PDA Parenteral Drug Association

Connecting People, Science and Regulation®

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PDA/EMA 2011 Conference

Regulation, Cooperation, Innovation: An Effective Partnership among Authorities and Industry in Europe

3-6 May 2011
Hotel Sofitel
London Heathrow, UK

3-5 May Conference, Exhibition
5-6 May Training Course, Workshop

Program Download:
https://europe.pda.org/PDAEMA2011

Brochure Update

A warm welcome from the conference co-chairs

Dear Colleagues,

PDA and the European Medicine Agency welcome you to the 2011 PDA/EMA Conference in London. Planning for this year's conference, the fourth in this series, started in May of 2010 with the recruitment of our superb scientific planning committee. The committee has worked over the intervening months to bring you a very special program. The 2011 Conference will be a milestone as there has been a decision to broaden the agenda beyond Good Manufacturing Practice (GMP) to include a full range of quality issues relating to pharmaceutical development, production and quality management. The committee's input from EMA's Quality Working Party (QWP), Biologics Working Party (BWP) and GMP/GDP Inspectors Working Group has resulted in substantial CMC-related content in the agenda. The agenda has been extended from two days to a full 2½ days, and the number of concurrent tracks increased from three to five, to make room for the expanded content. The number of EMA speakers, and speakers from the national health authorities, is impressive due in part to the convenience of the conference venue near London's Heathrow Airport.

"The agenda is broadened to include a full range of GMP, Quality and CMC issues relating to pharmaceutical development, production and quality management."

As a result of these efforts we present to you the 2011 PDA/EMA Conference, with the theme, "Regulation, Cooperation, Innovation: An Effective Partnership between Authorities and Industry in Europe." The plenary sessions on each morning of the conference will address universal themes of interest to all segments of our business. The five parallel tracks on the afternoons of 3 & 4 May will provide ½ day of coverage to more detailed technical or regulatory topics. The parallel tracks include: Process Optimization, Quality, Regulatory Affairs, Advanced Therapies, Supply Chain, Trends in Manufacturing, Biologics and Orphan Drugs (some tracks are repeated two times). There will be interactive panel discussions capping each of the parallel tracks. The planning committee has also focused on issues of interest to 'Start-up' and small & medium enterprises (SME).

We have listened to your comments and evaluations from the 2006, 2008 & 2009 conferences, and have structured the agenda in a way to allow ample time for questions, answers and discussion. Full information can be found in this brochure.

Please join us in London for this very special and unique opportunity to learn more about the future of pharmaceutical quality, GMP, development and manufacturing in our business.

Dr. Riccardo Luigetti
European Medicines Agency (EMA), London

Dr. Lothar Hartmann
F. Hoffmann-La Roche, Basel

Scientific Planning Committee

Co-Chairs

Riccardo Luigetti,
European Medicines Agency (EMA)
Lothar Hartmann,
F. Hoffmann-La Roche

Regulatory Authorities

David Cockburn, *EMA*
Nick Gate, *EMA*
Steffen Gross, *Paul-Ehrlich-Institut, Germany*
Anne Junttonen, *Finnish Medicines Agency*
Vasiliki Revithi, *National Organization for Medicines, Greece*
Peter Richardson, *EMA*
Jean-Louis Robert, *Laboratoire National de Santé, Luxembourg & Chair of Quality Working Party (QWP)*
Jean-Hugues Trouvin, *AFSSAPS, France & Chair of Biologics Working Party (BWP)*

Industry

Véronique Davoust, *Pfizer*
Gabriele Gori, *Novartis Vaccines & Diagnostics*
Frank Hallinan, *Pfizer*
Barbara Jentges, *PhACT*
José Luis Ortega Conejero, *PharmaMar*
Søren Pedersen, *NovoNordisk*
Siegfried Schmitt, *PAREXEL Consulting*

PDA Staff

Robert Dana, *PDA USA*
James Lyda, *PDA Europe*
Georg Roessling, *PDA Europe*

Confirmed Speakers In alphabetic order; correct at time of printing

EMA and National Health Authorities

Pavel Balabanov, *EMA*
Miguel Bley, *AFSSAPS, France*
Brigitte Brake, *BfArM, Germany*
Melanie Carr, *EMA*
Patrick Celis, *EMA*
David Cockburn, *EMA*
Emer Cooke, *EMA*
Martin Diller, *BfArM, Germany*
Lina Ertle, *AFSSAPS, France*
Zaide Frias, *EMA*
Kowid Ho, *AFSSAPS, France*
Anne Junttonen, *Finnish Medicines Agency*
Evdokia Korakianiti, *EMA*
François-Xavier Lery, *EDQM*
Jordi Llinares, *EMA*
Thomas Lönngren, *Consultant and former Executive Director of the EMA*
Riccardo Luigetti, *EMA*
Anabela Luis de Lima Marçal, *EMA*
Jacques Morénas, *AFSSAPS, France*
Katrin Nodop, *EMA*
Marisa Papaluca-Amati, *EMA*
Keith Pugh, *MHRA, UK*
Ian Rees, *MHRA, UK*
Peter Richardson, *EMA*
Jean-Louis Robert,
Laboratoire National de Santé, Luxembourg
Ian Thrussel, *MHRA, UK*
Jean-Hugues Trouvin, *AFSSAPS, France*
Diana van Riet, *RIVM, The Netherlands*
Noël Wathion, *EMA*

Industry Speakers

Alexandre Delacoux,
European Biopharmaceutical Enterprises
Marc Barthold, *MiltenyiBiotec*
Gabrielle Bodle, *Novartis Vaccines & Diagnostics*
Brendan Buckley, *University College Cork*
John-Edward Butler-Ransohoff, *Bayer Innovation*
Earl Dye, *Genentech*
Gemma Fernandez, *Cellerix*
Gavin Fitzgerald, *Amgen*
Georges France, *Pfizer*
Lothar Hartmann, *F. Hoffmann-La Roche*
Mary Heenan, *Pfizer*
Birgitte Holst, *NovoNordisk*
John Kerridge, *Eli Lilly*
Yves Mayeresse, *GSK Biologicals*
Steven Mendivil, *Amgen*
Mary Moran, *BMS*
Morten Munk, *CMC Biologics*
Alastair Nixon, *GSK*
Richard Peck, *Softbox Systems*
John Pinion, *F. Hoffmann-La Roche*
Thomas Schönknecht, *SCHOTT*
John Shabushnig, *Pfizer*
Robert Shaw, *Ark Therapeutics*
Hannelore Willkommen, *RBS Consulting*
Francois Vandeweyer, *Janssen Pharmaceutica*
Martin VanTrieste, *Amgen & Rx360*

Activities during PDA/EMA 2011 Conference at a Glance

2 May 2011	14:30	17:30	18:00	19:30
	PDA Executive Committee Meeting *(closed meeting)* **Athens**	**PDA Scientific Advisory Board Meeting** *(closed meeting)* **Athens**	**Program Planning Committee & Session Moderators Meeting** *(closed meeting)* **Paris Suite**	**Committee & Speakers Dinner** *(invitation only)* **Vivre Restaurant**
3 May 2011	**8:30 – 17:00**	**17:00**	**20:00**	
	PDA/EMA 2011 Conference **Arora Suite**	**Networking Reception** *(open to conference attendees)* **Foyer Arora Suite**	**PDA Chapters Meeting** *(closed meeting)* **Paris Suite**	
4 May 2011	**8:30 – 17:00**	**17:00**	**19:00**	
	PDA/EMA 2011 Conference **Arora Suite**	**Interest Group Meeting: Inspection Trends** *(open to conference attendees)* **Paris**	**PDA UK Chapter Reception** *(invitation only)* **TBA**	
5 May 2011	**8:30 – 12:15**	**13:00**	**13:00**	**13:30**
	PDA/EMA 2011 Conference **Arora Suite**	**PDA Board of Directors Meeting** *(closed meeting)* **Chicago**	**PDA Workshop** *(registration required)* **Washington** **PDA Training Course** *(registration required)* **New York Suite**	**Interest Group Meetings** *(open to conference attendees)* - **Quality Systems** **Paris Suite** - **Regulatory Affairs** **London**
6 May 2011	**8:30**	**8:30**	**8:30**	
	PDA Board of Directors Meeting *(closed meeting)* **Chicago**	**PDA Workshop** *(registration required)* **Washington**	**PDA Training Course** *(registration required)* **New York Suite**	

Times and locations are subject to change. Please inquire about changes on-site.

Conference Agenda

Tuesday, 3 May 2011

8:30	**Opening / Welcome**	Noël Wathion, *EMA* Maik Jornitz, *Sartorius Stedim/PDA* Richard M. Johnson, *PDA*
	Morning Plenary *Moderator:*	**Riccardo Luigetti,** *EMA* **Lothar Hartmann,** *F. Hoffmann-La Roche*
8:45	**EMA Roadplan 2015**	Noël Wathion, *EMA*
9:15	**Update on Regulatory, Quality & GMP Guidelines**	Riccardo Luigetti, *EMA* Peter Richardson, *EMA*
10:00	**Coffee Break & Exhibition**	
10:30	**Implementation of ICH Q8, Q9 and Q10 – Are we Going in the right Direction?**	Jean-Louis Robert, *Chair of QWP*
11:00	**Industry Perspective on Partnership with Authorities and Status of the Paradigm Change**	Georges France, *Pfizer*
11:30	**Q & A, Discussion**	
12:00	**Lunch Break & Exhibition**	
	Afternoon Concurrent Tracks 1 – 5	**13:30 - 17:00**
Track 1:	**Process Optimization** *Moderator:*	**Peter Richardson,** *EMA* **Gabriele Gori,** *Novartis*
13:30	**Bottle Necks in Supply – Lessons Learned from the Pandemic**	Gabrielle Bodle, *Novartis*
14:00	**Six Sigma and Lean Manufacturing Initiatives**	Mary Moran, *BMS*
14:30	**Coffee Break & Exhibition**	
15:00	**Platform Manufacturing**	Mary Heenan, *Pfizer*
15:30	**Single Use of Equipment**	Morten Munk, *CMC Biologics*
16:00	**Q & A, Discussion –** Ian Thrussel (Inspector, MHRA) will provide an inspector's view on the four industry presentations.	
Track 2:	**Quality** *Moderator:*	**Jean-Louis Robert,** *Chair of QWP* **Birgitte Holst,** *NovoNordisk*
13:30	**The Role of Quality after the Paradigm Change – Moving from Compliance to Strategic Quality Management**	Speaker invited
14:00	**'Knowledge Management' – a Mature Concept for the Pharmaceutical Industry**	Lothar Hartmann, *F. Hoffmann-La Roche*
14:30	**Coffee Break & Exhibition**	
15:00	**Lifecycle Approach to Process Validation**	Lina Ertle, *AFSSAPS* Birgitte Holst, *NovoNordisk*
15:30	**NIRs – Revised EMA Guideline and the Regulatory Impact**	Martin Diller, *BfArM*
16:00	**Q & A, Discussion**	
Track 3:	**Regulatory Affairs** *Moderator:*	**Zaide Frias,** *EMA* **Barbara Jentges,** *PhACT*
13:30	**Regulatory Harmonization Processes within the EU**	Anabela Luis De Lima Marçal, *EMA*
14:00	**Trends in European Submissions**	Zaide Frias, *EMA*
14:30	**Coffee Break & Exhibition**	
15:00	**How EMA Supports Submissions**	Pavel Balabanov, *EMA*
15:30	**Paperless Submissions – Current Situation within the EU**	Miguel Bley, *AFSSAPS* Alastair Nixon, *GSK*
16:00	**Q & A, Discussion**	

Please note that the agenda is subject to changes until very shortly before the event. Its final version may be viewed under https://europe.pda.org.

Tuesday, 3 May 2011

Track 4:	Advanced Therapy Medicinal Products (ATMP)	Moderator:	**Jean-Hugues Trouvin**, *Chair of BWP* **Karin Hoogendoorn**, *Centocor*
13:30	**The European Legislative Framework for ATMPs**		Patrick Celis, *EMA*
14:00	**Industry Perspective on Applying GMPs for ATMPs**		Gemma Fernandez, *Cellerix*
14:30	**Coffee Break & Exhibition**		
15:00	**Is Europe Prepared to Release Batches of ATMPs – Eligibility and Suitability Capabilities of a QP**		Robert Shaw, *Ark Therapeutics*
15:30	**Hospital Exemption – How to Release Cell-based Products in the European Environment**		Marc Barthold, *MiltenyiBiotec*
16:00	**Q & A, Discussion**		

Track 5:	Supply Chain	Moderator:	**Véronique Davoust**, *Pfizer* **Anne Junttonen**, *FIMEA*
13:30	**Challenges for Industry of Managing Quality in a Globalized Market**		John Kerridge, *Eli Lilly*
14:00	**Activities of EDQM in Ensuring Quality throughout the Supply Chain – Certificates of Suitability, Inspections and Track & Trace**		François-Xavier Lery, *EDQM*
14:30	**Coffee Break & Exhibition**		
15:00	**Ensuring Quality during Transportation**		Anne Junttonen, *FIMEA* Richard Peck, *Softbox Systems*
15:30	**Activities to Secure the Supply Chain – From Finished Product to Patient**		Martin VanTrieste, *Amgen*
16:00	**Q & A, Discussion**		
17:00	**Close of Day 1 & Networking Reception**		

Wednesday, 4 May 2011

	Morning Plenary	Moderator:	**David Cockburn**, *EMA* **Søren Pedersen**, *NovoNordisk*
8:30	**The Borderline between GMP and Submissions – Collaboration between Assessors and Inspectors**		Jean-Louis Robert, *Chair of QWP* Jacques Morénas, *AFSSAPS*
9:15	**What will be the Quality Issues for the next 25 Years for Biological Medicinal Products?**		Jean-Hugues Trouvin, *Chair of BWP*
9:45	**Coffee Break & Exhibition**		
10:15	**The Innovative Medicines Initiative**		Marisa Papaluca-Amati, *EMA*
10:45	**Annex 16 (Certification and Batch Release) – Time to Revise**		Anne Junttonen, *FIMEA*
11:15	**Q & A, Discussion**		
12:00	**Lunch Break & Exhibition**		

