BSI/UK/1914/TR/0121/EN/GRP

Combinations of Medicinal Products and Medical Devices: Requirements of the MDR Article 117 and the Impact on Product Documentation

Training course

STAGE 1 2 3

Essential information about the course

BSI's Medical Device Software with Cybersecurity one-day training course has been designed to provide you an understanding of the requirements of Article 117 and the impact of these requirements on the documentation needed to obtain market approval and post-market approvals for medicinal products with an integral medical device.

It will also provide you with a general overview of the new Medical Device Regulation (MDR 2017/745) and of the activities involved in demonstrating conformity with the relevant general safety and performance requirements of a medical device.

This course involves practical activities, group discussions and classroom learning to help you develop a deeper understanding of the material and have a greater impact on job performance.

Our course agenda

Day 1

- Welcome, course structure, benefits to you
- Boundaries: Conflicts of interest and expertise and introductions
- Course aims and objectives
- Module 1: Introduction to Article 117
- Module 2: The Medical Device Regulation – The MDR
- Module 3: Medical device classification
- Module 4: The General Safety and Performance Requirements (GSPRs)
- Module 5: Article 117 of the MDR – Impact on the product documentation
- Module 6: Building collaboration
- Module 7: Development and testing strategy
- Module 8: Compiling the documentation
- Module 9: Course review and summary

Book today at
bsigroup.com/medical-devices-training-il

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 involved in the planning of or preparation of documentation to support medicinal products with an integral medical device.

What will I learn?	What are the benefits?
Upon completion of this training, you'll be able to: • Appreciate the background and content of the Medical Device regulation (MDR) • Identify the classification of medical devices • Explain the General Safety and Performance Requirements (GSPRs), at a high level • Interpret the meaning and requirements of Article 117 of the MDR • Identify the impact of Article 117 on the planning and preparation of Marketing Authorization Approvals (MAAs) for medicinal products with an integral medical device • Facilitate collaboration between the pharmaceutical department and the medical device department within your organization	This course will help you to: • Obtain basic knowledge of the MDR • Be familiar with the key activities involved in demonstrating conformity with the relevant GSPRs for a medical device • Determine whether Article 117 is applicable to your product • Outline an overall documentation strategy for a medicinal product used with a medical device • Help and guide your organization in the development and preparation of documentation for medicinal products with an integral medical device

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

You should have a basic awareness of the legal framework governing the development of medicinal products.

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.

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.

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