Programme overview

FORUM

Regulatory e-Learnings & Webcasts

e-Learnings

- Introduction to EU Marketing Authorisation
- Common Technical Document & eCTD
- Stability Testing in the ICH Region
- Marketing Authorisation outside the ICH Region
- CTD Module 3

Webcasts

- Biologics: Development, Quality and Regulatory Affairs
- Global Drug Safety and Global Regulatory Affairs

Flexible education and training in pharmacovigilance and regulatory affairs:
- **Basis know how in several e-Learnings**
- **Advanced information in live webcasts**

Your benefits

- Up-to-date expert knowledge & flexibility in location and timing
- Multiple choice tests and personal certificate
- Intuitive Learning platform

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Introduction to EU Marketing Authorisation

This e-Learning programme will familiarise you with the regulatory affairs principles involved in applying for a marketing authorisation in Europe. It addresses the EU marketing authorisation procedures for the various products. It will also introduce you to post-authorisation duties.

Your programme

Module 1: Overview of the law and EU regulatory network

Module 2: Principles
- The European Economic Area
- The scope of Directive 2001/83/EC

Module 3: Procedures
- MRP, DCP, CP
- Referrals

Module 4: Application types
- Legal basis
- CTD requirements
- Products as generics, herbals

Module 5: Post authorisation
- Renewals
- Sunset Clause
- Variations

Your expert

Dr Christian M. Moers
Straeter Lawyers, Germany
Lawyer

Common Technical Document & eCTD (incl. CTD Module 3)

This e-Learning programme will provide you with detailed knowledge on the structure and content of the (electronic) common technical document. It will address full as well as abridged dossier application.

This e-Learning course includes the CTD Module 3 e-Learning, which may also be booked separately.

Your programme

Module 1: CTD principles and structure

Module 2: Format and content of CTD including Module 3 requirements (drug substance and drug product)

Module 3: Dossier requirements for generics and further abridged procedures

Module 4: Dossier requirements for ASMF and CEP submissions

Your experts

Lidia Cánovas
ASPHALION S.L., Barcelona
General Manager

Michael Schaub
ASPHALION S.L., Germany
Director Munich Office

Stability Testing in the ICH Region

This e-Learning programme will focus on stability testing for chemical and biological products in the ICH region. It will provide you with knowledge of the regulatory frameworks in Europe, the ICH region and the US and introduce you to post-authorisation duties.

Your programme

Module 1: Regulatory requirements

Module 2: Factors that influence stability testing

Module 3: Stability test requirements

Module 4: Bracketing and matrixing

Module 5: Shelf life and extrapolation

Module 6: Impact of changes on stability

Module 7: Challenges for biotechnological products

Your expert

Dr Beatrix Metzner
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Head of Global Tech RA

Marketing Authorisation Outside the ICH Region

This e-Learning programme will familiarise you with the regulatory affairs principles outside the ICH region and show you how to categorise the various regions in terms of regulatory requirements.

Your programme

Modul 1: Key principles
- ICH, WHO, non-ICH region

Modul 2: Marketing Authorisation Dossier
- CTD, eCTD, other formats
- Electronic submission
- Specialties in Asia, ASEAN, Middle East, LATAM, EAEU, Turkey...

Module 3: Countries with or without CPP requirements
- Regulatory submission strategy based on CPP?
- CPP dependent and non CPP dependent countries

Your expert

Karl-Heinz Loebel
PharmaLex GmbH, Germany
Associate Director
Regulatory Operations

PharmaFORUM Webcast Biologics: Development, Quality and Regulatory Affairs

Two-hour live webcasts will provide you with the latest information on issues related to development, quality and regulatory affairs of biologics every month. International experts will inform you of the latest news and trends, in particular with regard to CMC, and answer your questions directly.

Excerpts from the upcoming programme

Pharmaceutical development of biologic drug products: the interface of formulation, primary packaging and application

Stability concept: pre- and post-launch

- Stability programmes
- Use of bracketing/matrixing
- Extrapolation of the shelf life

Comparability – Similarity Assessment

- Differences and common features
  - Assessment of quality attributes
- Demonstration of analytical comparability
- Demonstration of analytical similarity
  - Different approaches to show similarity in the US and the EU
  - Justification of differences

CMC lifecycle management: ICH Q12 and others

- Post-approval change management protocol (PCMP)
- How to achieve regulatory flexibility?

