Quality Risk Management in Clinical Drug Development Workshop: Fundamentals and Practical Aspects

December 3-4
Sheraton Philadelphia Downtown Hotel,
Philadelphia, PA

PROGRAM CHAIRPERSONS

Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd, Switzerland

Briggs W. Morrison, MD
Head, Global Medicines Department
AstraZeneca

PROGRAM COMMITTEE

Hassan Ansari, MD
Exec. Director, Clin. Research/Head
Global Site Ready & Clin. Quality Management
Merck Sharp & Dohme Corp.

Brian J. Nugent, PhD
Associate Director
Clinical OperationsGilead Sciences

Ann Meeker-O'Connell, MS
Director, Division of GCP Compliance (Acting) CDER
FDA

Kenneth D. Schiff, MBA
President
Quality Risk Management Associates, LLC

Kenneth J. Sprenger, MD
Executive Director, Medicine Team Leader
Pfizer Inc

Beat E. Widler, PhD
Managing Partner
Widler & Schiemann AG, Switzerland

DIA Worldwide Headquarters
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
DIA Regional Offices
Horsham, PA, USA | Washington, DC, USA
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

CONFERENCE OVERVIEW

Learn How to Manage Quality Risks in Your Clinical Drug Development Process

Quality Risk Management (QRM) is a process designed to help companies proactively prevent shortfalls in quality and compliance standards during their clinical development process. By using a much broader scope than typical quality assurance and quality control methods, this methodology ensures greater patient safety and data integrity.

This process has gained wider acceptance in the clinical environment with the support of both the FDA and EMA. This two-day workshop will equip you with the background knowledge, as well as the practical tools to implement QRM within your drug development process.

IN TWO DAYS YOU WILL LEARN TO:

- Describe the principles of QbD and QRM and how they may be applied to clinical trials, safety reporting and/or clinical development programs
- Discuss industry trends and current regulatory guidance regarding a risk-based approach to managing clinical trials
- Examine different approaches to QbD and QRM from a diverse community of industry, academia, investigational sites and service providers

WHO SHOULD ATTEND?

Professionals Involved in:

- Quality Risk Management
- Quality Assurance/Clinical Compliance
- Clinical Development/Clinical Operations
- Clinical Trial Management
- Pharmacovigilance and Safety
- Biostatistics
- Clinical Project Management
- Trial Conduct/Site Coordination
- Data Management
- Vendor Oversight/Management
- Regulatory Affairs

DIA®
www.diahome.org

CONTINUING EDUCATION CREDITS

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer 1.3 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Tuesday, December 18, 2012.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for 12.5 contact hours or 1.25 continuing education units (CEU's).

DIA'S CERTIFICATE PROGRAM

This program is part of DIA's Certificate Program and is awarded the following:
• Clinical Safety & Pharmacovigilance Certificate Program: 4 Elective Units
For more information go to www.diahome.org/certificateprograms

PHARMACY CREDIT ALLOCATION

Day 1: 6.75 contact hours or .675 CEUs; 0286-0000-12-099-L04-P; Type of activity: Knowledge

Day 2: 5.75 contact hours or .575 CEUs; 0286-0000-12-100-L04-P; Type of activity: Application

ACPE Credit Request Update

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

Disclosure Policy

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association. Speakers, agenda and CE information are subject to change without notice. Recording of any DIA educational material in any type of media is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at www.diahome.org

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association.

Speakers, agenda, and CE information are subject to change without notice.

Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at www.diahome.org.

DAY 1, MONDAY, DECEMBER 3

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS

PROGRAM CO-CHAIRPERSONS

Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd, Switzerland

8:30-9:30 AM SESSION 1

QRM: A Regulatory and Business Perspective

SESSION CHAIRPERSON

Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd, Switzerland

This session will explore QRM from both a regulatory and business perspective. In the first talk, FDA will share current initiatives for establishing QRM guidelines. In the second talk, the business case for using QRM in the clinical process will be presented.

