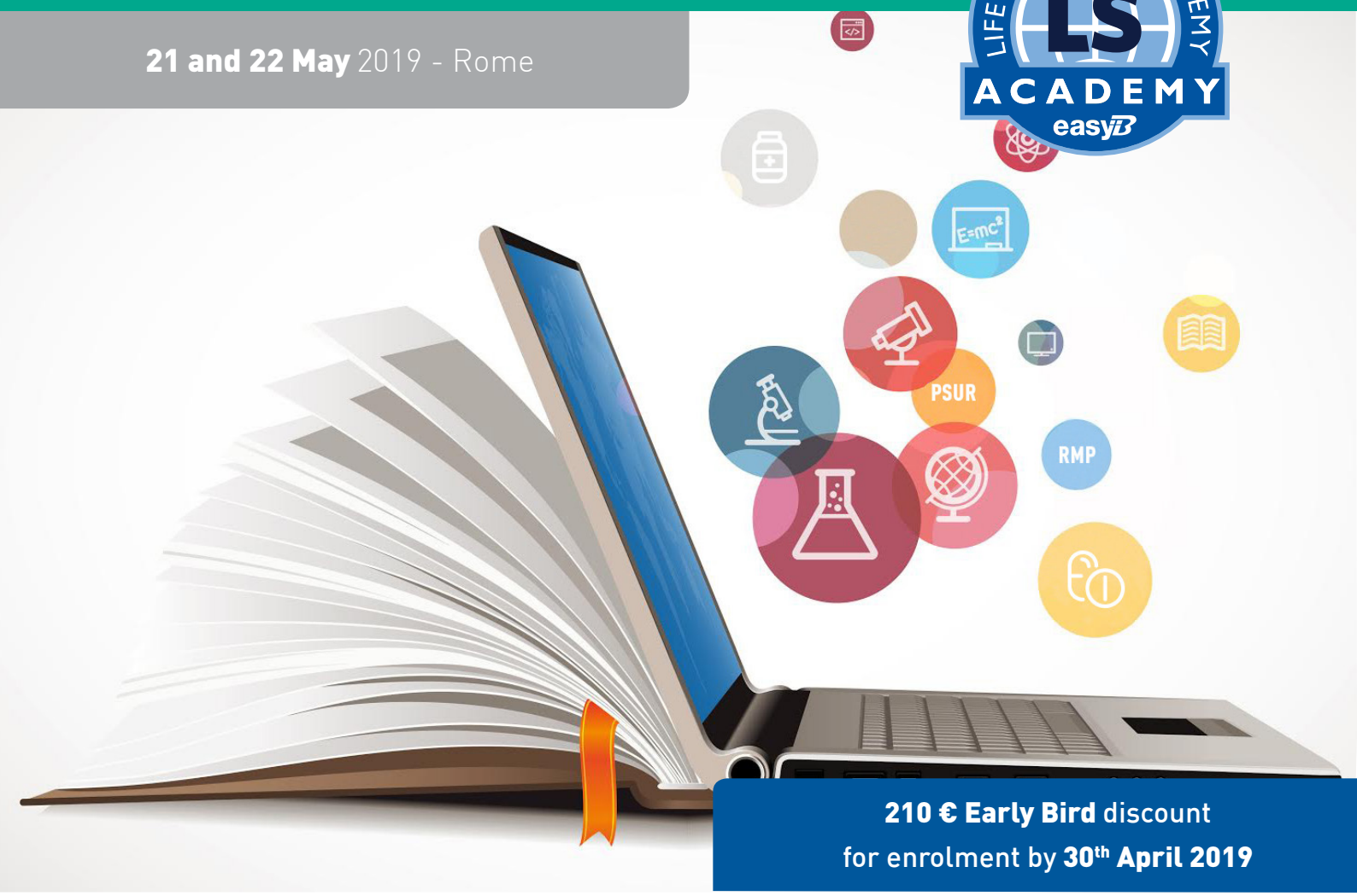
Pharmacovigilance documents in the life cycle of a medicinal product: DSUR, RMP, PSUR/PBRER, and Addendum to the Clinical Overview

