Preparation of a Successful CTD with Quality by Design (QbD)

December 8-10, 2014 | Qilu Courtyard Hotel Shanghai, China

The workshop will share and discuss requirements and experience on how to build up a high quality CTD dossier with focus on quality elements, considerations during the development of a new medicinal product (MP), and practices for compiling a high quality dossier for successful global submission and review for generic products.

FEATURED TOPICS

- CTD, eCTD
- Drug Legislation and Drug Regulation
- Residual Solvents – Case Study
- ICH Q8/Q9/Q10 and Q11 Quality by Design
- Communication Between Authority and Industry – Case Study
- Quality Target Product Profile – Interactive Workshop
- Quality Risk Management – Case Study

LEARNING OBJECTIVES

- Identify the recent requirements for developing drug substance and drug products and setting up a registration dossier
- Define the requirements for developing a product and discuss how to prepare the ICH Q8/Q9/Q10 and Q11 with Quality by Design
- Discuss the legal background of the dossier requirements and identify the relevant guidelines
- Demonstrate optimal presentation of information and justifications for regulatory submissions

WHO SHOULD ATTEND

- Reviewers from Regulatory Agencies
- Pharmaceutical Industry Professionals
- Regulatory Affairs, and R&D Professionals
- Quality Assurance and Manufacturing Professionals

PROGRAM COMMITTEE CO-CHAIRS

REN Yi, PhD
General Manager, Nanjing Medichem Bio-Pharmaceutical Development Co.

Melly LIN
Regulatory Manager Technical Regulatory Policy, Roche (China) Holding Ltd.

KEY INSTRUCTORS

Christa Wirthumer-Hoche, PhD
Head of Austrian Medicines and Medical Devices Agency (AGES) Head of Institute for Marketing Authorisation of Medicinal Products and Lifecycle Management

Fritz ERNI, PhD
CMC Consultant, Switzerland Member of the ICH Q8 Expert Working Group and ICH Q8/Q9/Q10 Implementation Working Group Topic Leader of the European Industry (EFPIA) for Drug Impurities

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DAY 1 | **MONDAY, DECEMBER 8**

07:30 – 09:00 **Registration**

09:00 – 09:30 **Welcome and Introduction**

09:30 – 10:30 **Session 1**

China CTD Requirements and Practices
CFDA Speaker Invited

10:30 – 11:00 **Session 2** *Christa Wirthumer-Hoche, PhD*

Drug Legislation and Drug Regulation
- Development of drug legislation
- Drug regulations in the EU
- Regulatory bodies, structure, responsibilities
- Communication with and between regulatory agencies

11:00 – 11:15 **Coffee Break**

11:15 – 12:15 **Session 3** *Christa Wirthumer-Hoche, PhD*

Introduction to the Common Technical Document Structure of the licensing dossier
- Structure of the CTD (Module 1 – 5)
  - Relevant guidance documents
  - Focus on Module 3 - Quality
- eCTD
  - current guidance documents
  - readiness to prepare (by industry) and accept eCTD (by authority)
  - future of the eCTD

12:15 – 13:30 **Lunch**

13:30 – 14:15 **Session 4** *Christa Wirthumer-Hoche, PhD*

Quality of Active Substance - necessary documentation
- Active Substance
  - Active Substance Master File
  - Certificate of Suitability
- Impact of the EU-Directive on Falsified Medicines

14:15 – 15:15 **Session 5** *Fritz Erni, PhD*

Impurity testing : Experience and new trends of ICH Q3A/B/C
- Impurities in drug substance
- Degradation products in drug products
- Residual solvents

15:15 – 15:30 **Coffee Break**

15:30 – 17:30 **Session 6** *All*

Case Study Residual Solvents
- Introduction to the Case Study residual solvents
- Start working in groups
- Discussion of the case study

17:30 **End of Day 1**

DAY 2 | **TUESDAY,** DECEMBER 9

08:30 - 10:00 **Session 7** *Christa Wirthumer-Hoche, PhD*

- Specific Requirements for Different Types of Applications
- Information for bibliographical applications
  – Legal provisions concerning well established use applications
- Information for generic, "hybrid" or bio-similar applications
  – Legal provisions concerning generics
  – Data protection period
- Information for Informed Consent Applications

10:00 – 10:15 **Coffee Break**

10:15 – 12:00 **Session 8**
Fritz Erni, PhD and Christa Wirthumer-Hoche, PhD

Quality Risk Management
- Introduction to the Quality Risk Management and to the case study
- Start working in groups
- Discussion of the case study
- Risk based review

12:00 – 13:30 **Lunch Break**

13:30 – 14:30 **Session 9** *Fritz Erni, PhD*

- Stability testing
  – Discussion of the relevant guidelines
  – Practical examples
- Setting of Specifications

14:30 – 14:45 **Coffee Break**

14:45 - 17:00 **Session 10** *All*

- Introduction to the Case Study stability /impurities
- Start working in groups
- final discussion of the case study in plenum
- conclusions

17:00 **End of Day 2**

DAY 3 | **WEDNESDAY,** DECEMBER 10

08:30 – 10:00 **Session 11** *Fritz Erni, PhD*

Pharmaceutical Development (3.2.P.2)
- Discussion of important chapters
- ICH Q8/Q9/Q10 and Q11 Quality by Design
  – What is Quality by Design
  – What are the optional possibilities and opportunities
  – ICH Q8 – drug product, ICH Q 11 - drug substance
  – Quality Risk Management (Q9) and how to implement Quality
  – Risk management in a dossier

10:00 – 10:15 **Coffee Break**

10:15 – 12:00 **Session 12** *Christa Wirthumer-Hoche, PhD*

The EU Regulatory Process
- Centralized / Decentralized / Mutual Recognition Procedure
- QbD – views of the regulators
- Cooperation between assessors and inspectors

12:00 – 13:30 **Lunch Break**

13:30– 14:30 **Session 13**
Fritz Erni, PhD and Christa Wirthumer-Hoche, PhD

Case Study
- Planning and organising a Meeting with authority
  – Scientific Advice, Pre-submission meeting, oral hearing during a procedure

14:30– 15:00 **Coffee Break**

15:00– 16:00 **Session 14** *Christa Wirthumer-Hoche, PhD*

Maintenance of Marketing Authorisations
- Variations / Post approval changes
- Legal framework
  – Definition of Variations
  – Classification of a variation
  – Procedural Guidance
- New provision for variations, to enhance regulatory flexibity
  – Post Approval Management Protocol
- The Classification Guideline

16:00 – 16:30 **Final discussion & Closing Remarks**

16:30 **End of the Workshop**