BSI/UK/1734/TR/0320/EN/GRP

Manufacturing Process Validation for Medical Devices: Introduction to Concepts and Methods

Training course

STAGE 1 2 3

Essential information about the course

BSI's 'Manufacturing Process Validation for Medical Devices: Introduction to Concepts and Methods Training Course' one day training course has been designed to give manufacturers an awareness of EU regulatory and quality requirements regarding manufacturing process validation and the nature of 'special processes'.

Practical activities throughout the day provide the opportunity to apply your knowledge. Learn the generally accepted principles of manufacturing process validation, understand installation, operational and process qualification so you can apply them to your organization.

Our course agenda

- Benefits to you, welcome and introductions
- Boundaries: Conflicts of interest and expertise
- Course aims, objectives and structure
- Process validation:
  - Overview
  - Terminology, standard and regulations
  - How to get started
  - When is process validation required?
  - Plans
  - Different types of process validation (prospective, concurrent and retrospective)
  - Process variation IMDRF Annex A
  - An introduction to process capability studies
  - Process validation protocols (IQ, OQ and PQ)
  - Monitoring the state of process validation
  - Process revalidation
- Course review and summary

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate

Make sure the course is right for you

Who is this course for?

This course is ideal for you if you're in a quality assurance/regulatory/engineering/manufacturing role involved in medical device design, development and manufacturing.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Appreciate concepts and rationale of manufacturing process validation • Recognize the importance of manufacturing process validation • Gain awareness of relevant ISO 13485:2016 expectations and IMDRF guidance (previously GHTF) • Recognize situations where a manufacturing process requires validation • Have the tools to create a Master Validation Plan and validation protocols • Define objectives of equipment and process validations • Recognize relevant and pertinent factors of manufacturing process validation studies • Plan for worst case conditions and challenges • Identify how process capability studies can be used to validate manufacturing processes • Complete installation, operational and performance qualification • Maintain a state of validation • Recognize when revalidation may be required	This course will help you to: • Understand manufacturing process validation • Improve your understanding of the Medical Device Regulation (MDR) and quality standards requirements relating to manufacturing process validation • Be able to apply your knowledge to your organization, to enable it to produce compliant devices • Ensure auditable technical documentation meets applicable EU regulatory requirements

Prerequisites - you are expected to have the following prior knowledge:

You should have experience or basic knowledge of manufacturing engineering or quality management systems for the medical device industry. We recommend you have a basic awareness of medical device development and quality assurance.

Why invest in training from BSI?

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire the skills that will continue to be of use beyond the course.

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered at your site could be a convenient and cost-effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

Next steps with the BSI Academy

Want to learn more? You may be interested in:

Requirements of the Medical Device Regulation (MDR) Training Course, Implementation of the Medical Device Regulation (MDR) for CE Marking Training Course, Implementation of the In Vitro Diagnostic Device Regulation (IVDR) for CE Marking Training Course, and Medical Device Directive (MDD) to Medical Device Regulation (MDR) Transition Training Course.

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BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP