

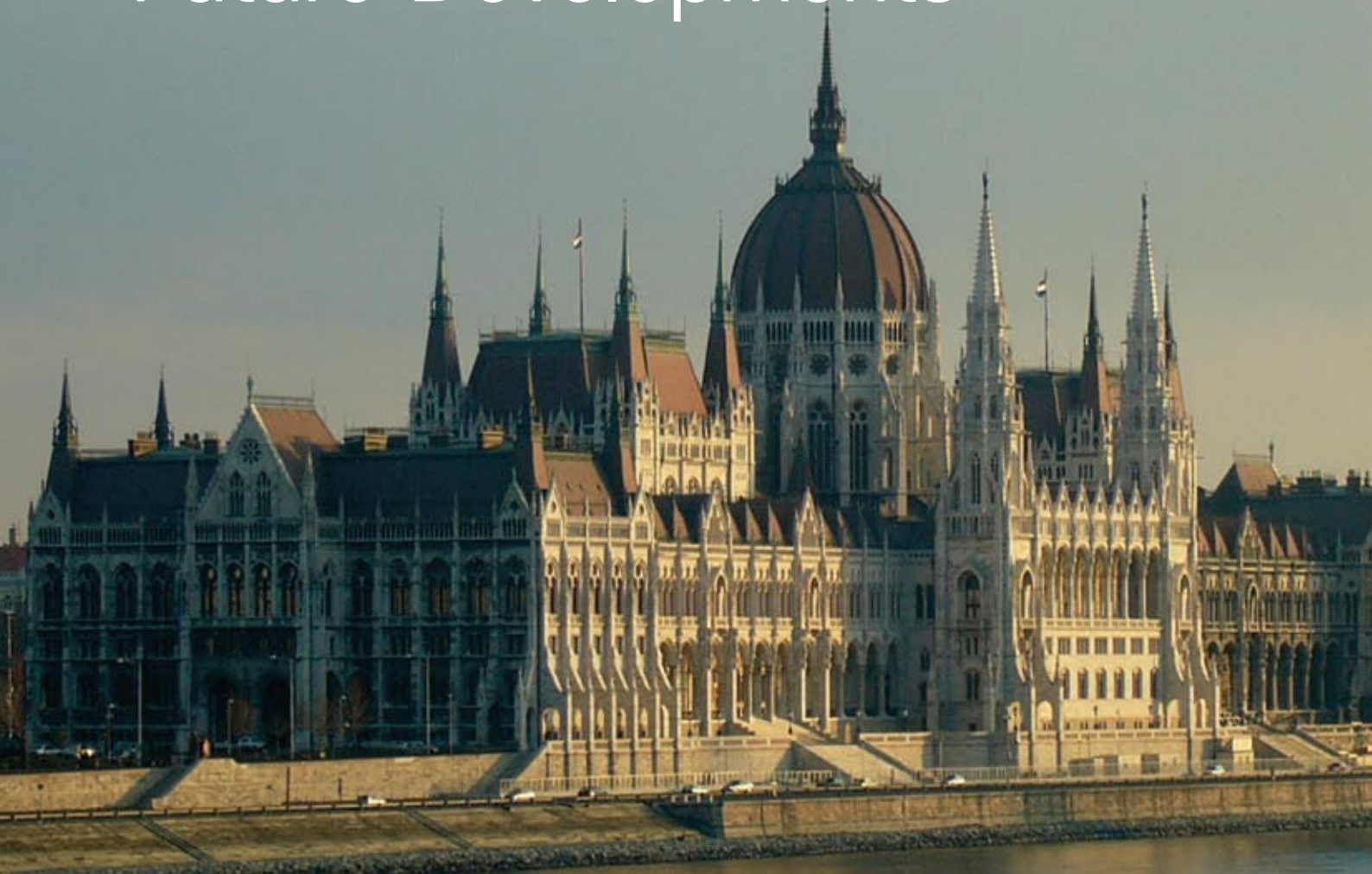


Connecting People, Science and Regulation®



## 2008 PDA/EMA Joint Conference

# European GMP: Current Issues and Future Developments



**18-21 February 2008  
Budapest, Hungary**

foto: Elias Bizannes

[www.pda.org/emea2008](http://www.pda.org/emea2008)

