Medical Devices | Post Market Surveillance and Vigilance under MDR and IVDR

International Training

Number of days **1**

Key information about the course

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 post-production phase from the range of devices they manufacture.

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Agenda

Day 1

- 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)
- Course review and summary
- End of the course

Once you have completed the training, you will receive a BSI training certificate.

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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

- 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.

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

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Prerequisites: There are no formal prerequisites for this course

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

Each delegate receives a training convention after the 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 of 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**

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