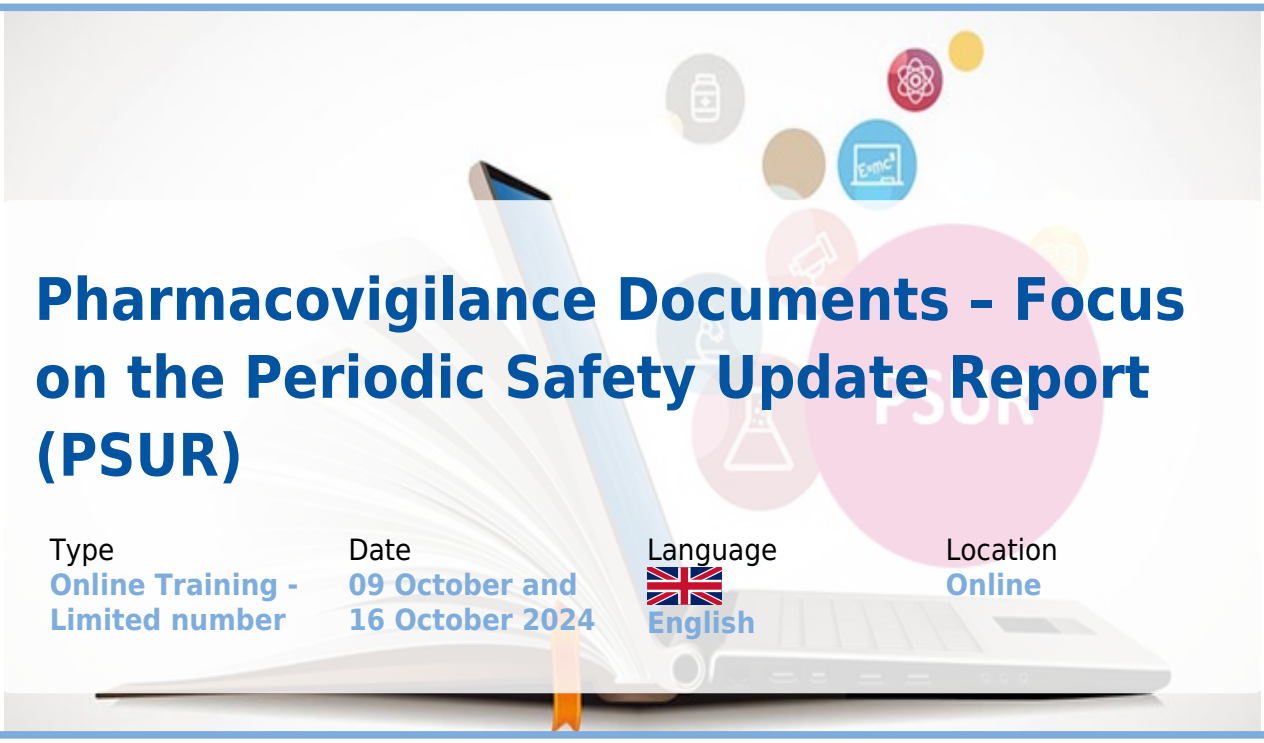
LIFE SCIENCE ACADEMY



Pharmacovigilance Documents – Focus on the Periodic Safety Update Report (PSUR)

Type	Date	Language	Location
Online Training - Limited number	09 October and 16 October 2024	English	Online

ABOUT

This course introduces the Periodic Safety Update Report (PSUR) and the related requirements, structure, content, and activities. Through selected exercises and a role play, relevant aspects of the PSUR preparation will be explored and discussed in view of the pharmacovigilance quality system and inspections. Besides sharing experience about pitfalls and challenges, the lecturers will discuss what is in the focus of Health Authorities' assessment. Key differences between PSURs and RMPs will be presented with a focus on the impact of RMP updates on PSURs.

