Medical Devices Periodic Safety Update Report (PSUR)

SOLD OUT

What’s behind the MDCG guidelines

Type	Date	Language	Location
Corso online - Limited number	12 and 13 March 2024	English	Online

ABOUT

THE TRAINING COURSE IS SOLD OUT

The registrations for the next ediiton are open: 15 and 16 October 2024
Click here to view all details

The Periodic Safety Update Report (PSUR) is an entirely new type of report that has been introduced in Article 86 of the Medical Device Regulation (MDR).
It requires manufacturer of class IIa, class IIb and class III devices to prepare a Periodic Safety Update Report (PSUR) for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the PMS data gathered.

The regulatory requirement is set, yet the PSUR is a new document and manufacturers often do not have a clear view of what it entails:

- What do MDCG guidelines say?
- What are the expected data sources that need to be analysed and presented?
- Which type of preventive and corrective actions need to be listed in the PSUR?

- What are the main findings that should come out of the PSUR?
- Where does it fit within the PMS context and other post-market documents such as the PMCF Evaluation Report, the CER and the SSCP?

This workshop will provide relevant information to draft a PSUR, including what data should be presented and how it should be reported. It will offer the experience of an industry-expert for all representatives involved in working with medical devices under the MDR umbrella.

PROGRAMME

- The regulation, the guidelines and their context
- Submission obligations and timelines
- Data to be presented and how it should be presented
- Reportable data and main findings
- Challenges and lessons learned from first experiences

WHO SHOULD ATTEND

The course is addressed to:

- Clinical Affairs
- Post-Market Surveillance
- Regulatory Affairs
- Medical Writers
- Product Managers
- CROs

TEACHING METHODS

Interactive training

LECTURERS

Markus Pöttker

PMS EU MDR Workstream Lead at Smith&Nephew

Markus is a member of the EU MDR Project team at Smith&Nephew leading the Post Market Surveillance work stream. In this role, he is responsible that the requirements of the EU MDR are correctly interpreted and implemented across the company. Prior to this, he spent seven years in Quality & Regulatory roles, at last he was the Director of Complaint Management and Head of Regulatory Compliance with global responsibility for Complaint Handling, Medical Device Reporting and interaction with Regulatory Agencies. Markus is co-chair of MedTech Europe's PMS & Vigilance Working Group and a member of the MDCG Task Forces for Vigilance, PSUR and PMS. Markus holds a master's degree in law from WWU Münster, Germany. Markus is a bridge builder between the regulatory requirements for medical devices and practical implementation in companies. In addition to complex regulatory issues, he is passionate about digitalisation and lean process optimization - but also about human communication. He believes that technical innovation will continue to transform the medical technology industry.

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Understand the regulatory requirements for PSUR
- Identify the relevant input documents for your PSUR
- Prepare PSURs for different device classifications
- Understand challenges and lessons learned from first experiences of PSUR preparations

USEFUL INFORMATION

Online Training – 2 modules

Module 1 | 12 March 2024 from 09:30 am to 12:30 pm CET
Module 2 | 13 March 2024 from 09:30 am to 1:00 pm CET

The course admits maximum 12 attendees

After the registration, you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

REGISTRATION FEE

Early Bird: € 680,00* (until 20 February 2024)

Ordinary: € 875,00*

Freelance – Individual – Academy – Public Administration**: € 445,00*

* for Italian companies: +22% VAT

** *Early Bird discount not applicable to Freelance – Individual – Academy – Public Administration fee*

The fee includes: tuition, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

COURSE VENUE

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.