

The objective of this course is to provide the student with knowledge about Good Manufacturing Practices, to ensure that medical device manufacture is consistently controlled according to a set of quality standards. This course introduces the main characteristics of the medical device industry and why it is highly regulated.



COURSE CONTENT

1. **GMPs Overview.**
2. **What are Good Manufacturing Practices.**
3. **Key elements in GMPs.**
 - Personnel.
 - Cleanliness and Hygiene.
 - Productive Process.
 - Documentation.
 - Quality Assurance.



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

- Understand the regulatory framework of medical device manufacture.
- Have a general understanding of what Good Manufacturing Practices (GMPs) are and why they are relevant for the Medical Devices Industry to ensure compliance to the quality system.
- Understand the importance of maintaining a contaminant-free environment.
- Learn key concepts of GMP for the manufacture of medical devices, such as:
 - Personnel
 - Cleanliness and Hygiene
 - Productive Process
 - Documentation
 - Quality Assurance
- Understand the importance of GMP audits and how they can help companies to comply with guidelines set by regulatory authorities.
- Learn about quality and discuss how quality products are important for safety and efficacy.
- Apply GMP requirements and gain knowledge to solve multiple real case situations throughout each class.