COURSE INTRODUCTION TO PROCESS VALIDATION

The objective of this course is to provide students with key concepts and fundamentals associated with the process validation cycle such as VMP, IQ, OQ and PQ, and the correlation with the regulations and standards.

COURSE CONTENT

1. **Purpose of Process Validation.**
2. **Process Validation from the regulation perspective.**
3. **Elements of Process Validation (IQ, OQ, TMV, PQ).**
4. **What is the starting point (MVP).**
5. **Other Elements to Get Started.**
6. **Process Validation Lifecycle – Maintaining the state of the art.**

Duration
4 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

At the end of the course you will be able to

- Understand the purpose of Process Validation (PV) in the medical device industry.
- Learn about the difference between the concepts of verification and validation as per ISO 13485 and 21 CFR Part 820 requirements.
- Learn about key process validation elements and their purpose for:
  - Validation Master Plan (VMP)
  - Test Method Validation (TMV)
  - Performance Qualification (PQ)
  - Equipment Qualification (EQ)
  - Operational Qualification (OQ)
- Understand the importance of other elements associated to process readiness such as:
  - Manufacturing Readiness
  - Material Readiness
  - Facilities Setup
  - Risk Management
  - System Setup
- Learn about the Process Validation Lifecycle – State of the Art.
- Apply the class learning to solve real cases associated to process validation.