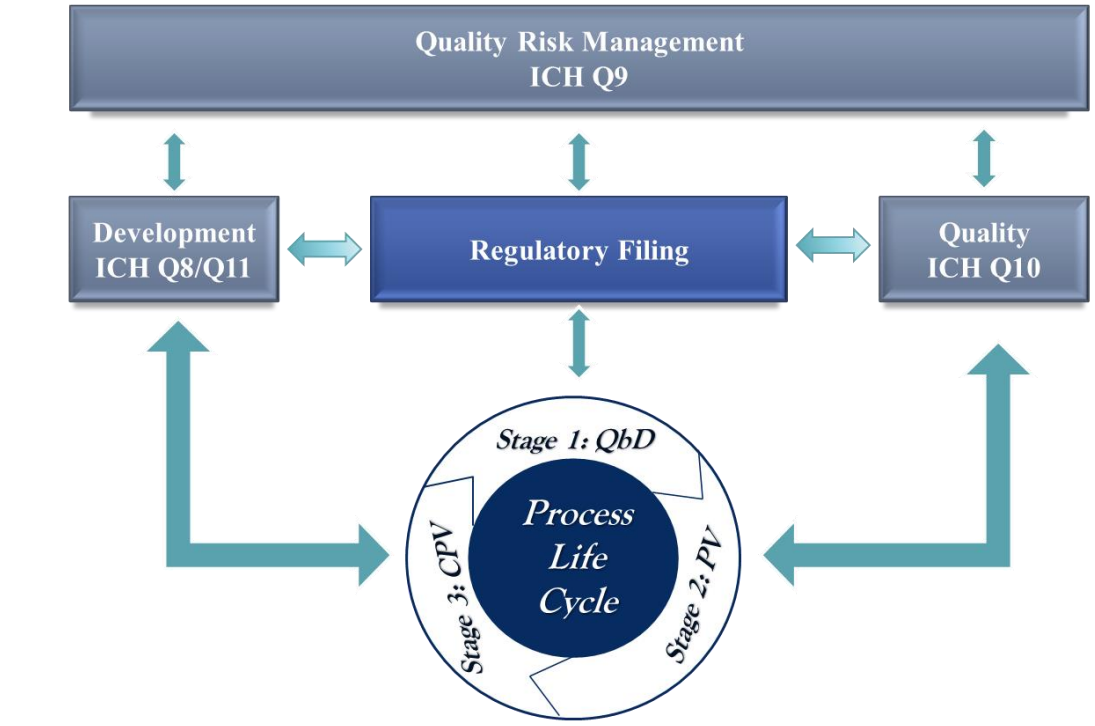


2.1.2 Risk Management

It allows to know preventively all the risk associated to the process and to implement preventive action in order to minimize the discarded units and process deviation.

It is a regulatory requirement to be included in the Quality System.

Figure 4: Risk Management in the Quality System



ICH Q12 - Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle - on going (2014-2018)

3 MORE INFORMATION

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