	Afternoon Concurrent Tracks 6 – 10	13:30 - 17:00

Track 6:	Trends in Manufacturing	Moderator:	**Ian Thrussel**, *MHRA* **Gabriele Gori**, *Novartis*
13:30	**Dedicated Facilities**		Speaker invited
14:00	**New Developments in Pharmaceutical Packaging**		Thomas Schönknecht, *SCHOTT*
14:30	**Coffee Break & Exhibition**		
15:00	**Visual Inspection – New Techniques & Latest Developments**		John Shabushnig, *Pfizer*
15:30	**Freeze Drying**		Yves Mayeresse, *GSK Biologicals*
16:00	**Q & A, Discussion –** Ian Thrussel (Inspector, MHRA) will provide an inspector's view on the three industry presentations.		

Conference Agenda

Wednesday, 4 May 2011

Track 7:	**Quality**	*Moderator:*	**Jean-Louis Robert,** *Chair of QWP* **Birgitte Holst,** *NovoNordisk*
13:30	**New Guideline on Pharmaceutical Development of Paediatrics**		Diana van Riet, *RIVM*
14:00	**Implementation of the Genotoxic Impurities Guideline**		Jean-Louis Robert, *Chair of QWP*
14:30	**Coffee Break & Exhibition**		
15:00	**API Audits**		Francois Vandeweyer, *Janssen Pharmaceutica* David Cockburn, *EMA*
15:30	**Quality as Competitive Advantage**		John Pinion, *F. Hoffmann-La Roche*
16:00	**Q & A, Discussion**		
Track 8:	**Regulatory Affairs**	*Moderator:*	**Keith Pugh,** *MHRA* **Barbara Jentges,** *PhACT*
13:30	**Experiences with the new EU Variations Regulations**		Keith Pugh, *MHRA* Gavin Fitzgerald, *Amgen*
14:00	**Comparison of EU and US Regulatory Change Requirements**		Earl Dye, *Genentech*
14:30	**Coffee Break & Exhibition**		
15:00	**ICH Q11 Update**		Steven Mendivil, *Amgen*
15:30	**Filing a Dossier Using QbD (including Real Time Testing) – Case Study**		Evdokia Korakianiti, *EMA*
16:00	**Q & A, Discussion**		
Track 9:	**Biologicals**	*Moderator:*	**Jean-Hugues Trouvin,** *Chair of BWP* **Georg Roessling,** *PDA Europe*
13:30	**Adventitious Viruses – Current Testing Developments**		Hannelore Willkommen, *RBS Consulting*
14:00	**The new GMP Annex 2 – Consequences for European Manufacturers**		Ian Rees, *MHRA*
14:30	**Coffee Break & Exhibition**		
15:00	**EMA Guideline on the Requirements for Quality Documentation Concerning Biological IMPs**		Brigitte Brake, *BfArM*
15:30	**Comparability versus Filiation**		Kowid Ho, *AFSSAPS*
16:00	**Q & A, Discussion**		
Track 10:	**Orphan Drugs & SMEs**	*Moderator:*	**Jordi Llinares,** *EMA* **Lothar Hartmann,** *F. Hoffmann-La Roche*
13:30	**Regulatory Environment of Orphan Medicinal Product in the EU (incl. Incentives) and Procedual Steps for Orphan Drug Designation (ODD)**		Jordi Llinares, *EMA*
14:00	**Developing Drugs for Rare Diseases: Opportunities, Misconceptions and Challenges**		Brendan Buckley, *University College Cork*
14:30	**Coffee Break & Exhibition**		
15:00	**The Situation of SME Biological Manufacturers in Europe**		Alexandre Delacoux, *EBE*
15:00	**How EMA Supports SME's**		Melanie Carr, *EMA*
16:00	**Q & A, Discussion**		
17:00	**Close of Day 2**		

Additional Activities

17:00	**Interest Group Meeting: Inspection Trends** *(open to conference attendees)*
19:00	**PDA UK Chapter Reception** *(invitation only)*

Conference Agenda

Thursday, 5 May 2011

	Morning Plenary	Chair: **Riccardo Luigetti,** *EMA* **Frank Hallinan,** *Pfizer*
8:30	**Impact of the new Falsified Medicines Legislation**	Katrin Nodop, *EMA*
9:00	**EMA International Collaboration Programs**	Emer Cooke, *EMA*
9:30	**Coffee Break & Exhibition**	
10:00	**The Future of the Pharmaceutical Business: Personalized Medicines**	John-Edward Butler-Ransohoff, *Bayer Innovation*
10:45	**How the European Regulatory Network will Develop in the next 20 Years**	Thomas Lönngren, *Consultant and former Executive Director of the EMA*
11:30	**Q & A, Discussion**	
12:00	**Closing Comments**	Georg Roessling, *PDA Europe*
12:15	**End of Conference & Lunch**	

