Overview

- Quality Risk Management is a process for identifying quality-related hazards associated with a product, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the control. Effective quality risk management ensures the high quality of drug product for the patient. The FDA has been particularly active in fostering this concept - FDA's Quality by Design (QbD) initiative emphasises building quality into a product during development rather than attempting to “test” quality into a product retrospectively.

- Quality by Design (QbD) and Quality Risk Management (QRM) have become established in areas such as manufacturing which are characterised by strong process dependency and precise quality specifications for deliverables. To date, in the pharmaceutical industry, there has been less application of these principles in activities such as clinical drug development which are based on data-driven, iterative decision-making processes, complex multifactorial internal and external influences, human experience and expert judgment.

- More recently, however, the application of the QRM/QdD approach has been expanding to clinical drug development as a means of enhancing work in highly regulated areas such as GCP compliance, data integrity and patient safety and protection. The natural further evolution would be to examine the potential of such a systematic risk-based approach to support other activities of clinical drug development such as decision-making, planning and contingency planning, and proactive project de-risking, where there would be obvious advantages in optimising the efficiency of clinical drug development.

- The purpose of this conference is to share industry and regulators’ experience in the application of QRM/QdD to the entire spectrum of clinical drug development. The goal is to increase the accessibility of such experience and to stimulate its wider use.

Key Topics

DAY 1
- Overview of Regulatory Initiatives on QRM
- QRM – Key Principles
  - Risk management - Lessons learned from other industries and their application to clinical drug development
  - Risk identification – our biggest challenge
  - Role of standards and benchmarking in clinical trials
- QRM in Clinical Trials - a Comprehensive Approach to Quality Management
  - Applying QRM to design and management of clinical trials – real-life experience from large and small organisations and academia
  - The regulators’ perspective
  - An investigator's perspective
  - A service provider's perspective

DAY 2
- Expanding the QRM Vision
  - Industry insights and opportunities
  - Opportunities for investigators
  - Regulators’ vision
THURSDAY | 10 NOVEMBER 2011

08:30  REGISTRATION AND WELCOME COFFEE

09:00  WELCOME & INTRODUCTION
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

09:15  Session 1
THE REGULATORY CONTEXT FOR QRM IN CLINICAL DRUG DEVELOPMENT
Session Chair:
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Overview of Regulatory Initiatives on QRM
Fergus Sweeney, Head of Sector, Compliance and Inspection, European Medicines Agency, European Union

10:00  COFFEE BREAK

10:30  Session 2
QRM – KEY PRINCIPLES
Session Chair:
Peter Schiemann, Quality Risk Management Expert, Switzerland

Risk Management - Lessons learned from other industries and their application to clinical drug development
Michael Forstner, Integrated Safety Risk Manager, F. Hoffmann-La Roche Ltd., Switzerland

Risk Identification – Our biggest challenge
Barbara Leishman, Head, Quality Risk Management-Safety Science, F. Hoffmann-La Roche Ltd., Switzerland

Role of Standards and Benchmarking in Risk Management of Clinical Trials
Guy Mascaro, President, Metrics Champion Consortium (MCC), USA

12:00  PANEL DISCUSSION

12:30  LUNCH

13:30  Session 3
QRM IN CLINICAL TRIALS – A COMPREHENSIVE APPROACH TO QUALITY MANAGEMENT
Session Chair:
Beat E. Widler, Clinical Quality and Risk Management Expert, Switzerland

The Regulator`s Perspective
• Katharina Kurpanek, GCP Inspector, BfArM, Germany
• Ann Meeker-O'Connell, Acting Associate Director, Risk Science, Intelligence, and Prioritization, Office of Scientific Investigations, Office of Compliance, CDER, FDA, USA
• Vincent Yeung, GCP Operations Manager, Inspection, Enforcement and Standards Division, MHRA, United Kingdom

15:30  Session 3 (continued)
An Approach to Quality Risk Management in Clinical Development
Chris Shepherd, Vice President, Clinical Quality Assurance, GlaxoSmithKline, UK

