# *Pharma Validation Engineer Course Syllabus*
# *Rev.3 – 16AUG2023*

| Day 1 | |
|---|---|
| Module | Topics |
| **Session Kick-Off** | • Introductions<br>• Section 1 objectives and expectations |
| **Introduction** | • General Background<br>• Relevant regulation review<br>• Validation life Cycle approach<br>• Change control |
| **Risk based approach for validation** | • Risk assessment<br>• Methods for performing risk assessment<br>• Implications for the product/ process<br>• Implementation of quality in design |
| **Validation Master Plan** | • Validation policy characterization<br>• VMP approach<br>• Document scope<br>• Validation management |
| **User Requirements Specification (URS)** | • Purpose<br>• Requirements characterization process<br>• Best practices for writing good requirements<br>• Main contents<br>• Examples |
| **Session Wrap-Up** | • Feedback |

## Day 2

| Module | Topics |
|---|---|
| **Commissioning** | • General Background<br>• The need for Validation<br>• Regulatory requirements<br>• The Commissioning Plan<br>• Supporting IQ's and OQ's |
| **Design Qualifications** | • User Requirement Specifications<br>• Request for Purchase<br>• Functional Requirements<br>• Detail Design Specifications<br>• The DQ work<br>• FAT/SAT and Examples (Autoclave case) |
| **Validation Rationale** | • Key Concepts for Quality<br>• The V-model |
| **Installation Qualifications** | • Guidance and regulations<br>• Testing Installations<br>• IQ Examples including a Liquid Filling machine |

## Day 3

| Module | Topics |
|---|---|
| **Operational Qualifications (OQ)** | • Definitions, Approaches and Regulations<br>• HVAC example<br>• Autoclaves and a Fluid Bed Granulator<br>• Incubators and Liquid Filling Machine |
| **Performance Qualifications (PQ)** | • Temperature Mapping with Stabilization time example<br>• PQ Examples for HVAC<br>• Autoclave and Liquid Filling Performance Qualification |
| **Requalification's** | • What triggers a revalidation?<br>• The Risk Assessment approach<br>• Managing Qualifications |
| **Session Wrap-Up** | • Feed-back and Certificate distribution |