# Final Program

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### Registration Hours in the Hotel Lobby

**Pre-Registration**  
Sunday, 17 Feb 2008  
16:00 – 20:00

**Pre-Registration  
Conference**  
Tuesday, 19 Feb 2008  
15:00 – 21:00

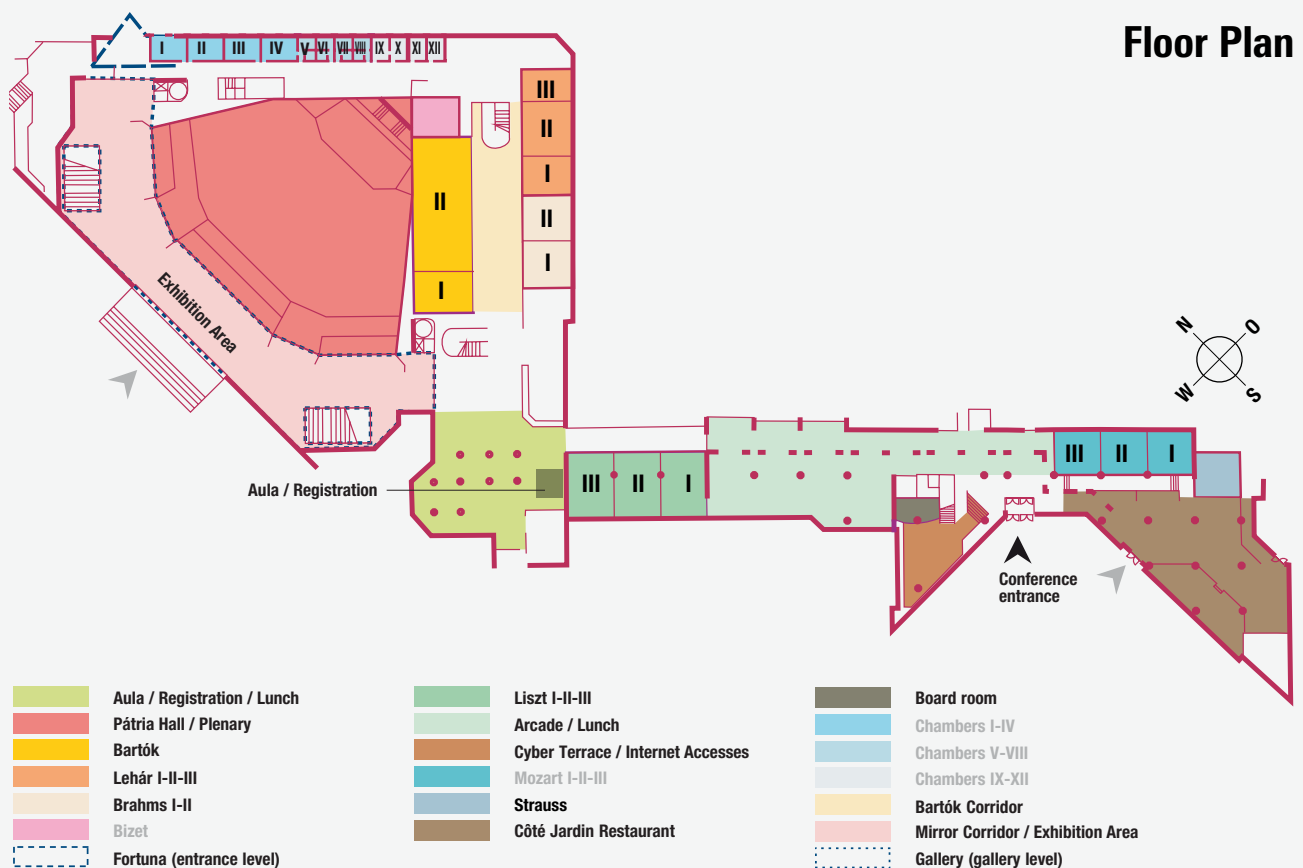
### Registration Hours in the Aula

**Annex 2 – Open Meeting**  
Tuesday, 19 Feb 2008  
12:30 – 13:30

**PDA TRI Training Courses**  
Monday, 18 Feb 2008  
08:00 – 09:00  
Tuesday, 19 Feb 2008  
08:00 – 09:00

**PDA Workshop**  
Monday, 18 Feb 2008  
10:00 – 11:00  
Tuesday, 19 Feb 2008  
07:00 – 08:30

**Conference/Exhibition**  
Wednesday, 20 Feb 2008  
07:00 – 08:30  
Thursday, 21 Feb 2008  
07:00 – 08:30



**Sunday, 17 February 2008**

**16:00 – 20:00**

**Pre-registration for all events listed below**

Monday, 18 February 2008	Tuesday, 19 February 2008	Wednesday, 20 February 2008	Thursday, 21 February 2008
<b>Training Courses</b>	<b>Training Courses</b>	<b>Conference/Exhibition</b>	<b>Conference/Exhibition</b>
<p><b>08:00 – 09:00</b> Registration</p> <p><b>09:00 – 16:30</b> ICH Q10 and its Potential Impact on the Pharmaceutical Industry – <b>NEW COURSE!</b> <b>Room: Liszt I-II</b></p> <p>Drug Registration in Europe – An Insight View – <b>NEW COURSE!</b> <b>Room: Lehár III</b></p> <p>Preparing for and Passing a European or United States GMP Inspection (Day 1) <b>Room: Lehár I-II</b></p> <p>Quality System Strategies for Investigational Drugs (Day 1) <b>Room: Liszt III</b></p>	<p><b>08:00 – 09:00</b> Registration</p> <p><b>09:00 – 16:30</b> Risk-Based Approach and Risk Management in Pharmaceutical Manufacturing Processes <b>Room: Liszt I-II</b></p> <p>Briefing Meetings, Scientific Advice/Protocol Assistance, Pre-Submission Meetings with EMEA – When to Do What and How to Prepare – <b>NEW COURSE!