The Clinical Trial Enterprise: Defining Quality
Jean Mulinde, MD
Sr. Advisor in the Division of GCP Compliance, Office of Scientific Investigations, CDER
FDA

Case for Change - Business Case for QRM
Ken Schiff
President
Quality Risk Management Associates, LLC

9:30-10:00 AM REFRESHMENT BREAK

10:00-12:00 PM SESSION 2

Practical Aspects of Implementing a Risk-based Approach in Clinical Drug Development

SESSION CHAIRPERSONS

Ken Schiff
President
Quality Risk Management Associates, LLC

Kenneth J. Sprenger, MD, MBBCh
Executive Director, Medicine Team Leader
Pfizer Inc.

This session will provide a look at practical aspects of implementing QbD into the clinical development process by focusing on designing protocols, study set up, site monitoring and safety reporting.

Designing Protocols
Kenneth J. Sprenger, MD, MBBCh
Executive Director, Medicine Team Leader
Pfizer Inc.

Study Set-up
Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd, Switzerland

Conducting Clinical Trials/Site Monitoring
Brian Nugent
Associate Director, Clinical Operations
Gilead Sciences

Pro-active Safety Risk Management
Barbara Leishman, MA
Head, Quality Risk Management - Safety Science
F. Hoffmann-La Roche Ltd., Switzerland

12:00-1:00 PM LUNCH

1:00-3:00 PM SESSION 3

Practical Aspects of Implementing a Risk-based Approach in Clinical Drug Development (continued)

SESSION CHAIRPERSONS

Ken Schiff
President
Quality Risk Management Associates, LLC

Kenneth J. Sprenger, MD, MBBCh
Executive Director, Medicine Team Leader
Pfizer Inc.

This session will continue the discussion of implementing a risk-based approach in the clinical development process by focusing on risk assessment and reporting. Speakers will address the practical aspects of data management, risk-based monitoring and trial oversight.

Ensuring Regulatory Compliance: Is QRM The Answer?
Jean Mulinde, MD
Sr. Advisor in the Division of GCP Compliance, Office of Scientific Investigations, CDER
FDA
Ann Meeker-O'Connell, MS
Director, Division of GCP Compliance (Acting)
Office of Scientific Investigations, Office of Compliance, CDER
FDA

Investigative Sites
Sina Djali
Director, Quality Monitoring and Compliance
Janssen Family of Pharmaceuticals

Trial Oversight
David F. Nickerson
Senior Director
Pfizer Inc.

Implementation of Methodology and Tools to Make it Happen - Implementing a QRM System: A Report from the Front
Randy Ramin-Wright, MS
Director of Quality Risk Management Consulting
International Institute for the Safety of Medicines (ii4sm), Switzerland

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 4

Practical Aspects of Implementing a Risk-based

Approach in Clinical Drug Development – Case Studies

Session Chairperson

Briggs W. Morrison, MD
Head, Global Medicines Development
AstraZeneca

This session will conclude the discussion of implementing a risk-based approach in the clinical drug development process by presenting case studies and hands-on experience from the Pharma, CRO and Investigative Site perspective.

Pharma Perspective

Carol A. McKenna, RN
Director, Clinical Trial Excellence and Analytics/Quality Risk Management, Biogen Idec

CRO Perspective

Heide Sterckx
Associate Director Quality Risk Management, GQ&C
PPD

Academic Perspective

David Alan Schoenfeld, PhD
Professor of Medicine, Harvard Medical School
Professor in the Department of Biostatistics
Harvard School of Public Health
Massachusetts General Hospital

5:00-6:00 PM NETWORKING RECEPTION

DAY 2, TUESDAY, DECEMBER 4

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM SESSION 5

Panel Discussion - Future Requirements – How to Implement the Current Guidelines into Practice?

Session Chairperson

Briggs W. Morrison, MD
Head, Global Medicines Development
AstraZeneca

This panel discussion, featuring regulatory speakers from FDA and EMA, will address implementation of the current QRM guidelines and what to expect for future requirements.

