DIA Training Course on

Quality by Design - New concepts for Chemical and Biotech Product Development and Optimisation

Course #14543
22-24 September 2014
Pharmig Academy, Vienna, Austria

Faculty

DI Dr Christa Wirthumer-Hoche
Head, AGES PharmMed, Austria

Prof. Dr Johannes Khinast
Head of the Institute for Process and Particle Engineering, University of Technology; Scientific Director of the Research Centre for Pharmaceutical Engineering, Austria

Dr Siegfried Adam, MBA
QA Manager, Hermes Pharma, Austria

Dr Fritz Erni
Consultant, Switzerland

Dr Erich Hochuli
ICB Consulting, Switzerland

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

Overview

In this hands-on course the key elements of Quality by Design for small molecules and biotech products will be discussed. Participants from pharmaceutical, biotech and generic industry as well as regulators will learn, with practical work on case studies (solid dosage form of a small molecule and manufacturing process for a biotech product), how to use Quality Risk Management (QRM), Process Characterisation, Design of Experiments (DoE), Development of a Design Space and Control Strategy, as well as the tools of Knowledge Management (KM). In the case studies all participants will prioritise the potential critical formulation and process parameters with QRM, propose, execute and evaluate a DoE to define the critical parameters and eliminate uncritical parameters. The knowledge gained will be used to establish a Design Space and essential elements of the control strategy. Knowledge Management will be introduced to keep the information and knowledge gained transparent and available for the full lifecycle of the product. The case study will demonstrate that a systematic approach to pharmaceutical development and optimisation, respectively, will be faster and will lead to robust processes. Potential internal savings and the regulatory flexibility will be discussed with a key European regulator. The course will also give an overview on global requirements including new relevant EU regulations and discuss opportunities for an optimal QbD submission.

Key Topics

- Quality by Design for biotech products and small molecules
- Prior Knowledge, Knowledge Management and QTPP Development
- Initial Risk Assessment (FMEA), Introduction to Process Characterisation and Design of Experiments
- Experimental Work, Multi-variate Data Analysis (MVA) and Knowledge Space Establishment
- Design Space Definition
- Control Strategy
- Technologies Assisting QbD Approach
- Regulatory Flexibility and QbD submission strategies
- Post-Approval Change Management Protocol

Who Will Attend

Pharmaceutical scientists, chemist, biologists and engineers. Experts from industry (pharmaceutical companies, biotech companies, generic industry) and regulators with experience in pharmaceutical, chemical and biotech development, manufacturing, quality assurance and CMC.

Learning Objectives

At the conclusion of this course, participants should be able to:
- Understand what QbD for biotech and small molecules is
- Define how critical formulation and process parameters are identified
- Use Quality Risk Management in the context of QbD
- Use tools of scientific process characterisation
- Plan and evaluate basic experimental designs
- Develop a Design Space
- Develop a Control Strategy
- Develop a Knowledge Management structure
- Understand how to submit QbD data and get regulatory flexibility

This course is a hands-on course full of practical work. It is necessary that you bring your laptop with you.

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DAY 1

12:30 **REGISTRATION**

13:30 **Session 1**

INTRODUCTION

- Basic concept of QbD according to ICH Q8/Q11
  Fritz Erni
- Quality risk management according to ICH Q9
  Fritz Erni
- The QbD development process
  Fritz Erni

15:00 COFFEE BREAK

15:30 **Session 2**

PRIOR KNOWLEDGE, KNOWLEDGE MANAGEMENT AND THE QUALITY TARGET PRODUCT PROFILE

- Introduction to mock projects/prior knowledge
  Siegfried Adam and Erich Hochuli
- Knowledge management – presentation of a simple KM concept (including practical work)
  Fritz Erni
- Development of a QTPP for the 2 mock projects (practical work)
  Fritz Erni and Erich Hochuli

17:00 **DRINKS RECEPTION**

18:00 **END OF DAY ONE**

DAY 2

9:00 **Session 3**

INITIAL RISK ASSESSMENT (FMEA), INTRODUCTION TO PROCESS CHARACTERISATION AND DESIGN OF EXPERIMENTS

- Initial risk identification and prioritisation (practical work)
  Fritz Erni and Erich Hochuli
- Introduction to tools for process characterisation
  Siegfried Adam and Johannes Khinast
- Design of experiments
  Siegfried Adam and Johannes Khinast

10:30 COFFEE BREAK

11:00 **Session 4**

EXPERIMENTAL WORK

- Experimental work for evaluation of potentially critical process parameters
  Siegfried Adam
- Data analysis and evaluation
  Siegfried Adam and Erich Hochuli

12:30 LUNCH

13:30 **Session 5**

DATA ANALYSIS AND KNOWLEDGE SPACE ESTABLISHMENT

- Data analysis and evaluation (continued from Session 4)
  Siegfried Adam and Erich Hochuli
- Establishment of simple knowledge management
  Johannes Khinast
- Update knowledge management
  Johannes Khinast

15:00 COFFEE BREAK

15:30 **Session 6**

DISCUSSION OF THE EXPERIMENTAL DESIGN GROUP WORK

18:00 **END OF DAY TWO**

DAY 3

9:00 **Session 7**

DESIGN SPACE

- Rules for the selection of a design space
  Fritz Erni, Erich Hochuli and Siegfried Adam
- Design space for the 2 mock projects (exercise)

10:30 COFFEE BREAK

11:00 **Session 8**

CONTROL STRATEGY

- Elements of a control strategy
  Fritz Erni, Erich Hochuli and Siegfried Adam
- Control strategy for the 2 mock project