</b> <b>Room: Lehár III</b></p> <p>Preparing for and Passing a European or United States GMP Inspection (Day 2) <b>Room: Lehár I-II</b></p> <p>Quality System Strategies for Investigational Drugs (Day 2) <b>Room: Liszt III</b></p> <p><b>EU GMP Annex 2 - Open Meeting</b></p> <p><b>13:30 – 17:30</b> Manufacture of Biological Medicinal Products for Human Use <b>Room: Bartók</b> followed by Cocktail Reception</p>	<p><b>07:00 – 08:30</b> Registration and Welcome Coffee</p> <p><b>08:30 – 12:15</b> <b>Plenary Session 1</b> The European Environment <b>Room: Patria Hall</b></p> <p><b>12:15 – 13:15</b> <b>Lunch Break</b> <b>Aula and Arcade</b></p> <p><b>13:15 – 14:30</b> <b>Plenary Session 2</b> Survey of New, Revised and Pending European Guidance <b>Room: Patria Hall</b></p> <p><b>15:00 – 17:00</b> <b>Concurrent Sessions</b></p> <p><b>Session 1</b> Sterile Operations <b>Room: Patria Hall</b></p> <p><b>Session 2</b> ICH Quality Related Topics <b>Room: Bartók</b></p> <p><b>Session 3</b> Advanced Therapies Regulation <b>Room: Lehár I-III</b></p> <p><b>Session 4</b> Dedicated Facilities <b>Room: Brahms I-II</b></p> <p><b>19:00 – 22:00</b> <b>Networking Event</b> (including a dinner)</p>	<p><b>07:00 – 08:30</b> Registration and Welcome Coffee</p> <p><b>08:30 – 12:00</b> <b>Concurrent Sessions</b></p> <p><b>Session 5</b> Regulatory Quality <b>Room: Bartók</b></p> <p><b>Session 6</b> Starting Materials <b>Room: Lehár I-III</b></p> <p><b>Session 7</b> GMP Inspections <b>Room: Patria Hall</b></p> <p><b>Session 8</b> Investigational Medicinal Products (IMPs) <b>Room: Brahms I-II</b></p> <p><b>12:00 – 13:00</b> <b>Lunch Break</b> <b>Aula and Arcade</b></p> <p><b>13:00 – 16:45</b> <b>Plenary Session 3</b> Looking into the Future <b>Room: Patria Hall</b></p>
<b>Workshop</b>	<b>Workshop</b>		
<p><b>10:00 – 11:00</b> Registration</p> <p><b>11:00 – 18:30</b> Cleaning and Disinfection – An Advanced Workshop (Day 1) <b>Room: Brahms I-II</b></p>	<p><b>07:00 – 08:30</b> Registration</p> <p><b>08:30 – 17:30</b> Cleaning and Disinfection – An Advanced Workshop (Day 2) <b>Room: Brahms I-II</b></p>		

