Quality by Design: A Hands-on Short Course for Pharma

Course #10565
4-5 November 2010
University of Technology, Graz, Austria

Course Faculty

Dr. Siegfried Adam
Senior Researcher, University of Technology, Austria

Dr. Fritz Erni
Consultant, Switzerland

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

Course Overview

In this short course the key elements of Quality by Design, i.e. 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 will be introduced. In a case study all participants will prioritise the potential critical formulation and process parameters with QRM, propose 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 gained information and knowledge transparent and available for the full lifecycle of the product. The case study will demonstrate that a systematic approach to pharmaceutical development will be faster and will lead to robust processes. Potential internal savings will be discussed and the regulatory flexibility will be discussed with a key European regulator.

Key Topics

- 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

Who Will Attend

Postgraduate studies (Masters-level) for pharmaceutical scientists and engineers. Experts from industry with experience in pharmaceutical development, manufacturing and quality assurance.

Learning Objectives

At the conclusion of this course, participants should be able to:
- Understand what Quality by Design is
- Define how critical formulation and process parameters are identified
- Use of Quality Risk Management in the context of QbD
- Use tools of scientific process characterisation
- Develop a Design Space
- Develop a Control Strategy
- Develop a Knowledge Management structure

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

Continuing Education

The "Quality by Design: A Hands-on Short Course for Pharma" training course has been accredited with 2 ECTS credits. These equals a workload of 50-60 hours that would be needed to achieve the learning outcomes that enables the participants to understand and use the Quality by Design approach. As this course is a combination of intensive theory lectures together with effective practical examples promoting an interactive learning process, the learning objectives are achieved within the two course days.

This course has limited capacity. Register early.
### THURSDAY | 4 NOVEMBER 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00</td>
<td>Registration</td>
</tr>
<tr>
<td>09:00</td>
<td>Session 1</td>
</tr>
<tr>
<td></td>
<td><strong>INTRODUCTION</strong></td>
</tr>
<tr>
<td></td>
<td>• Basic concept of QbD according to ICH Q8</td>
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<td>• Quality risk management according to ICH Q9</td>
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<td></td>
<td>• The QbD development process</td>
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<tr>
<td>10:30</td>
<td>Coffee Break</td>
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<tr>
<td>11:00</td>
<td>Session 2</td>
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<tr>
<td></td>
<td><strong>PRIOR KNOWLEDGE, KNOWLEDGE MANAGEMENT AND QTPP-DEVELOPMENT</strong></td>
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<tr>
<td></td>
<td>• Introduction to the mock project / prior knowledge</td>
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<td>• Knowledge management – presentation of a simple KM-concept</td>
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<tr>
<td></td>
<td>(including practical work)</td>
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<td></td>
<td>• Development of a QTPP for the mock project</td>
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<tr>
<td></td>
<td>(practical work)</td>
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<tr>
<td>12:30</td>
<td>Lunch</td>
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<tr>
<td>13:30</td>
<td>Session 3</td>
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<tr>
<td></td>
<td><strong>INITIAL RISK ASSESSMENT (FMEA), INTRODUCTION TO PROCESS CHARACTERISATION AND DESIGN OF EXPERIMENTS</strong></td>
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<tr>
<td></td>
<td>• Initial risk identification and prioritisation (practical work)</td>
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<td></td>
<td>• Introduction to tools for process characterisation</td>
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<td></td>
<td>• Design of experiments</td>
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<tr>
<td>15:00</td>
<td>Coffee Break</td>
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<tr>
<td>15:30</td>
<td>Session 4</td>
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<tr>
<td></td>
<td><strong>EXPERIMENTAL WORK, MULTIVARIATE DATA ANALYSIS (MVA) AND KNOWLEDGE SPACE ESTABLISHMENT</strong></td>
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<tr>
<td></td>
<td>• Experimental work for evaluation of potentially critical process parameters</td>
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<td></td>
<td>• Multivariate data analysis and evaluation</td>
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<td>• Establishment of a simple knowledge space</td>
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<td>• Update knowledge management</td>
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<tr>
<td>17:00</td>
<td>Reception</td>
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<tr>
<td>18:00</td>
<td>End of Day One</td>
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</tbody>
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### FRIDAY | 5 NOVEMBER 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Session 5</td>
</tr>
<tr>
<td></td>
<td><strong>DESIGN SPACE DEFINITION</strong></td>
</tr>
<tr>
<td></td>
<td>• Rules for the selection of a design space</td>
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<tr>
<td></td>
<td>• Design space for the mock project</td>
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<td>10:30</td>
<td>Coffee Break</td>
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<tr>
<td>11:00</td>
<td>Session 6</td>
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<tr>
<td></td>
<td><strong>CONTROL STRATEGY</strong></td>
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<tr>
<td></td>
<td>• Elements of a control strategy</td>
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<td></td>
<td>• Control strategy for the mock project</td>
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<tr>
<td>12:30</td>
<td>Lunch</td>
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<tr>
<td>13:30</td>
<td>Session 7</td>
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<tr>
<td></td>
<td><strong>TECHNOLOGIES ASSISTING QBD-APPROACH, REGULATORY FLEXIBILITY</strong></td>
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<tr>
<td></td>
<td>• QbD key platform technologies</td>
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<td></td>
<td>• Regulatory flexibility</td>
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<tr>
<td>15:00</td>
<td>Coffee Break</td>
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<tr>
<td>15:30</td>
<td>Session 8</td>
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<td><strong>SUMMARY AND FINAL DISCUSSION</strong></td>
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<td>• Summary and discussion of results of the QbD process</td>
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<td></td>
<td>• Final discussion, Q&amp;A, conclusions</td>
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<tr>
<td>17:00</td>
<td>End of Training Course</td>
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</tbody>
</table>

