COURSE PROCESS CHANGE ASSESSMENT

The objective of this course is to provide students with an understanding of the change control process, interaction with different elements of the quality system and considerations when creating a process change assessment in the medical devices industry.

COURSE CONTENT

1. **Regulatory Requirements.**
2. **Definition of Change.**
3. **Change Workflow.**
4. **Change Types.**
5. **The Impact Assessment:**
   - Change Description
   - Scope of Chance
   - Risk Assessment
   - Validation Assessment
   - Production and Process Assessment
   - Regulatory Assessment

Duration
9 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 concepts of change control in the medical device industry.
- Understand an overview of the medical device change control and regulatory and quality management system (QMS) compliance.
- Understand the types of changes according to different criteria.
- Learn the elements of the impact assessment in medical device change control process.
    - Change Description
    - Scope of Chance
    - Risk Assessment
    - Validation Assessment
    - Production and Process Assessment
    - Regulatory Assessment
- Experience in a practical way, real-world situations, and examples on change control.