SiTec PharmaBio

CMC Simulation:
A Hands-on Approach to Global Marketing Applications

Interactive Workshop on the Quality Section of Regulatory Submissions

30 June - 1 July 2016

Parc Científic de Barcelona

Baldiri Reixac, 10 - 08028 Barcelona - Spain

Course Topics Include:

- Real hands-on, practical Case Studies, for small and large biological molecules, in a Simulation Format
- Strategic writing for the CMC section of Global Marketing Application(s)
- Traditional and enhanced (Quality by Design) approaches
- Agency reviewer assessment – key technical/ regulatory issues
- Special considerations and best practices for ICH (US, EU and Japan) and major ex-ICH countries

Who Should Attend

This workshop is intended for individuals responsible for R&D/technical writing/quality management of original NDAs/ ANDAs/BLAs/MAAs/etc. and post-approval submissions in pharmaceutical companies, especially those in:

- Regulatory Affairs
- QA/QC
- Process Chemistry
- Analytical Chemistry
- Preformulation and Formulation Development
- Scale-up and Technology Transfer

Experience of one year or more in one of the above areas is recommended to fully benefit from this course-workshop.

Learning Objectives

Upon completion of this course, you will be able to:

- Demonstrate enhanced skills in formulating a typical global marketing application from technical data reports
- Show an increased knowledge of the delineation between regulatory CMC and GMP information
- Identify pros and cons of Quality by Design and traditional filings
- Display improved techniques in analyzing critical review and "pushback" issues for agency assessors
- Demonstrate a better understanding of best practices in upfront vs. reactive approaches and agency response strategies

Course Description

This advanced, highly interactive course will take CMC submission training to the next level. This two-days course-workshop will allow participants to simulate steps involved in the creation of the CMC section (CTD Modules 2.3 and 3) of global marketing applications in a hands-on setting through guided role-playing and analysis of outcomes. The simulation will cover technical data collation, application of relevant regulatory guidelines, creation of a cohesive submission, and strategies during agency review. Case studies pertinent to NDAs/ANDAs/BLAs, MAAs and JNDAs will be used and include drug substance and oral and parenteral dosage forms.
The simulation will conclude with an interactive discussion of the case studies in terms of best practices for critical thinking and informed decision-making to increase the chances of regulatory success.

To achieve the maximum learning benefit, pre-workshop preparation documents activity will be available for completion. You are encouraged to register early to allow sufficient time to access and complete the necessary pre-work, which will be made available approximately 2 weeks prior to the start date.

Course Director

Cheenu Murti is Director, Global CMC Regulatory Affairs, Merck & Co., Rahway, NJ, USA and Adjunct Faculty, University of the Sciences, Philadelphia, PA, USA. He has a B.Pharm. from the University of Bombay, India, a Ph.D. in Pharmaceutical Sciences from the University of Missouri and an MBA in General Management from Rutgers University. Over a professional career spanning more than 20 years, Dr. Murti has worked in preformulation, formulation development and technology transfer. He moved to CMC Regulatory Affairs in 2000 and held positions of increasing responsibility at Organon and Schering-Plough, including three years at N.V. Organon, Oss, The Netherlands. He has served as a member of cross-industry working groups on regulatory issues through PhRMA and the Innovation and Quality (IQ) Consortium and as Organon's liaison with USP. He led global regulatory CMC teams internally and in collaboration with other major companies. He has directly interacted with health authorities in the US, Canada and Europe and has developed global regulatory submission strategies and written submissions for drugs belonging to different therapeutic classes and dosage forms. Dr. Murti has been a member of several professional associations over his career including AAPS, AAiPS, PDA, DIA and RAPS and given invited presentations in the US and in Europe.

Course offered by CfPA
THE CENTER FOR PROFESSIONAL ADVANCEMENT
FOUNDED 1967

COURSE OUTLINE

Pre-Workshop Preparation:

Approximately 2 weeks prior to start date, participants will be asked to access and complete recommended pre-course material.

FIRST DAY

Registration

8:30-9:00

Introduction

- Participant introductions
- Online pre-work recap

Unit 1: Small Molecule Original Drug Application

Roundtable

- Regulatory content and strategies
- Agency review expectations and experiences
- Critical Points to Consider

Case Study

- Overview of mock small molecule registration file
- API issues
- DP issues – solid oral
- DP issues – parenteral

Unit 2: Regulatory Starting Materials

Roundtable

- Regulatory expectations
- Practical selection approaches
- Control strategy for potential mutagenic impurities

Case Study

- Proposal for regulatory starting material candidate(s)
- Agency engagement

Unit 3: Bridging Strategy for Innovator and Generic Drugs

Roundtable

- Guidelines for immediate- and modified-release drug products
- Regional differences/challenges and solutions
- Considerations for biosimilars

Case Study

- Formulation considerations for biowaiver
- In-vitro dissolution issues

Unit 4: Quality by Design (QbD)/ Process Analytical Technologies (PAT)

Roundtable

- ICH Q8 and Q11
- Opportunities and Challenges

Case Study

- Risk assessment/control strategy (30 mins)
- Real time release testing

SECOND DAY

9:00-17:00

Unit 5: Therapeutic Biomolecule Original Drug Application

Roundtable

- Regulatory content and strategies
- Agency review expectations and experiences

Case Study

- Overview of mock biomolecule registration file
- API issues
- Analytical issues

Unit 6: Analytical and Stability Topics

Roundtable

- Strategic specification setting
- Stability challenges

Case Study

- Justification of specifications
- Registration stability

Unit 7: Manufacturing Topics

Roundtable

- Key current regulatory issues
- File maintenance

Case Study

- Cocrystal drugs
- API attributes in drug product manufacturing
- Batch size flexibility
- Bulk hold time
- Continuous manufacturing
- Non-standard processes

Open Forum/Wrap Up

TUITION AND PAYMENT

Early registration:
(received before May 2th, 2016) - Euro 1700+VAT/1530+VAT (group discount*)

Regular registration:
(received after May 2th, 2016) - Euro 1900+VAT/1710+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)
Participants are responsible for their own hotel reservations.

*Group discount is for two or more enrollments from the same company.

Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

Registration

Name .....
Surname .....
Position .....
Organization .....
VAT .....
Address. .....
Postal Code .....
City .....
Country .....
Phone/Fax .....
Participant e-mail .....
Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL

General information

Cancellations received after June 10, 2016 will be invoiced completely. All cancellations will be subject to euro 250 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:

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