12:30 LUNCH

13:30 **Session 9**

REGULATORY FLEXIBILITY

- The view of the regulators
  Christa Wirthumer-Hoche
- Regulatory flexibility
  Christa Wirthumer-Hoche
- Post-Approval Change Management Protocol
  Christa Wirthumer-Hoche

15:00 COFFEE BREAK

15:30 **Session 10**

SUMMARY AND FINAL DISCUSSION

16:20 **COURSE ASSESSMENT (50 multiple choice questions)**

17:00 **END OF TRAINING COURSE**

VENUE INFORMATION

The training course will take place at the:
Pharmig Academy
Garnisiongasse 4/4
1090 Vienna
Austria
E-mail: office@pharmig-academy.at
www.pharmig-academy.at

REGISTRATION FORM

DIA Training Course on Quality by Design
22-24 September 2014 | Pharmig Academy, Vienna, Austria

ID #14543

FEES

	Member*	Non-Member*
Industry	€ 1'550.00 ❑	€ 1'680.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 775.00 ❑	€ 905.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

*All fees will be subject to the Austrian VAT at 20 %

"Please advise your European VAT number _____"

TOTAL AMOUNT DUE: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #14543 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

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By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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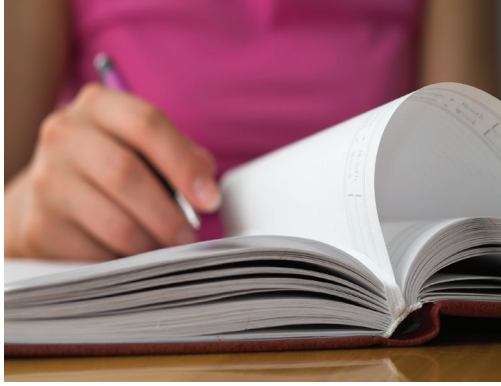

DIA EUROPE MIDDLE EAST & AFRICA TRAINING COURSES

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Quality by Design - New concepts for chemical and biotech product development and optimisation**
  22-24 September 2014 | Vienna, Austria I ID 14543
- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  November 2014 | Location to be confirmed I ID 14553

Clinical Research

- **Clinical Project Management – Part I**
  22-24 September 2014 | Paris, France I ID 14542
- **Practical GCP Compliance Auditing of Trials and Systems**
  22-24 October 2014 | London, United Kingdom | ID 14531
- **Clinical Statistics for Non-Statisticians**
  23-24 October 2014 | London, United Kingdom | ID 14532
- **Essentials of Clinical Study Management**
  5-7 November 2014 | London, United Kingdom I ID 14557
- **Clinical Project Management – Part II**
  10-12 November 2014 | Barcelona, Spain I ID 14555

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  Date and location to be confirmed

Regulatory Affairs

- **Essentials of European Regulatory Affairs** **NEW OFFERING!**
  23-24 June 2014 | Amsterdam, The Netherlands | ID 14541
  3-4 November 2014 | Paris, France I ID 14556
- **Good Management of Medical Devices** **COMBO PRICING!**
  23-25 June 2014 | Amsterdam, The Netherlands | ID 14536
- **EU Regulation of In Vitro Diagnostics (IVDs)**
  26 June 2014 | Amsterdam, The Netherlands | ID 14538
- **Health Technology Assessment (HTA)**
  13-14 October 2014 | Paris, France I ID 14551
- **How to Prepare for your Meeting with Health Authorities**
  14-15 October 2014 | Paris, France I ID 14546
- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  22-24 October 2014 | London, United Kingdom I ID 14545
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  5-7 November 2014 | London, United Kingdom I ID 14554
- **Approval of generic medicines in the EU. Focus on CMC requirements and bioequivalence**
  Date and location to be confirmed
- **Paediatric Investigation Plans (PIP)**
  Date and location to be confirmed

Safety and Pharmacovigilance

- **Benefit/Risk Management**
  10-11 November 2014 | Barcelona, Spain I ID 14547
- **Signal Management in Pharmacovigilance**
  November 2014 | Paris, France I ID 14549
- **Pre-Marketing Clinical Safety**
  16-17 June 2014 | Amsterdam, The Netherlands | ID 14539
- **Post-Authorisation Safety Studies (PASS)** **NEW OFFERING!**
  18-19 June 2014 | Amsterdam, The Netherlands | ID 14535
- **Medical Approach in Diagnosis and Management of ADRs** **COMBO PRICING!**
  22-23 September 2014 | Paris, France I ID 14540
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  23-24 September 2014 | Paris, France I ID 14544
- **ICH Endorsed Pharmacovigilance**
  21 October 2014 | Dakar, Senegal I ID 14559
  November 2014 | Algiers, Algeria I ID 14560
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  November 2014 | Paris, France I ID 14550

European Medicines Agency Information Days and Courses

- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  13-17 October 2014 | London, United Kingdom I ID 14548

EudraVigilance courses:

- EudraVigilance – Electronic reporting of ICSRs in the EEA
- eXtended EudraVigilance Medicinal Product Dictionary
- Introduction to Pharmacovigilance and Rules for Expedited Reporting of Individual Case Safety Reports (ICSRs) in Europe

For information on EudraVigilance courses, please visit www.diahome.org > Meetings & Training > About Meetings & Training > In-Person Instruction > EudraVigilance > EudraVigilance Courses

DIA In-house Training

Do you have a team to train, but do not want to send them all on a training course because of the out-of-office time, travel and accommodation costs and high registration fees? The solution is to bring the training course in house – tailored to your specific needs. DIA In-house Training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. Schedule your training course when it suits you best, at the venue of your choice. You can even adapt the content to include areas specific to your environment, and to match the level of expertise of the audience.

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The DIA In-house Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

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