# *Pharma in Practice* - *Minitab*

## *Information about the course*

Daily work in the Pharmaceutical industrial context continuously requires the application of several Statistical tools. Since standard statistical training programs have been derived from Automotive sector due to historical reasons, they often fail to match attendee expectations. In fact, although Statistical tools used in Pharma are the same as used in Automotive, the related concrete application in actual use cases are completely different as shown by the most important Pharmacopoeia Guidelines (ICH, FDA, EMA, MHRA).
The current Training Program has been designed in order to overcome the forementioned limitations, and to provide a practical application of Statistical tools on use cases as well as participants are used to dealing with them on a daily basis.

***Program***

- Introduction and Background (Part 1)
- Introduction and Background (Part 2)
- Analytical Methods
- Product & Process Development (Part 1)
- Product & Process Development (Part 2)
- Control Measurements

***Delivery mode and course duration***

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

# Course Programme

1. ***Introduction and Background (Part 1)***

    1.1. Overview of Industrial Statistics

    1.2. Essential Descriptive Statistics

    1.3. Essential Inference Statistics

        1.3.1. Hypothesis Test

2. ***Introduction and Background (Part 2)***

    2.1. Essential Inference Statistics

        2.1.1. Superior vs. Non-Inferior Hypothesis Test

        2.1.2. Equivalent Hypothesis Test

        2.1.3. Regression & ANOVA Analysis

3. ***Analytical Methods***

    3.1. Homogeneity Test

    3.2. Accuracy and Linearity Validation

    3.3. Repeatability & Intermediate Precision Validation

4. ***Product & Process Development (Part 1)***

    4.1. Essentials on DoE tools

    4.2. Factorial and Fractional Factorial DoE

    4.3. Formulation and Mixture DoE: Regression of CQAs as a function of CPPs & CMAs

5. ***Product & Process Development (Part 2)***

   5.1. Design Space Modeling defined by Optimization

   5.2. Specification and Acceptable Range setting of CPPs, and CMAs

   5.3. Stability Studies on CQAs

6. ***Control Measurements***

   6.1. Input material controls (Acceptance Bulk Sampling on CMAs)

   6.2. In-process and Parameters controls and monitoring (Control Charts and Process Capabilities)

   6.3. Output material controls (Acceptance Discrete Sampling on CQAs)