Additional Activities

13:30 **Interest Group Meetings** *(open to conference attendees)*
- **Quality Systems**
- **Regulatory Affairs**

This agenda shows the plenary topics and concurrent track topics to be presented at the conference. The agenda is subject to change. This information is accurate at the time of printing. For the up-to-date agenda go to the homepage for the conference, **https://europe.pda.org/PDAEMA2011**

2011 PDA Europe Conference & Event Calendar

3-6 May	PDA/EMA Joint Conference	Conference, Exhibition Training Courses	London, England
25 May	IG Visual Inspection	Interest Group Meeting	Berlin, Germany
26-27 May	An Introduction to Visual Inspection	Training Course	Berlin, Germany
7-8 June	Advanced Therapy Medicinal Products (ATMPs)	Workshop, Exhibition	Helsinki, Finland
7-8 June	4th Monoclonal Antibodies Workshop	Workshop, Exhibition	Basel, Switzerland
27-30 June	Virus / TSE Safety Forum	Pre-Conference Workshop Conference, Exhibition	Barcelona, Spain
27-30 September	Pharmaceutical Cold Chain Management & Good Distribution Practice	Conference, Exhibition Training Courses	Berlin, Germany
25-28 October	Freeze Drying Technology	Conference, Exhibition Training Courses	Barcelona, Spain
7-11 November	The Universe of Pre-filled Syringes and Injection Devices	Pre-Conference Workshop Conference, Exhibition Training Courses	Basel, Switzerland
15-16 November	Green Pharmaceutical Production	Conference, Exhibition	Copenhagen, Denmark

For latest info: http://europe.pda.org

Subject to change

Shortlist 2011-03-09

For more information, please do not hesitate to contact us:

PDA Europe gGmbH, Adalbertstr. 9
16548 Glienicke / Berlin, Germany
Tel: +49 (0) 33056- 23 77 10
Fax: +49 (0) 33056- 23 77 77
info-europe@pda.org
http://europe.pda.org

For exhibition information, please contact:
Katharina Keisers-Engstfeld
Manager Exhibition & Sponsorship
Tel: + 49 (0) 33056-237714
keisers@pda.org

Join PDA Today!

PDA is a global non-profit organization of over 9,500 members. Our focus and emphasis is in the areas of sterile product technology, biotechnology and quality and regulatory compliance concepts and systems - become a part of our community, join PDA today! **www.pda.org/join**

Thursday, 5 May 2011 13:00 – 18:00 | Friday, 6 May 2011 8:30 – 13:00

Development and Manufacture of a Pharmaceutical Product with Benefit of QRM / ICH Q9 Methodology

Workshop Description

Like the weather, everyone in the pharma business is talking about the value of risk managment in the development and manufacture of pharmaceutical products, both small molecule and biological/biotech. And like the weather, many people feel they are unable to control or change their current practices or systems and incorporate risk management methodologies and tools to improve their operations. This workshop will provide practical and 'hands on' information from experienced industry professionals on how ICH Q9 and quality risk managment principles can be brought into everyday operations to improve decision making, productivity & product quality – providing overall savings and profitability. Don't believe it? Take a day and join us for this special workshop to find out how.

The workshop will cover:

- What does ICH Q9 really tell us and the key messages, i.e. a way of thinking
- How can you identify critical quality attributes in Phase 3 studies?
- How can we use QRM to improve scheduling of internal and supplier audits?
- How can we apply QRM to existing products and benefit commercial manufacturing?
- How can we better implement QRM in PQS elements like discrepency analysis, change control and CAPA?
- How can we use these tools to better define a control strategy?

Workshop Facilitators

Stephan Rönninger, *Head External Relations Europe/Japan, F. Hoffmann-La Roche, CH (Workshop Leader)*
Mark Birse, *GMP Operations Manager, MHRA, UK*
Véronique Davoust, *PGM Global Quality Operations, Quality Strategy, Pfizer, F*
Malcolm Holmes, *Independent Consultant, UK*
Robert Puskeiler, *Manager Development Fermentation, Roche Pharma Biotech, D*
Emma Ramnarine, *Head of Global Quality Risk Management, Genentech (Roche), USA*

Workshop Leader

The workshop leader is **Dr.-Ing. Stephan Rönninger**, of the global quality and compliance organization in F. Hoffmann-La Roche, Basel. Before joining Roche's quality operations, Dr. Rönninger worked in manufacturing for many years. He is a leader on the ICH Q9 Expert Working Group, a current member of the ICH Quality Implementation Working Group and is well known for popularizing risk mangment principles backed up by practical experience. Dr. Rönninger will be supported by additional guest speakers during the workshop.

