Seminar

FORUM
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CMC Management in Regulatory Affairs

Quality data for marketing authorisation in Europe

Topics

- Regulatory requirements in the EU and the ICH region
- Essential quality data for marketing authorisation
- CMC documentation: Module 3, ASMF, CEP and Quality Overall Summary
- Management of post-approval changes
- Classification of quality related variations

Interactive session on the
- evaluation of CMC data
- classification of quality-related variations

Your speakers

André Mota
ASPHALION S.L.,
Spain

Jan-Jaap Scherpbier, MSc
Garden State Pharmatech,
The Netherlands

Aimad Torqui
MSD Netherlands,
The Netherlands

Dr Helmut Vigenschow
ViPharmaService,
Germany

25 - 26 September 2019 in Amsterdam

CMC Management in Regulatory Affairs

Aims and objectives

This training course will give you in-depth knowledge of CMC requirements for marketing authorisation. Our experts will address essential quality data and provide strategic information on CMC writing and maintenance.

Learning outcomes

- Knowledge of regulatory framework in Europe and the ICH region
- Ability to choose the essential quality data for drug substance and drug product section of module 3
- CMC writing skills
- Background knowledge in interdisciplinary field: non-clinical, GMP and clinical meets CMC
- Familiarity with life cycle management in a global environment
- The ability to classify quality-related changes

Who should attend?

This seminar addresses the needs of those working in the pharmaceutical industry. It will particularly benefit CMC managers, regulatory affairs managers and managers of the quality assurance department dealing with the

- compilation and the maintenance of Module 3 of the CTD,
- classification of quality-related changes.

Your speakers

André Mota
ASPHALION S.L., Spain

Madrid Office Director

Jan-Jaap Scherpbier, MSc
Garden State Pharmatech, The Netherlands

Managing Partner

Aimad Torqui
MSD Netherlands, The Netherlands

Director Global Regulatory Policy

Dr Helmut Vigenschow
ViPharmaService, Germany

Questions in advance

To make the most of our seminar, you may submit your individual questions to l.vogelmann@forum-institut.de four weeks prior to the event.

Further information

For further details on the speakers and the detailed programme please enter the web-code 1909273 in the search field on www.forum-institut.com.

Quality data for marketing authorisation

Day 1

Regulatory requirements

Aimad Torqui

- The regulatory framework: regulations, directives and guidelines
- Introduction to submission basics (EU)
- ICH requirements: structure of the CTD
- CTD modules

Quality data for marketing authorisation

André Mota and Jan-Jaap Scherpbier

- Essential quality data for Module 3:
  - Drug substance
    - Starting material
    - Physico-chemical properties
    - Manufacturing process and process development
    - Impurities
    - Stability (re-test period)
- Drug product
  - Pharmaceutical development (including Quality by Design)
  - Manufacturing and control
  - Process validation
  - Impurities; specifications
  - Analytical methods and validation
  - Reference standards; excipients
  - Stability (shelf-life)

CTD CMC documentation: practical aspects

André Mota and Jan-Jaap Scherpbier

- Pharmaceutical writing - essential data vs dossier maintenance burden
- Quality Overall Summary
- Drugs Substance: How to avoid common mistakes?
- Active Substance Master Files (ASMF), Certificate of Suitability (CEP)
- Drug Substance analysis by finished product manufacturer

Day 2

Challenges in the interdisciplinary field

Jan-Jaap Scherpbier

- GMP meets Regulatory Affairs
- Mandatory documents (QP-declaration, GMP certificates, process validation, etc)
- Non-clinical and clinical meets CMC

Management of post-approval changes

Dr Helmut Vigenschow

- Life cycle management
- Renewals
- Variations
- Grouping, work-sharing
- Art 61(3)
- Life cycle management in global environment

Case study: evaluation of the CMC data

Jan-Jaap Scherpbier

- Assessing whether or not data is CTD relevant
- Data requirements for a planned variation

Classification of quality-related variations

Dr Helmut Vigenschow

- Interactive session:
- Drug substance example
- Drug product example
- Pitfalls/grey areas within regulations

Registration recommended 30 days in advance

Registration under

service@forum-institut.com or

Fax +49 6221 500-555 or + 962 65512563

Registration Form

Yes, I will attend the seminar

☐ CMC Management in Regulatory Affairs

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

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How to register

- **Registration: +49 6221 500-500**
- **Conference-No. 19 09 273**

- **Website:**
www.forum-institut.com

- **Date/Venue:**
25 - 26 September 2019 in Amsterdam
NH Amsterdam Centre
Stadhouderskade 7 · NL 1054 ES Amsterdam
Tel. +31 20 685 1351

- **Fee:**
€ 1790.00 (+ 21% VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.
Day 1: 09:00 - 17:00 (08:30 registration)
Day 2: 09:00 - 17:00

Any Further Questions?

Please feel free to contact me if you have any questions.

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Cancellation Policy

Our general terms and conditions apply (as of 1. January 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