



Post Market Surveillance under MDR & IVDR - International



Your partner
in progress



Course descriptive

This one-day intensive course enables manufacturers to learn about the key requirements, concepts and the overall process for post-market surveillance and vigilance under the MDR and IVDR.

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 provide manufacturers with the tools to implement an appropriate system for gaining and reviewing experience in the postproduction phase from the range of devices they manufacture.

Pedagogical objectives

- Understand the key requirements and concepts of the post-market surveillance and vigilance for the MDR and IVDR
- Gain 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

Skills to be acquired

On completion of this training, you'll be able to:

- Interpret regulatory requirements for post-market surveillance and vigilance under the MDR and IVDR
- Identify how these requirements relate to 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 appropriate post-market clinical follow-up (PMCF) and post-market performance follow-up (PMPF) as per the MDR and IVDR respectively
- 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



Targeted audience

This course is ideal for you if you're in a quality assurance/quality control/regulatory/patient safety/customer facing role involved in continuous improvement and customer advocacy.

Prerequisites

There are no formal prerequisites for this course.

Duration

1 day – 7 hours

Pedagogical, technical and framing means

Course materials including :

- Introduction to the training, detailed program and security assignments
- Course presentation, theory and activities/ role plays
- Answers to the activities
- Videos
- Additional documents, distributed during the sessions, to use for the activities
- Attendance sheet to be signed



Assessment specifics

- Questionnaire to assess the knowledge at the end of the training
- Customer survey

What is included?

- Course materials, provided electronically
- Letter of attestation
- Official certificate



Agenda - Day 1

Time	Topic
09:00	Benefits to you, welcome and introductions
	Boundaries: Conflicts of interest and expertise
	Course aims, objectives and structure
	Post-market surveillance: <ul style="list-style-type: none">• 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)
Course review and summary	
17:00	End of course

*These training modules are eligible to the subsidizing by the public institutions in France (OPCO);

**Each delegate receives a training convention after enrolment.

***Please note that for the public sessions, you have until 48h before the start of the course to confirm your enrolment. For the in-house sessions, the deadline would be two weeks prior to the start of the course.

****Should you be in a disabled situation, please contact us and indicate what details should be taken into account.

*****You can contact us on training.france@bsigroup.com or **01 89 79 00 40**.