Approaches to Build Risk Management into Clinical Trials in Resource-Poor Settings
Gabriele Pohlig, Head of Quality Management Services and Project Leader, Department of Medicines Research, Swiss Tropical and Public Health Institute, Switzerland

QRM in Clinical Trials - The perspective of academia
Oana Brosteanu, Clinical Trial Centre Leipzig, University Leipzig, Germany

17:00  Wrap-up and discussion
17:30  DRINKS RECEPTION

FRIDAY | 11 NOVEMBER 2011

08:30  Session 3 (continued)

10:00  COFFEE BREAK

10:30  Session 3 (continued)

The Investigator’s Perspective
Denis Lacombe, Director European Organisation for Research and Treatment of Cancer (EORTC), Belgium

The Service Provider’s Perspective
• Small CRO
  Regina Freunscht, Director Marketing and Communication, Accovion, Germany
• Large CRO
  Elizabeth Troll, Senior Director, Global Quality Office, Quintiles, USA

11:40  LUNCH
TRAVEL INFORMATION

The hotel is situated approx. 23 km away from the airport Berlin-Tegel and 19 km away from the airport Berlin-Schoenefeld.

DIA has blocked a limited number of rooms at the following hotel:

**nhow Berlin**  
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10246 Berlin  
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Email: h.wieck@nhow-hotels.com

at the special rate of EUR 150.00 per room/day excluding breakfast of € 22 per person/day.

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In case of cancellation:

Cancellation of the hotel booking must be made in writing directly to the hotel 48 hours prior to the arrival date. Cancellations made at least 48 hours prior to arrival will not incur any cancellation charges. Any cancellation made less than 48 hours prior to arrival will be subject to the first night being charged at the full agreed rate. All no shows will be billed for the entire stay.

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**Session 4**

**EXPANDING THE QRM VISION – INDUSTRY INSIGHTS AND OPPORTUNITIES**

Session Chair:  
Roland Rich, Operational Expert, Clinical Quality Assurance, Novartis Pharma AG, Switzerland

**QRM in Drug Safety**  
Michael Forstner, Integrated Safety Risk Manager, F. Hoffmann-La Roche Ltd., Switzerland

**Opportunities in Regulatory Programme Management**  
Katrin Rupalla, Executive Director, Regulatory Affairs, Celgene, Switzerland

**QRM Implementation in Clinical Perimeter by Bridging with other Operational Perimeters**  
Xavier Dubarle, Global Quality Risk Management Expert, sanofi-aventis, France

**The Investigator’s Perspective**  
Jacques Demotes, INSERM ECRIN Coordinator, France

**Joining the Dots – A holistic approach to QRM**  
Beat E. Widler, Clinical Quality and Risk Management Expert, Switzerland

15:00 COFFEE BREAK

15:15 **Session 5**

**REGULATORS’ VISION – PANEL DISCUSSION**

Session Chair:  
Leslie Ball, Director of the Division of Scientific Investigations, OC, CDER, FDA, USA

**How will the QbD/QRM Vision be applied? What do regulators expect?**

- Pierre Henri Bertoye, Deputy Director in charge of National and International Medical Affairs, AFFSAPS, France
- Katharina Kurpanek, GCP Inspector, BfArM, Germany
- Fergus Sweeney, Head of Sector, Compliance and Inspection, European Medicines Agency, European Union
- Vincent Yeung, GCP Operations Manager, Inspection, Enforcement and Standards Division, MHRA, United Kingdom

16:15 END OF CONFERENCE
REGISTRATION FORM
Quality Risk Management in Clinical Drug Development Conference 2011
10-11 November 2011 | nhow Hotel, Berlin, Germany

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes lunch and coffee breaks.
* All fees are subject to local German VAT of 19%

Early-Bird rates available for Members: Deadline on or before 30 September 2011
Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/non-profit members

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<th>Non-Member Fee*</th>
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TOTAL AMOUNT DUE: €___________________

NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT THE DIA FOR MORE INFORMATION.

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CANCELLATION POLICY: All cancellations must be in writing and received with DIA Europe by 17:00 CET on 2 November 2011

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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 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 Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

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Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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