

# 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

Join our new online trainings – live and on demand!

## 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

# The basics: International e-Learning programmes

## 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

# Advanced information in a series of live webcasts

## 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

## 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](http://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](http://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](mailto:h.wolf-klein@forum-institut.de)