From patients to health authorities: data collection, signal management, document preparation, authority assessment

21 and 22 May 2019 - Rome



210 € Early Bird discount
for enrolment by **30th April 2019**

Hotel Diana Roof Garden

Via Principe Amedeo, 4 00185 Roma

Tuesday 21 and Wednesday 22 May 2019

09:00-18:00

Course Language: *English*

If all participants will be Italian,
the training course will take place in Italian

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Introduction

This course gives an overview of the pharmacovigilance activities and the related documents throughout the life cycle of a medicinal product. After an introduction on benefit-risk analysis, signal management, and data collection process, the presentations will focus on regulatory, format and content requirements of the main pharmacovigilance documents. 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 documents in the life cycle and how to address selected challenges of document preparation.

Who is this course for?

This course targets participants coming from 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 e medical evaluators/advisors, document quality and compliance managers).

Programme

- The life cycle of a medicinal product from the pharmacovigilance perspective
- Benefit-risk analysis
- Signal management and data collection
- 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)
- Document assessment
- Referrals
- Planning, gap analysis and preparation of PV documents.

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Agenda

Day 1

9:00 - 9:30		Participants registration
9:30		Course commences
11:00 - 11:15		Coffee Break
13:00 - 14:00		Lunch
16:15 - 16:30		Coffee Break
18:00		End of day 1

Day 2

9:00		Course commences
11:00 - 11:15		Coffee Break
13:00 - 14:00		Lunch
16:15 - 16:30		Coffee Break
17:30		Q&A and Conclusion

Teaching methods

Presentation, hands-on exercises, group and class discussions

Required Experience

Basic knowledge of drug development and pharmacovigilance.

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 DSURs, PSURs/PBRERs, RMPs, and AddCOs, exploting similarities and synergies among the different documents.
- ✓ Apply writing skills to the preparation of pharmacovigilance documents

Lecturer's Bio

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. Previously, Marco has been R&D Director at Keypharma, an Italy-based ProductLife Group company, and 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 recent years, has worked extensively in the fields of pharmacoeconomics and health technology assessment. He has a medical degree from Milan University, specializations in Medical Statistics and Clinical Pharmacology from Pavia University and an international master's degree in health economics and pharmacoeconomics from Pompeu Fabra University in Barcelona. As "Deputy Chief Scientific Officer" of PLG, Marco is coordinating all delivery and research projects (internal and on behalf of clients) linked to Big Data, Knowledge Management, Artificial Intelligence and Machine Learning.

Tiziana **von Bruchhausen**

Senior Global Pharmacovigilance Writer - Boehringer Ingelheim

Vice President of the European Medical Writers Association

Dr von Bruchhausen is a senior pharmacovigilance writer with profound knowledge and hands-on experience in various areas of pharmacovigilance ranging from case processing to preparation of regulatory documents, global submissions, and interactions with health authorities. She gained her background in pharmacovigilance while working at a contract research organisation, where she headed teams with tasks of literature safety review, case processing, and pharmacovigilance writing. Before holding her current position, she worked as a freelance pharmacovigilance writer for international middle-sized and big pharmaceutical companies. Dr von Bruchhausen is a highly engaged member of the European Medical Writers Association (EMWA), regularly presents workshops at EMWA conferences, leads the EMWA pharmacovigilance special interest group, and currently represents the association as vice president 2017 / president 2018.

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND **THE REGISTRATION FORM**

OR DIRECTLY **REGISTER ONLINE:** https://psur-it-2019.lsacademyevents.it/orders/new

REGISTRATION FEES:

- ☐ Early bird: **€ 1670,00*** until 30/04/2019
- ☐ Ordinary: **€ 1880,00***
- ☐ Freelance – Academy – Public Administration: **€ 890,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)

P. IVA **03633040161**

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Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities. LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, following this link.

LSACADEMY.com **Date** _____ **Signature** _____