LIFE SCIENCE ACADEMY

Pharmacovigilance Documents in the Life Cycle of a Medicinal Product: From Patients to Health Authorities

Development Safety Update Report (DSUR), Risk Management Plan (RMP), Periodic Safety Update Report (PSUR) / Periodic Benefit-Risk Evaluation Report (PBRER), and Addendum to the Clinical Overview

Type	Date	Language	Location
Online Training - Limited number	6-8-13-15 October 2020	English	Online

ABOUT

This course gives an overview of the pharmacovigilance activities and the related documents throughout the life cycle of a medicinal product. We will address:

- benefit-risk analysis
- signal management
- data collection process
- regulatory, format and content requirements.

While the course is based on the EU requirements, a few relevant insights about the most relevant local requirements will be provided. The participants will learn how to plan and manage PSURs and other pharmacovigilance documents in the life cycle and how to address selected challenges of

document preparation.

PROGRAMME

MODULE 1: “A never ending story (life cycle management in pharmacovigilance)”
•Introduction of participants
•Objectives of the modules
•Fine-tuning according to the participants’ needs
•The life cycle of a medicinal product from the pharmacovigilance perspective
•Benefit-risk analysis
•“Deep dive” – topics of common interest
•Be your own documentalist and statistician”:
– Signal management and data collection
– Evaluation of sources and data
– Planning, gap analysis and preparation of PV documents T
•Breakout sessions and interactive discussion of the results
•“Deep dive” – causality judgment
•Assessment and review of key concepts

MODULE 2: “The main actors”
•Basic concepts and definitions for pharmacovigilance writing
•Breakout sessions and interactive discussion of the results
•Interaction of the main pharmacovigilance documents through the life cycle of medicinal products:
– Development Safety Update Report (DSUR)
– Periodic Safety Update Report (PSUR) / Periodic Benefit-Risk Evaluation Report (PBRER)
– Risk Management Plan (RMP)
– Addendum to Clinical Overview (AddCO)
•Focus on DSURs
•Breakout sessions and interactive discussion of the results
•Focus on RMPs
•Breakout sessions and interactive discussion of the results
•“Deep dive” – Social networks in pharmacovigilance
•Assessment and review of key concepts

MODULE 3: “The life beyond submission”
•Life cycle of the safety concerns in RMPs: not all risks are created equal
•Breakout sessions and interactive discussion of the results
•Assessment reports on RMPs and PSURs
•Requirements, structure and contents of PSURs
•Strategic planning of PSURs, global management
•Breakout sessions and interactive discussion of the results
•“Deep dive” – Referrals
•Assessment and review of key concepts

MODULE 4: “Focus on PSUR”
•PSUR writing: challenges and pitfalls
•Document assessment
•Preparation for the role playing: plan, plan, plan
•Role play: design your own PSUR
•“Deep dive” – New technologies in pharmacovigilance
•Assessment and review of key concepts

WHO SHOULD ATTEND

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

Basic knowledge of drug development and pharmacovigilance.

TEACHING METHODS

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

LECTURERS

Marco Anelli

Head of Medical Affairs and Pharmacovigilance Advisory Practice - PLG (Product Life Group)

Marco Anelli has been appointed in January 2016 “Head of Pharmacovigilance and Medical Affairs Advisory Services” at PLG. As “Deputy Chief Scientific Officer” of PLG, Marco coordinates 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 ProductLife Group company, where was responsible for the coordination 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 25 years, Marco provides expert oversight on a wide range of R&D and Medical Affairs related activities. Marco has participated in and coordinated 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. In the last few years, he has extensively worked in the fields of pharmacoeconomics and health technology assessment. He 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, along with formal training in Data Science (Johns Hopkins University) and a Professional Certificate on Applied AI from IBM.

Tiziana von Bruchhausen

Senior 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 senior 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

- Understand the main pharmacovigilance activities in the life cycle of the medicinal product
- Plan and prepare DSUR, PSUR/PBRER, RMP, and AddCO, exploiting similarities and synergies among the different documents
- Apply writing skills to the preparation of pharmacovigilance documents

USEFUL INFORMATION

This online training is divided in 4 modules:

– Module 1 | 6 October 2020 – 2:00 – 5:30 pm CEST
– Module 2 | 8 October 2020 – 2:00 – 5:30 pm CEST
– Module 3 | 13 October 2020 – 2:00 – 5:30 pm CEST

– Module 4 | 15 October 2020 – 2:00 – 5:30 pm CEST

Some days before the online training you will receive all details about the connection.

This online training admits a maximum number of 10-12 attendees

Course Language: English. If all participants will be Italian, the training course will take place in Italian.

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: **€ 1.420,00*** (until 15 September 2020)

Ordinary: **€ 1.520,00***

Freelance – Academy – Public Administration**: **€ 852,00***

* for Italian companies: +22% VAT

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

The fee includes: Access to the online training, teaching materials in pdf format provided post-webinar, organizational office support, certificate of attendance.

SEDE DEL CORSO

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