BSI/UK/1772/TR/0620/EN/GRP

Post-market Surveillance and Vigilance under the Medical Device Regulation (MDR) and In Vitro Diagnostics Medical Devices Regulation (IVDR)

Training course

STAGE 1 2 3

Essential information about the course

BSI's 'Post-market Surveillance and Vigilance under the Medical Device Regulation (MDR) and In Vitro Diagnostics Medical Devices Regulation (IVDR)' one-day training course has been designed to ensure manufacturers must have an appropriate system for gaining and reviewing experience in the post production phase from the range of devices they manufacture.

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

- Benefits to you, welcome and introductions
- Boundaries: Conflicts of interest and expertise
- Course aims, objectives and structure
- Post-market surveillance:
  - Overview
  - Interpret regulatory requirements for post-market surveillance and vigilance under the MDR and IVDR
  - Why is Post-Market Surveillance (PMS) necessary?
  - PMS requirements and the Quality Management System (QMS)
  - PMS plan contents
  - Periodic Safety Update Report (PSUR): IVDR Article 81/MDR Article 86
  - Proactive versus reactive sources of post-market surveillance data
  - Post-market clinical follow-up and post-market performance follow-up requirements
  - Vigilance
  - Vigilance requirements as defined in the MDR and IVDR
  - Vigilance: The forms
  - Details of how to submit vigilance reports
  - Adverse event reporting during clinical investigations (pre-CE marking)

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: • Interpret regulatory requirements for post-market surveillance and vigilance under the MDR and IVDR • Identify how these requirements relate to equivalent requirements ISO 13485:2016, ISO 14971:2019 and various European and IMDRF (GHTF) guidance documents • Create a post-market surveillance plan that includes both proactive and reactive sources of information • Implement cost effective and targeted post-market clinical follow-up (MDR) and post-market performance follow-up (IVDR) • Recognize when incidents and adverse event need to be reported to the Competent Authorities and Notified Bodies for both pre and post CE marked devices	This course will help you to: • Understand the key requirements and concepts of the post-market surveillance and vigilance for the MDR and IVDR • Gain a sufficient understanding to be able to write your PMS and vigilance procedures • Communicate the impact of these key requirements introduced by the MDR and IVDR to your organization • To obtain essential knowledge to implement a compliant post-market surveillance and vigilance quality management system • To understand how the PMS and vigilance processes integrate into the quality management system

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

You should have experience or basic knowledge of quality management systems for the medical device industry. We recommend you have a basic awareness of medical regulations, medical device development or 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 – Italia
Sede di Milano
Via Gustavo Fara, 35
20124, Milano

Find out more.
Call: +39 02 66 79 09 210
Email: training.italy@bsigroup.com
Visit: bsigroup.it/formazione