### VENUE INFORMATION

The training course will take place at the:

University of Technology
Petersgasse 14
Meeting Room Number BKEG 053
Graz, Austria
The DIA has blocked a limited number of rooms at the:

ROMANTIK PARKHOTEL GRAZ
Leonhardstraße 8
8010 Graz
Austria
Tel: +43 316 3630-27
Fax: +43 316 3630 -50
Email: romantik.sales@parkhotel-graz.at

at the special rate of:
Single room: EUR 115.00
Double room for single use: EUR 127.50
Double room: EUR 174.25

This rate is per room, per night and includes the VAT, service, taxes, buffet breakfast as well as access to the indoor pool and fitness area. To reserve a room, please call the hotel mentioning the code: DIA2010 or use the hotel booking form on the DIA website.

HOTEL GOLLNER
Schlögelgasse 14
8010 Graz
Austria
Tel.: +43 316 82 25 21-0
Fax: +43 316 82 25 21-7
Email: office@hotelgollner.at
Website: www.hotelgollner.at

Single room: EUR 91.00 incl. breakfast

MERCURE GRAZ MESSE
Waltendorfer Gürtel 8-10
8010 Graz
Austria
Tel.: +43 316 826 300
Fax: +43 316 8263 00630
Email: H2212@accor.com
Website: http://www.accorhotels.com/de/hotel-2212-mercure-graz-messe/index.shtml

Single room: EUR 78.00 incl. breakfast

IMPORTANT: To be assured of accommodation at the hotels, registrants are recommended to complete their reservation by 3 October 2010 at the latest. Reservations received after that date are subject to availability.
**REGISTRATION FORM**

Quality by Design: A Hands-on Short Course for Pharma
4–5 November 2010 | University of Technology, Graz, Austria

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>FEE</th>
<th>MEMBERSHIP VAT 20%</th>
<th>TOTAL</th>
<th>NON-MEMBER (with optional membership) FEE</th>
<th>VAT 20%</th>
<th>MEMBERSHIP TOTAL</th>
<th>TOTAL</th>
<th>NON-MEMBER (without optional membership) FEE</th>
<th>VAT 20%</th>
<th>TOTAL</th>
</tr>
</thead>
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<td>€ 1’365.00</td>
<td>€ 273.00</td>
<td>€ 1’638.00</td>
<td>€ 1’365.00</td>
<td>€ 273.00</td>
<td>€ 1’115.00</td>
<td>€ 1’753.00</td>
<td>€ 1’480.00</td>
<td>€ 296.00</td>
<td>€ 1’776.00</td>
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<tr>
<td>Government/Academia (Full-Time)</td>
<td>€ 683.00</td>
<td>€ 136.60</td>
<td>€ 819.60</td>
<td>€ 683.00</td>
<td>€ 136.60</td>
<td>€ 115.00</td>
<td>€ 934.60</td>
<td>€ 798.00</td>
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<td>€ 957.60</td>
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</table>

**TOTAL AMOUNT DUE:** €

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**PAYMENT METHODS**

- Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.
- **VISA**
- **MC**
- **AMEX**

**Responsibility/Interest Area**

Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

___ Advertising & Promotion
___ CMC
___ Clinical Data Management/eClinical
___ Clinical Research
___ Clinical Safety/Pharmacovigilance
___ Document Management/eSubmissions
___ Manufacturing
___ Medical Communications
___ Medical Writing
___ Nonclinical
___ Outsourcing
___ Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine
___ Pharmacology
___ Pricing/Reimbursement
___ Project Management
___ Professional Education, Training & Development
___ Public Policy/Law/Corp. Compliance
___ Quality Assurance/Quality Control
___ Regulatory Affairs
___ Research & Development
___ Statistics
___ Strategic Planning
___ IT/Validation

**REGISTRANT**

Please complete in block capital letters or make registration even simpler by attaching the registrant's business card here.

- Prof.
- Dr.
- Ms.
- Mr.

Last Name: [Enter Last Name]
First Name: [Enter First Name]
Company: [Enter Company]
Job Title: [Enter Job Title]
Street Address / P.O. Box: [Enter Street Address]
Postal Code: [Enter Postal Code]
City: [Enter City]
Country: [Enter Country]
Telephone: [Enter Telephone]
Fax (Required for confirmation): [Enter Fax]
Email (Required to receive presentation download instructions): [Enter Email]

Please indicate your professional category:
- [ ] Academia
- [ ] Government
- [ ] Industry
- [ ] Contract Service Organisation

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**CANCELLATION POLICY**

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date.

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

**IMPORTANT:**

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

**HOW TO REGISTER**

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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First Name: [Enter First Name]
Company: [Enter Company]
Job Title: [Enter Job Title]
Street Address / P.O. Box: [Enter Street Address]
Postal Code: [Enter Postal Code]
City: [Enter City]
Country: [Enter Country]
Telephone: [Enter Telephone]
Fax (Required for confirmation): [Enter Fax]
Email (Required to receive presentation download instructions): [Enter Email]

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