COURSE GOOD DOCUMENTATION PRACTICES

The objective of this course is to provide the student with a good understanding and the best practices for medical device documents, documentation, and record keeping known as Good Documentation Practices through hands-on experiences.

COURSE CONTENT

1. **Generalities on GMPs.**
2. **What are Good Documentation Practices.**
3. **Data Record Elements:**

Data Accuracy - Data Integrity / Validation - Time - Legibility - Identifiable

4. **Good Documentation Standards:**

Creation – Approval – Signatures - Handwritten Entries – Corrections - Review

Duration
2 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

- Develop general understanding of what Good Documentation Practices (GMPs) are and why the same are relevant for the Medical Devices Industry to ensure compliance to the quality system.
- Learn about key concepts of GMPs for data records elements such as:
  - Data Accuracy
  - Data Integrity
  - Precision
  - Time
  - Legibility
  - Identifiability
- Learn about Good Documentation Standards and the best practices for:
  - Creation
  - Approval
  - Signatures
  - Handwritten Entries
  - Corrections
  - Review
- Apply GDP requirements and gain knowledge to solve multiple real case situations through out the class.