Development and Manufacture of a Pharmaceutical Product with Benefit of QRM / ICH Q9 Methodology

Thursday, 5 May 2011

13:00	**Introduction and Welcome**	Stephan Rönninger
	Orientation to QRM	
13:05	**What does ICH Q9 tell us?**	Stephan Rönninger
14:00	**Key Messages for Implementation of ICH Q9**	Stephan Rönninger
14:30	**Q & A**	
14:45	**Coffee Break**	
	QRM in Development	
15:15	**Identify Critical Quality Attributes and Process Parameters in a Phase 3 Study**	Robert Puskeiler
16:15	**Q & A Discussion: Options in Defining a Control Strategy**	Robert Puskeiler, Stephan Rönninger
	QRM in Quality System Elements Relating to Development and Manufacturing	
17:00	**Scheduling of Audits**	Malcom Holmes
18:00	**Close of Day 1**	

Friday, 6 May 2011

8:30	**Wrap Up of the Day before**	Stephan Rönninger
	QRM in Quality System Elements Relating to Development and Manufacturing (continued)	
8:40	**Risk Based Scheduling of Inspections**	Mark Birse
9:10	**Technical Transfer: Approach and Case Study**	Emma Ramnarine
9:55	**Coffee Break**	
10:20	**Integration in the Quality System for Existing Products (e.g. CAPA)**	Emma Ramnarine
	QRM in Quality System Elements to Commercial Manufacturing	
11.00	**Implementation in Commercial Manufacturing (Result of PCMO)**	Véronique Davoust, Emma Ramnarine
	QRM: The Way Forward	
12:00	**Q & A and Panel Discussion Challenges and Opportunities**	Stephan Rönninger and all facilitators
13:00	**End of Workshop**	

Please note that the agenda is subject to changes until very shortly before the event. Its final version may be viewed under https://europe.pda.org.

Thursday, 5 May 2011 13:00 – 18:00 | Friday, 6 May 2011 8:30 – 12:00

The Expanding Role of the Quality Professional in Europe and USA

EU, US GMPs and Responsibilities of QPs in the Supply Chain

Course Description

The face of the pharmaceutical industry is changing. Increased use of contractors has resulted in the replacement of the current Chapter 7 – Contract Manufacture and Analysis with a new title "Outsourced Activities." The responsibility of the Qualified Person in Europe and the Quality Unit personnel releasing batches according to US GMPs is evolving into a complex and challenging task. As of 01 January 2011, FDA is a member of PIC/S and will share inspectional findings. What are the implications for corporate compliance profiles? This course will review current GMPs both US and EU in the light of recent updates and trends and will allow participants to understand the legal and professional duties, responsibilities and authorities of the person signing off a batch release. Presented by a certified QP who is also an assessor of QP candidates and a quality professional with over 20 years of global QA experience this is a not to be missed opportunity to refresh your perspective of GMPs and gain global insights into batch release.

This one day course will address the following points:

- Review of EU and US GMPs
- Highlight updates of GMPs in progress
- Corporate cGMP compliance in the context of batch release
- Management leadership as a pre-requisite for batch release
- Managing outsourced activities in the scope of batch release
- The role of the QP / QA in the Quality Management System
- Supply chain issues in the context of batch release
  - Actives
  - Inactives
- Batch release enablers:
  - Product quality review and ongoing verification
  - Management review
  - Lifecycle approach to quality

Course Faculty

Sue Mann is a certified QP from England. She is also a QP Assessor representing the Royal Pharmaceutical Society of Great Britain (RSPGB) and assesses candidate QPs. Sue is expert in both commercial and investigational product manufacture, control and release.

Karen Ginsbury is a pharmaceutical consultant with more than 20 years of hands on experience in the pharmaceutical industry working in the field of quality assurance and compliance. Having released batches herself, she has a unique understanding of the issues involved and pressures to which quality professionals may be subjected.

The Parenteral Drug Association Presents...

