Process Validation Course for the Medical Device Industry

A content-rich course which provides tools and techniques of Process Validation to cope with the day-to-day manufacturing and regulatory challenges in the medical device industry.

How will I benefit?

The benefit from the course is to learn a process for validating manufacturing at different stages any medical device of this industry. The course will provide the participants with the methods that will allow them successfully face challenges that are found every day in the field of process validations.
Other benefits obtained by the participants are:

- Understand the regulatory requirements of process validation for the medical device industry.
- Distinguish when it is required to carry out and evaluate the content of the process validation for medical devices.
- Write a Master Validation Plan.
- To reduce the development time of the protocols for installation, operation and performance while complying with the regulatory requirements.
- Evaluate and analyze measurement systems in the manufacturing process (TMV).
- Determining limits for critical parameters in the production processes and how to attack them.
- Determining the size of the sample required to perform a successful validation in the production process.

Target Audience

- R&D, QA /QC professionals
- Engineering employees and managers
- Project managers
- Development teams involved in the development of medical products
- Production personnel
- Entrepreneurs who intend to develop a medical product

Basic Requirements

Participants are not required to have practical experience in the medical device industry, but awareness of the requirements of ISO 13485:2016 and FDA CFR 21 Part 820 is recommended.

Link to Syllabus

Certification seminar

For more information
lital@gsap.co.il 052-3610566