PROGRAMME

Pharmacovigilance Documents – Focus on the Periodic Safety Update Report (PSUR)

MODULE 1

"The life beyond submission: The PSUR (Periodic Safety Update Report)"

- Focus on PSURs: requirements, structure and content
- *Breakout sessions and interactive discussion of the results*
- RMPs and PSURs: things to consider

- *Assessment and review of key concepts*

MODULE 2

“The life beyond submission: The PSUR, again”

- PSUR writing: challenges and pitfalls
- Document assessment and evaluation
- Experience from PSUR authority assessment reports: what really matters
- Preparation for the role playing: “plan, plan, plan…!”
- *Role play: design your own PSUR*
- *Assessment and review of key concepts*

WHO SHOULD ATTEND

Professionals involved in the planning, preparation, coordination and review of aggregated safety reports.
In particular:
Drug Safety and Pharmacovigilance department, Regulatory Affairs department and Quality and Compliance department (e.g. medical writers, pharmacovigilance writers, pharmacovigilance officers, pharmacovigilance managers, QPPVs, safety physicians, managers regulatory affairs and medical evaluators/advisors, document quality and compliance managers).

Participant experience:

For the participation in these training courses is required:

- Previous attendance to the “Pharmacovigilance Documents – Basic Concepts and Definitions for Pharmacovigilance Writing” training
- In alternative, a basic knowledge of PV writing

TEACHING METHODS

Presentation, hands-on exercises, group, and class discussions with a limited number of attendees.

LECTURERS

Marco Anelli

Medical Affairs and Pharmacovigilance consultant

Marco has a medical degree from the University of Milan, specializations in Medical Statistics and Clinical Pharmacology from the University of Pavia and an international master's degree in health economics and pharmacoeconomics from the University of Pompeu Fabra in Barcelona, plus formal training in Data Science and Artificial Intelligence. In the last few years, he has extensively worked in the fields of pharmacoeconomics and health technology assessment. Marco has been a free-lance consultant in Medical Affairs and Pharmacovigilance/ Drug Safety since 2022. Before that, he has been "Head of Pharmacovigilance and Medical Affairs Advisory Services" at ProductLife Group (PLG). As "Deputy Chief Scientific Officer", always at PLG, Marco has also coordinated all delivery and research projects (internal and on behalf of clients) linked to Big Data, Knowledge Management, Artificial Intelligence and Machine Learning. Previously, Marco was R&D Director at Keypharma, an Italy-based consultancy company (later acquired by PLG), where was responsible for the oversight of all clinical and preclinical aspects of projects run internally and on behalf of clients. Drawing on a career in the pharmaceutical industry that spans more than 30 years, Marco provides expert oversight on a wide range of R&D and Medical Affairs related activities. Marco has participated in and supervised all stages of drug development - from formulation to Phase I-IV and pharmacovigilance. In addition, Marco is a qualified QPPV and has prepared and overseen more than 200 non-clinical and clinical overviews and summaries. Before joining Keypharma and PLG, Marco was Medical Affairs Director at Eurand.

Tiziana von Bruchhausen

Principal Pharmacovigilance Writer at Boehringer Ingelheim

Tiziana von Bruchhausen, PhD specialises in pharmacovigilance writing and has gained over 10 years' experience while working in various roles for mid-sized and large pharmaceutical companies. She is currently employed as a principal pharmacovigilance writer at Boehringer Ingelheim. Her tasks and responsibilities cover pre- and post-submission activities related to the global strategic planning and the preparation of pharmacovigilance documents with a focus on DSURs, RMPs, PSURs, and health authorities' assessment reports. Tiziana actively promotes the professional role of medical writers in pharmacovigilance through workshops and lectures Europe-wide and has served as a session chair at international conferences. She is an active volunteer at the European Medical Writers Association (EMWA), where she has been chairing since 2017 the Pharmacovigilance Special Interest Group Committee. She was Vice President of EMWA in 2017-2018 and President in 2018-2019.

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

- Know the requirements for PSURs, the document structure and content, and where to find guidance
- Understand the importance of PSURs for the pharmacovigilance system and will be able to identify relevant topics and issues to be discussed in the document, as well as to plan the document preparation
- Discuss whether, how and where to present information in PSURs following RMP updates

USEFUL INFORMATION

Online training in 2 modules

MODULE 1 | 09 October 2024 – h.01:30 pm / 05:30 pm CET

MODULE 2 | 16 October 2024 – h.01.30 pm / 05:30 pm CET

The training course admits maximum 12 attendees.

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.

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This course is part of the training path Pharmacovigilance Documents in the Life Cycle of a Medicinal Product.

REGISTRATION FEE

Early Bird: **€ 990,00*** (until 18/09/2024)

Ordinary: **€ 1.185,00** *

Freelance – Academy – Public Administration:** **€ 645,00***

* for Italian companies: +22% VAT

** Early Bird discount not applicable to Freelance – 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.