Panelists

Ann Meeker-O'Connell, MS
Director, Division of GCP Compliance (Acting)
Office of Scientific Investigations, Office of Compliance, CDER
FDA

Noemi Manent
Scientific Administrator, Compliance and Inspection
European Medicines Agency

Rehbar H. Tayyabkhan
Executive Director, GDO Business Operations and RCO Latin America
Bristol-Meyers Squibb Company

John H. Alexander, MD, MHS
Associate Professor of Medicine, Division of Cardiology
Director Cardiovascular Research,
Duke Clinical Research Institute, Duke Medicine

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 6

Current Initiatives and Updates on CTTI

Session Chairperson

Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd., Switzerland

This session will include a high-level summary of the CTTI workshop that was held in September 2012. The speakers will share the CTTI principles document and overview of the current CTTI initiatives.

Speakers

Ann Meeker-O'Connell, MS
Director, Division of GCP Compliance (Acting)
Office of Scientific Investigations, Office of Compliance, CDER
FDA

Briggs W. Morrison, MD
Head, Global Medicines Development
AstraZeneca

12:00-1:00 PM LUNCH

1:00-3:00 PM SESSION 7

Workshop Activity – How Do you Identify Risk and Apply QbD?

Participants will break into small groups and complete a case study. This hands-on activity will encourage attendees to engage with their colleagues to discuss identifying risk and applying QbD principles.

3:00-3:15 PM REFRESHMENT BREAK

3:15-4:00 PM SESSION 8

Wrap Up/Closing Remarks

Each breakout group will present a brief summary of their workshop activity discussion.

Session Chairperson

Peter Schiemann, PhD
Managing Partner
Widler & Schiemann Ltd, Switzerland

4:00 PM MEETING ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Quality Risk Management in Clinical Drug Development Workshop: Fundamentals and Practical Aspects
Event #12024 • December 3-4
Sheraton Philadelphia Downtown Hotel, Philadelphia, PA

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Member Early-bird Opportunity Available on nondiscount member fee only	On or before NOV. 12, 2012	After NOV. 12, 2012
Member Fee	US $1340 ❑	US $1490 ❑

Join DIA now to qualify for the early-bird member fee!
www.diahome.org/Membership

MEMBERSHIP
US $175 ❑

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/nonprofit members.

Nonmember Fee US $1665 ❑

A one-year membership to DIA is available to those paying a nonmember registration fee. *If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER
Government (Full-time)	US $595 ❑	US $770 ❑
Charitable Nonprofit/Academia (Full-time)	US $745 ❑	US $920 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.**

1. _____

2. _____

3. _____

Payment options: Register online at www.diahome.org or check payment method.

❑ **CREDIT CARD** number may be faxed to: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX Exp Date_____

Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** 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. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Philadelphia International Airport - PHL and attendees should make airline reservations as early as possible to ensure availability. Sheraton Philadelphia Downtown Hotel is holding a block of rooms at the reduced rate below until **November 10, 2012** for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $149 **Double $149**

Attendees must make their own hotel reservations. Contact the Sheraton Philadelphia Downtown Hotel by telephone at +1.215.448.2000 or 1.800.325.3535 and mention the DIA event. The hotel is located at 201 North 17th Street, Philadelphia, PA 19103, USA.

CANCELLATION POLICY: On or before NOVEMBER 19, 2013
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Preconference Workshop (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

REGISTRATION QUESTIONS
Contact **Marilyn Ginsberg, Customer Service Associate,** Phone **+1.215.442.6135**
Fax **+1.215.442.6199,** email **Marilyn.Ginsberg@diahome.org**

AGENDA AND EVENT DETAILS
Contact **Rachel Minnick, Content Lead,** Phone **+1.215.442.6131**
Fax **+1-215.442.6199,** email **Rachel.Minnick@diahome.org**

Contact **JoAnn Boileau, Event Planner,** Phone **+1.215.442.6175**
Fax **+1.215.442.6199,** email **JoAnn.Boileau@diahome.org**

TABLETOP EXHIBIT INFORMATION
Contact **Jeff Korn, Exhibits Associate,** Phone **+1.215.442.6184**
Fax **+1.215.442.6199,** email **Jeff.Korn@diahome.org**

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student
(Call for registration information)

Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Address (As required for postal delivery to your location) _____ Mail Stop

City _____ State Zip/Postal Country

email **Required for confirmation**

Phone Number _____ Fax Number **Required for confirmation**