Quality by Design - *Minitab Suite*

Information about the course

Since its early applications, which were strongly recommended from FDA during decade 2000/2010, Quality by Design (QbD) successively imposed as the standard of Product/Process development methodology to be included in the approval submission of new medicine to the territorially-based Regulatory Medicine Agencies, such as FDA, EMA, and MHRA.
The main innovation introduced with QbD is represented by an organically supervising of previously existing Statistical tools, which were needed to demonstrate the objective efficiency of medicines, with specific Risk-Based Approach tools, which are developed to systematically enhance medicine quality by minimizing failure risks during its whole lifecycle. Correspondingly, the Minitab company has been one of firsts software house enabling to provide to their own customer not only Statistical calculation tool (the well-known “Minitab”) but also a tools Ecosystem expressly dedicated to the management of Quality By Design, Continuous Improvement, and Design for Six Sigma projects, which is currently named as "Workspace" and "Engage".
The current Training Program is intended to provide all Risk Management and Statistical tool knowledges required to apply the QbD methodology by means through the development of an actual and concrete Pharma use-case.

Program

- Introduction and Background
- Presentation of a Company Use Case (Part 1)
- Presentation of a Company Use Case (Part 2)
- Product Development
- Analytical Methods for CQAs
- Process Development or Process Design (scale-down)
- Process Risk Assessment
- Process Characterization Studies and Design Space
- Control Strategy
- Scale-up and Technology Transfer

Delivery mode and course duration

- On-site training: five full days, in your company.
- Online training: ten half-day online sessions.

Course Programme

1. ***Introduction and Background***

   1.1. QbD approach: Background, history and drivers

   1.2. Regulatory frame: ICH guidelines series

   1.3. Cause vs. Effect Matrix: deployment of Critical Parameters identification

   1.4. Overview of Statistical Tools

2. ***Presentation of a Company Use Case (part 1)***

   2.1. Project Scope

   2.2. Project Submission to a Public Pharmaceutical Agency

   2.3. Identification of Target Product Profile (TPP), such as drug description, Drug desired Efficacy (DE), safety claim, desired drug format, etc…

   2.4. Essential Statistical Tools

3. ***Presentation of a Company Use Case (part 2)***

   3.1. Superior Hypothesis Test of DE

   3.2. Non-Inferior Hypothesis Test of DE

   3.3. Equivalent Hypothesis Test of DE

4. ***Product Development***

   4.1. Early Product Development

   4.2. Definition of Quality Target Product Profile (QTPP) and Quality Attributes

   4.3. Definition of Critical Quality Attribute (CQAs) by means Risk Assessment

   4.4. CQAs vs. QTTP revision by means of Cause vs. Effect Matrix

   4.5. First Level Transfer Function: Regression Analysis of QTPP as a function of CQAs

5. ***Analytical Methods for CQAs***
   - 5.1. Homogeneity Test
   - 5.2. Accuracy Validation
   - 5.3. Repeatability Precision Validation
   - 5.4. Intermediate Precision Validation
   - 5.5. Specification setting of CQAs
6. ***Process Development or Process Design (scale-down)***
   - 6.1. Early Process Development
   - 6.2. Definition of Process Parameters and Material Attributes
   - 6.3. Critical Process Parameters (CPPs) & Critical Material Attributes (CMAs) vs. CQAs defined by means of Cause vs. Effect Matrix
   - 6.4. Deeply Understanding Process by means of Process Map
7. ***Process Risk Assessment***
   - 7.1. Failure Mode Effect Analysis approach
   - 7.2. Risk Priority Number (RPN) evaluation
   - 7.3. Recommended Actions to reduce Risks
   - 7.4. Analytical Methods for CPPs, and CMAs
8. ***Process Characterization Studies and Design Space***
   - 8.1. Entire Process vs. Single Unit Operation approaches
   - 8.2. Second Level Transfer Functions: DoE and Regression Analysis of CQAs as a function of CPPs & CMAs
   - 8.3. Design Space Modeling by means of Optimization and Overlaid Contour Plot
   - 8.4. Stability Studies on CQAs
   - 8.5. Specification and Acceptable Range setting of CPPs, and CMAs