Your experts

Dr Susanne Jörg
Lonza AG, Switzerland
Head of Formulation Development

Dr Rainer Ilg
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Senior Associate Director, Global Technical Regulatory Affairs

Dr Beatrix Metzner
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Head of Global Tech RA

Dr Manuel Wittner
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
Associate Director, Global Technical Regulatory Affairs

Dr Steffen Groß
Paul-Ehrlich-Institut (PEI), Germany

PharmaFORUM Webcast International: Global Regulatory Affairs and Pharmacovigilance

Two-hour live webcasts will provide you with the latest information on international regulatory affairs and pharmacovigilance every two months. International experts will inform you of the latest news and trends in global marketing authorisation and drug safety within and beyond the ICH region, and answer your questions directly.

Excerpts from the upcoming programme

IDMP & SPOR

- Master Data Management
- Implementation of SPOR/IDMP and the impact on regulatory processes
- GAP analyses & data collection

Pharmacovigilance in Russia

- Local PSMF
- EAEU QPPV
- PV inspections

Marketing authorisation in Turkey

- How to become a marketing authorisation holder in Turkey
- Marketing authorisation application and procedure
- Localization, Turkish GMP inspections

Your experts

Remco Munnik
ASPHALION S.L., Spain
Regulatory Information Director

Anna Kramar
Eisai LLC, Russia
Regulatory Affairs, Quality and Pharmacovigilance Director

Seda Kadioglu
Seda Kadioglu Consulting, United Kingdom
Independent consultant on drug development, clinical trials and regulatory affairs

Previous webcasts available in your learning centre

- Regulatory Affairs in China
- Regulatory affairs and pharmacovigilance in Brazil
- PSURs & RMPs in int. markets
- Russia as part of the new EAEU, changes in RA and PV
- Regulatory affairs and pharmacovigilance in Saudi Arabia
- Marketing authorisation in the US
- Global CMC requirements

Regulatory e-Learnings & Webcasts

Group accounts also available

Our e-Learning concept

Our e-Learning programmes convey the basics. They comprise between three and seven didactic modules, including videos in which our experts share their expertise with you. You may download and print the related presentation documents.

Each module is concluded with an online-test or practical exercise. Once you have completed all the modules and passed all the tests, you will be awarded a certificate.

Our webcast concept

Our webcasts provide you with the latest information in the subject area. You will meet our experts in a virtual conference room.

Each meeting will be in the form of a two-hour live webcast and will present the latest news with supporting presentation slides (which you may also download for your personal use). Your practice-related questions will be addressed directly via the chat function, which is coordinated by the meeting's chair.

Are you unable to attend one of the webcasts? No problem! After each live meeting, you will be able to retrieve the recorded webcast from our learning centre.

Benefits of our e-Learning programmes and webcasts

- Up-to-date expert knowledge
- Flexible time and place
- Multiple-choice tests and personalised certificate
- Intuitive Learning platform

More information

Further information about the concept, content, fees, dates and speakers is available at www.forum-institut.com by searching for the relevant webcode.

- e-Learning: Introduction to EU Marketing Authorisation **Webcode: 1912220**
- e-Learning: Common Technical Document & eCTD **Webcode 1912222**
- e-Learning: Stability Testing in the ICH Region **Webcode 1912276**
- e-Learning: Marketing Authorisation Outside the ICH Region **Webcode: 1912221**
- e-Learning: CTD Module 3 **Webcode: 1912277**
- PharmaFORUM Webcast Biologics: Development, Quality and Reg. Affairs **Webcode: 1910279**
- PharmaFORUM Webcast International: Global Drug Safety and Global Regulatory Affairs **Webcode: 1911214**

Would you like to try us out, without obligation?

Demo versions of our e-learning programmes and trailers for our webcasts are available free of charge on our YouTube channel: www.youtube.com/user/FORUMInstitut

Would you like a free demo account? Just get in touch!

Dr Henriette Wolf-Klein
Tel. +49 6221 500-680
h.wolf-klein@forum-institut.de

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