2011 PDA ANNUAL MEETING

Harnessing the Power of Knowledge to Drive World Class Science and Technology

1946 65TH ANNIVERSARY 2011

April 11-15, 2011 | JW MARRIOTT SAN ANTONIO HILL COUNTRY | SAN ANTONIO, TEXAS

Join PDA for the 65th PDA Annual Meeting, themed *Harnessing the Power of Knowledge to Drive World Class Science and Technology*, which will support over 45 presentations in sessions which will include:

Keynote Speakers:

M. Lynn Crismon, PharmD, Dean, School of Pharmacy, *University of Texas*
Janet Walkow, PhD, Director, Drug Dynamics Institute, *University of Texas*
Fostering Academic-Industry Collaboration for Product Development

Tara Gooen, Team Leader for the New and Generic Drug Manufacturing Team, DMPQ, *FDA*
Achieving the ICH Pharmaceutical Quality Vision through Real-Time Monitoring of Manufacturing Data

Colonel David Bobb, Head of Pharmacy and Ancillary Services, *Wilford Hall Medical Center*
The Voice of the Customer

Hot Topics at this Year's *2011 PDA Annual Meeting* Include:

Microbiology – Product Lifecycle

- Product Disposition & Solutions' Shelf Life
- Use of Water Activity as a Microbial Growth Predictor for Establishing Hold-Time Expiry of Manufacturing Process Solutions
- Environmental Monitoring
- Statistical Process Control (SPC) Chart for Setting Alert/ Action Limits for Environmental Monitoring Programs or In-process Bioburden Testing Based on Negative Binomial

Single Use Systems

- Producing Vaccines for the Global Marketplace - Flexible Facility Design

Supply Chain

- Securing the Transportation and Storage Supply Chain
- Managing Supply Channel Information in a Global Enterprise System Shared Learnings on Building a New System
- The Art of Managing an Outsourcing Program
- Outsourcing: Challenging the Project Management System at Your Organization

Analytical Methods

- Analysis of Glycoform Characterization within Monoclonal Antibody Regulatory Submissions
- Analytical Method Transfer and Monitoring - Key Elements of the Analytical Method Life Cycle Management

Risk Management

- Integration of Quality Risk Management and Discrepancy Management
- Sterility Assurance Risk Management - One Company's Approach

Quality Science

- Getting Technology Transfer Right the First Time, How to Train and Learn in Day to Day Manufacturing
- Best Practices for an Aseptic Process Technology Transfer and Case Study
- Lessons Learned: Implementation of a Fully Electronic and Compliant Learning Management System for GlaxoSmithKline Biopharmaceuticals R&D

And much more will be covered at this year's meeting!

PDA will be hosting a post conference workshop on *The FDA's Process Validation Guidance Meeting Compliance Expectations and Practical Implementation Strategies* with open plenary speaker and closing panelist **Grace McNally**, Consumer Safety Officer, CDER, *FDA* on April 13-14.

PDA's Training and Research Institute will also be hosting seven courses on April 13-15. Please visit www.pdaannualmeeting.org/courses to learn more.

www.pda.org/annual2011

MEETING April 11-13 | **EXHIBITION** April 11-12 | **WORKSHOP** April 13-14 | **COURSES** April 13-15

Venue, Accommodation, Exhibit & Contact Information

Venue of the Conference:
The 2011 PDA/EMA conference will be held at the Sofitel Hotel London Heathrow conveniently with a direct walkway to Terminal 5 at the airport.

Sofitel London Heathrow
Terminal 5, London Heathrow Airport
TW6 2GD London, United Kingdom
Tel : +44 208 757 7777
Fax : +44 208 757 7788
Web: www.sofitel.com

Special Rates
Single Room: **£ 159,** plus 20% VAT.
Rates per room and night, breakfast included.

Room Reservations
PDA has secured a limited number of rooms at a special group rate until **4 April 2011**.
Via email: h6214-re@sofitel.com
Code word: **PDA020511**

Housing at the selected hotels will be in high demand, so we strongly recommend to make your reservations early.

PDA Contacts
For additional conference information, please contact:
PDA Europe gGmbH
Adalbertstr. 9
16548 Glienicke/ Berlin, Germany
Tel: +49 33056 23 77 10
Fax: +49 33056 23 77 77
info-europe@pda.org

For exhibition information, please contact:
Katharina Keisers-Engstfeld
Manager Exhibition & Sponsorship PDA Europe
Tel: + 49 33056 23 77 14
Email: keisers@pda.org

BRITISH AIRWAYS

If you decide to fly British Airways, you can take advantage of our special PDA Europe discount. You will be provided with further information when registering for the event.

For more details: https://europe.pda.org/PDAEMA2011

Who Should Attend

This conference will supply value-added information to all companies and individuals, including 'Start-up' and Small to Medium Enterprises, involved in the development, production and quality management of medicinal and biopharmaceutical products. Technical and regulatory information and case studies will address process optimisation, quality management, CMC and regulatory affairs, GMP, advanced therapies, supply chain, trends in manufacturing, biologics and orphan drugs. Persons involved in those disciplines, for API or medicinal products, will benefit from attending, in particular: Inspection/Audit, Process Development, Validation, Pharmaceutical R&D, CMC and Regulatory Affairs, Manufacturing, cGMP, Quality Assurance/Quality Control, Compliance, Qualified Person, and all related disciplines.

