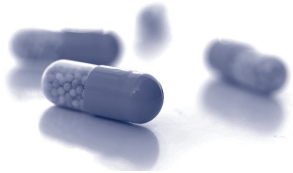
Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

EU Regulatory Affairs Introductory Training Course



Day 1 Marketing Authorisation Procedures in Europe

- Legal basis for marketing authorisation in Europe
- Mutual recognition, decentralised and centralised procedures in detail

Day 2 Marketing Authorisation Documents

- Data for the dossier: module by module
- Key elements and structure of the SmPC and the package leaflet

Day 3 Regulatory Life Cycle Management

- Variations and renewals
- eCTD and electronic submission

Each day may be booked separately!

Your experts

Pauline Dal Molin
DADA Consultancy, Netherlands

Kora Doorduyn-van der Stoep
Medicines Evaluation Board, Netherlands

Michiel Hendriks
DADA Consultancy, Netherlands

Remco Munnik
ASPHALION S.L., Spain

Geeske van Heel
DADA Consultancy, Netherlands

Aimad Torqui
MSD Netherlands, Netherlands

27 - 29 November 2017 in Amsterdam

EU Regulatory Affairs Introductory Training Course

Aim of this course

This introductory training course will inform you about all the important obligations and challenges in regulatory affairs. You will learn about the different procedures in Europe and about the data and documents required for successful marketing authorisations. Moreover, you will gain practical knowledge about the regulatory life cycle management for a product and the structure and submission of an electronic dossier.

Learning outcomes

- Knowledge of the regulatory affairs procedures in Europe.
- Knowledge of the requirements and deadlines for each procedure.
- The ability to choose the most suitable procedure for your product.
- The ability to contribute to the submission process.
- Familiarity with the peculiarities of generics.
- Proficiency in compiling the necessary documents.
- Knowledge of the structure and content of the SmPC and the package leaflet.
- Understanding of the principles of electronic submission.
- Knowledge of the requirements for regulatory life cycle management.

Who should attend

This seminar will be of benefit to all those working in regulatory affairs or in related departments that need essential European regulatory affairs expertise. Basic pharmaceutical knowledge is recommended but not prerequisite.

Seminar recommendation

Do you work in regulatory affairs and already have solid EU regulatory affairs knowledge? Then we would like to draw your attention to the seminar:

The EU Regulatory Affairs Expert
Amsterdam, 6 December 2017
Webcode: 1712235

We will address current challenges in EU regulatory affairs, including dealing with national peculiarities, regulatory optimisation challenges and duties with regard to Brexit, and much more.

Programme Day 1
Marketing Authorisation Procedures in Europe

27 November 2017, 09:00 – 17:00

Kora Doorduyn-van der Stoep

Medicines Evaluation Board, Netherlands

Governance, Regulatory and International Affairs Department, CMDh member

Geeske van Heel

DADA Consultancy, Netherlands

Consultant Regulatory Affairs

Basic principles and terminology

- The regulatory framework: regulations, directives and guidelines
- Involved authorities
- The available marketing authorisation procedures: centralised, decentralised and national

Legal basis for marketing authorisation procedures in Europe

- Full application, generic application, hybrid application and biosimilars
- Bibliographic application and informed consent
- Registration

Mutual recognition and decentralised procedures

- Common principles
- Deadlines and clock stops
- Role of the Co-ordination Group (CMDh)

Centralised procedure

- Scope and mandatory products
- Roles of the European Medicines Agency (EMA), the Committee for Medicinal Products for Human Use (CHMP) and national authorities
- The procedure in detail

Specifics for generics

- Data exclusivity and innovation protection
- European reference product

May be booked separately according to your needs!

Programme Day 2
Marketing Authorisation Documents

28 November 2017, 09:00 – 17:00

Pauline Dal Molin
DADA Consultancy, Netherlands

Consultant Regulatory Affairs

Aimad Torqui
MSD Netherlands, Netherlands

Director Global Regulatory Policy

Marketing authorisation dossier – Module 1
- Cover letter, application form, etc.
- National peculiarities

Data for the dossier: Modules 3, 4 and 5
- Module 3: core documents and data
- Compilation of preclinical and clinical data
- How to present study reports
- Common errors and authority findings

Module 2: data structuring and evaluation
- Common principles for overviews and summaries

Pharmacovigilance requirements for marketing authorisation applications

SmPC and the package leaflet
- Key elements and structure of the SmPC and the package leaflet
- QRD templates
- Educational material

Excursus: Specifics for Conditional Approval, PRIME. etc.

Programme Day 3
Regulatory Life Cycle Management

29 November 2017, 09:00 – 17:00

Michiel Hendriks
DADA Consultancy, Netherlands

Consultant Regulatory Affairs

Remco Munnik
ASPHALION S.L., Spain

Regulatory Information Director

Marketing authorisation granted – overview of subsequent duties
- Variations, renewals, pharmacovigilance and further responsibilities

Variations
- Type IA/B notifications and Type II variations – correct classification
- How to complete the application form
- Grouping and worksharing
- Classification with the help of practical examples
- Practical exercises

eCTD and electronic submission
- eCTD basic principles: Structure, document requirements and lifecycle management
- EU Module 1 requirements

Electronic Life Cycle Management
- Submission to the authorities: electronic application forms and portals (CESSP and EMA Gateway)
- Other eSubmission projects: xEVMPD and ISO IDMP

EU Regulatory Affairs Introductory Training Course

About FORUM Institut

The FORUM Institut für Management, founded in 1979 in Heidelberg, is an international group of institutes that concerns itself with the training of corporate specialists and executives. Firstclass speakers, current topics, high-quality seminar materials and excellent on-site support ensure the high quality of our seminars and symposia.

Submit your questions in advance

To make the most of our seminar, you may submit your individual questions to j.jegodka@forum-institut.de four weeks prior to the event. Our speakers will try to include your topics in the programme.

Further Information

For further details on the speakers and the detailed programme please enter the webcode 1711204 in the search field on www.forum-institut.com.

Quality guaranteed!

IMI (Innovative Medicines Initiative) defined quality criteria for professional training and education. We follow these criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards. An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 10.2015 - 09.2016) produced a result of 1.7 (based on a school grading system of 1-6).

Booking options

You have the option to organise your training according to your level of expertise and requirements. Each day can either be booked separately or in combination with another day. Simply choose the topics you need. For further information please see the booking details below.

Registration: +34 91 372 83 99 or email: formacion@qualitecfarma.com

Yes, I will attend the seminar

- ☐ Day 1: Marketing Authorisation Procedures in Europe (27 November 2017)
- ☐ Day 2: Marketing Authorisation Documents (28 November 2017)
- ☐ Day 3: Regulatory Life Cycle Management (29 November 2017)

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

Registration: +34 91 372 83 99
Conference-No. 17 11 204

Date/Venue:
27 - 29 November 2017 in Amsterdam
DoubleTree by Hilton Amsterdam Centraal Station
Oosterdoksstraat 4 · 1011 DK Amsterdam
Tel. +31 20 5300800 · Fax +31 20 5300801

Fee:
One day: € 1090 (+ 21% VAT)
Two days: € 1790 (+ 21% VAT)
Three days: € 2490 (+ 21% VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch and certificate.
Invoice and confirmation will be forwarded to you.

Questions and information:
Pablo García, Conference Manager (QualitecFarma®)
Tel. +34 91 372 83 99 ·formacion@qualitecfarma.com

Cancellation Policy:
Our general terms and conditions apply (as of 01.01.2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.com/t&c