DIA Training Course on

Quality by Design – Making Next Generation Process Efficiency a Reality for Chemical and Biotech Product Development and Optimisation



Course #15543
21-23 September 2015
Vienna, Austria

OVERVIEW

Quality by Design (QbD) concepts are becoming the de facto best practice spearheaded by the FDA and EMA. But how can you implement ICH Q8-Q11 with confidence for small molecules and biotech products?

As part of our Chemical Manufacturing series, DIA brings together expert faculty from Regulatory agencies, academia and industry. ICH and DoE expertise will accompany you to building a practical knowledge base.

METHODOLOGY & OUTCOMES

By the end of this 2.5-day course, you will have enough knowledge and reference points to establish a Design Space and essential elements of the Control Strategy. Through a series of case studies you will learn 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).

Case scenarios include:

- solid dosage form of a small molecule
- manufacturing process for a biotech product

You will learn how to prioritise the potential critical formulation and process parameters with QRM, propose, execute and evaluate a DoE to define the critical parameters and eliminate non-critical parameters.

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 investigate how a systematic approach to pharmaceutical development and optimisation, respectively, will be faster and will lead to robust processes. Potential internal savings and regulatory flexibility will be discussed with a key European regulator.

The course will also provide an overview on global requirements including new relevant EU regulations and discuss opportunities for an optimal QbD submission.

FACULTY

Christa Wirthumer-Hoche
Head, AGES PharmMed, Austria

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

Siegfried Adam
QA Manager, Hermes Pharma, Austria

Fritz Erni
Consultant, Switzerland (ICH expert)

Erich Hochuli
ICB Consulting, Switzerland (DoE expert)

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PHARMIG ACADEMY Am Puls.
PharmaTrain MASTERING MEDICINES DEVELOPMENT

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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, Multivariate 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

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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 for a QbD submission
- 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.

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

WHO WILL ATTEND

Pharmaceutical scientists, chemists, 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.

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DAY 1

12:30 — **REGISTRATION**

13:30 — **SESSION 1**

INTRODUCTION

Basic concept of QbD according to ICH Q8/Q11 and the QbD development process
Fritz Erni

Quality risk management according to ICH Q9
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
Johannes Khinast

Design of experiments
Siegfried Adam

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

Multivariate Data Analysis and evaluation
Johannes Khinast, Siegfried Adam and Erich Hochuli

Update knowledge management
Fritz Erni

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 projects (exercise)

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 THE TRAINING COURSE**

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

Venue Information

Pharmig Academy
Garnisongasse 4/4
1090 Vienna, Austria

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www.pharmig-academy.at

DIA has blocked a limited number of hotel rooms at the nearby Hotel Regina at the rate of EUR 115.00 single / EUR 140.00 double room per night, including breakfast and VAT. Please contact the hotel directly with the reference "DIA" if you would like to make a booking. The room rate is available until 20 August 2015 or until the room block is sold-out, whichever comes first. Rooms can be cancelled free of charge 24 hours before the arrival.

Hotel Regina
Rooseveltplatz 15
1090 Vienna, Austria

Tel: +43 1 404 46 0
E-mail: regina@kremslehnerhotels.at
www.kremslehnerhotels.at/en/hotel-regina-vienna

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 12 credits for pharmaceutical medicine. All participants are eligible for these credits.

ABOUT DIA

In 1964, 30 visionary pharmaceutical research professionals came together with a noble mission – to increase communication and collaboration in drug development in order to improve safety and advance therapeutic success.
Over the next 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.
DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: to improve health and well-being by transferring knowledge from those who have it to those who need it.
DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

Want to continue the discussion from sessions?



DIA Communities - a members-only benefit

Stay connected even after the meeting ends! DIA Communities allow members to exchange information, explore hot topics, and grow their professional network. With more than 30 interest-specific areas to choose from, DIA Communities keep you connected.

DIA Membership

DIA member benefits offer exclusive access to DIA's scientific journal and magazine; educational materials and resources; special member pricing and discounts; as well as enhanced access to a global community of more than 30,000 stakeholders in the life sciences product development arena.

Exchange knowledge, increase your connections, and foster relationships faster by taking advantage of DIA membership.

DIA member benefits help professionals develop, innovate, and advance their careers, as well as the industry.

Join today!

diahome.org/Membership
diahome.org/Communities

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REGISTRATION FORM

Quality by Design # 15543 | 21-23 September 2015
Pharmig Academy, Vienna, Austria

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and training course material.

FEES	MEMBER*	NON-MEMBER*
INDUSTRY	€ 1'550.00 ❑	€ 1'710.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 775.00 ❑	€ 935.00 ❑
BECOME A DIA MEMBER NOW	€ 155.00 ❑	

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

Please enter your Company's Austrian VAT number: _____

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

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit **www.DIAHome.org** and click on Membership for more details.

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

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52

Email: diaeurope@diaeurope.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.diahome.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East & Africa office four weeks 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
- Tutorial cancellation € 50.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

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 office of any such substitutions as soon as possible.

Photography Policy

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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation)

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

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **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 # 15543 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, Middle East & Africa.**

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

Date	Signature

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