Registration Form

2011 PDA/EMA Conference
Regulation, Cooperation, Innovation
3-6 May 2011 | London Heathrow, England

4 Ways to register

ONLINE: https://europe.pda.org/PDAEMA2011 **FAX: +49 33056 23 77 77**
EMAIL: petzholdt@pda.org **MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany**

1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

☐ Mr. ☐ Ms. ☐ Dr. ☐ PDA Member ☐ Nonmember

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

Business Phone Fax

☐ Subsituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

2 Conference + Training Courses Registration

All fees given in Euro and excluding VAT (20%)

Conference

PDA Member	☐	**1845**
Nonmember	☐	**2095***
Govern./Health Authority/Academic	☐	**920***

	PDA Member		Nonmember	
Training Course	☐	**895**	☐	**1145***
Workshop	☐	**895**	☐	**1145***

Conference + Training Course or Workshop

PDA Member	☐	**2445**
Nonmember	☐	**2695***

Group Registration Discount
Register 4 people from the same site as a group (at the same time) for the conference and receive the 5th registration free. Other discounts cannot be applied.

☐ **Exhibit Company**
Please mark here if your company will be an exhibitor of this event.

PDA Member	☐	**1666**
Nonmember	☐	**1866***

*Registration fee includes a one-year PDA membership if no further special discount is granted (except discount for exhibit companies). If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

3 Payment Options

☐ **By Credit Card** ☐ American Express* ☐ MasterCard* ☐ VISA*

Total Amount (+ 20% VAT)

Card Number Exp. Date

Name
(exactly as it appears on card)

Signature

***All cards are charged in Euro.**

☐ **By Bank Transfer**

Beneficiary: PDA Europe gGmbH
Account No: 09 228 735 00
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDEDBBER

Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

Invoice ☐ Please mark here to request an invoice from PDA. You are not considered registered for a PDA event until payment is received and a confirmation letter is issued by PDA. Should you attend an event without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment.

PDA Europe VAT I.D.: DE254459362

Billing Address: ☐ Same as contact information address above.
If not, please send your billing address to: **petzholdt@pda.org**

Your VAT I.D.:

Date Mandatory Signature

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or have received an invoice please be advised that you are not a confirmed registrant. You are not confirmed until payment has been received. Please submit payment for the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on site at the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference of the non-member fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. **REFUNDS: Refund requests must be in writing and faxed to PDA at +49 (33056) 23 77 77** (emails are not accepted). If your written request is received on or before **19 April 2011,** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee if your cancellation has not been received in writing on or before **4 April 2011.** On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. **Refund for Courses:** If your written request is received by **18 April 2011,** you will receive a full refund less a 150 € excl. VAT processing fee. After that time, no refund or credit requests will be approved. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **info-europe@pda.org or fax to +49 (33056) 23 77 77.**

Registration Form

Helpful Hints When Registering for PDA Europe Events

MAKING IT EASIER FOR BOTH OF US

For PDA Europe events:

1 Please include your member ID number on registration form if available/ known.

If uncertain about your member ID number and/or your membership status, call or email Ms. Antje Petzholdt (+49 (0)33056 2377-10) **petzholdt@pda.org**

2 Don't send money in advance

Please wait until we send our invoice to you.
It is helpful to reference our invoice number in your bank transfer details.

3 Complete and sign the event registration form

Please note the registration and cancellation policies at the bottom of the form.

4 Purchase Orders

Registration cannot be completed by sending Purchase Order alone. A Purchase Order is only accepted if a complete registration form is enclosed or follows very soon.

5 Please state your company's VAT ID number

This number starts by your country code
(example: PDA Europe's VAT ID number = DE254459362)

6 Please state the correct billing address on the registration form

This is particularly important if billing address and site address are different.
Contact your accounting department for correct address and company name.
There could be special requirements for accounting.

7 Confirmation of your registration

Credit card charges are confirmed immediately if successfully approved.
Bank transfers are confirmed upon receipt of full payment.

8 Refund/ Credit Notes

Refunds to credit card can be done immediately.
For refund to bank accounts please provide:

a) name of your bank
b) IBAN number
c) Swift/ BIC code

9 For assistance contact: Antje Petzholdt, PDA Europe

Tel: +49 (0)33056 2377-10 **Email: petzholdt@pda.org**

WE SEND A KIND 'THANK YOU' FOR YOUR COOPERATION!

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB, United Kingdom
Tel: +44 20 7418 8400
www.ema.europa.eu

PDA®
Parenteral Drug Association

Connecting People, Science and Regulation

PDA Europe gGmbH, Adalbertstr. 9
16548 Glienicke / Berlin, Germany
Tel: +49 33056 23 77 10
Fax: +49 33056 23 77 77
info-europe@pda.org
https://europe.pda.org