## Additional Events of Interest

### New Member Breakfast

**Wednesday, 20 Feb 08**  
**07:00 - 08:00**  
**Room: Bartók**

### RAQC Meeting

**Wednesday, 20 Feb 08**  
**17:15 - 18:15 (closed event)**  
**Room: will be announced**

### Meeting of the Presidents of the European Chapters

**Wednesday, 20 Feb 08**  
**Details will be given at the Registration Desk**

## Wednesday, 20 February 2008

**08:30**      **Opening/Welcome**

**John G. Shabushnig,**  
*Chair of PDA, Pfizer, USA*  
**Tamás L. Paál,** *OGYI, Hungary*  
**Lothar Hartmann,**  
*F. Hoffmann - La Roche, Switzerland*

### **PLENARY SESSION 1: The European Environment**

*Chair: Emer Cooke, EMEA*

The European Union has evolved an elegant and effective set of procedures, official bodies and communications systems to effectively conduct the business of pharmaceutical authorization and supervision. In this session, attendees will learn about how the system is defined and organized to further the regulatory mission of the European Commission and the EMEA. They will also hear a multi-national 'user' experience in navigating the system. Finally, a report will be given on the status of Mutual Recognition Agreements managed by the EMEA, and the evolving role of the Qualified Person in the release of products for the European market.

**08:45**      **Competences Among the European Bodies –  
The Role of the Various European Bodies**

**Sabine Atzor,** *EU Commission*

**09:30**      **Operating Successfully in the European Environment**

**Michael Doherty,**  
*F. Hoffmann - La Roche, Switzerland*

**10:00**      **Q & A**

**10:15**      **Coffee Break and Exhibition**

**10:45**      **Mutual Recognition Agreements – The Impact in Practice**

**Katrin Nodop,** *EMEA*

**11:15**      **Role of the QP in Product Release for the European Market**

**Eija Pelkonen,** *NAM, Finland*

**11:45**      **Q & A**

**12:15**      **Lunch Break**

### **PLENARY SESSION 2: Survey of New, Revised and Pending European Guidance**

*Chair: Timea Molnarne Lakatost,  
Vet Products Agency, Hungary*

In this session attendees will be given an most current report on the GMP-related guidances which define the latest requirements for manufacturers, distributors and importers of pharmaceuticals in Europe. This includes the GMP Guide, the various Annex's to the Guide, Notes for Guidances and reflection papers bearing on GMP issues. There is a lot going on in the area of GMP in Europe, and this survey will prove it. In addition, there will be a brief industry reaction to selected GMP guidances offered for consultation in 2007.

**13:15**      **EU Guidance Documents – Purpose, Types, Legal Relevance  
and New GMP Related Documents in the EU – An Overview**

**Katrin Nodop,** *EMEA*

**14:15**      **PDA Perspective on European Regulatory Guidance**

**Jim Lyda,** *PDA Europe*

**14:30**      **Coffee Break and Exhibition**

## CONCURRENT SESSIONS:

The balance of the afternoon will be divided into four parallel topical sessions which will allow attendees to learn in detail about specific technical or regulatory subjects. These topics range from the PDA expertise in sterile products and operations, to the emerging European guidance on dedicated manufacturing facilities. In addition, there are sessions covering the new ICH Q8, Q9 and Q10 and the impact of the Advanced Therapies Regulation manufacturing and GMP.

### Session 1: Sterile Operations

Chair: **Véronique Davoust**, Pfizer, France

<b>15:00</b>	<b>Revised EU GMP Annex 1</b>	<b>Paul Hargreaves</b> , MHRA, United Kingdom
<b>15:30</b>	<b>Sterile Requirements Around the World</b>	<b>Nigel Halls</b> , IAGT Ltd., United Kingdom
<b>16:00</b>	<b>Sterility – What is an Acceptable Level?</b>	<b>Martyn Becker</b> , MSD, United Kingdom
<b>16:30</b>	<b>Q &amp; A</b>	

### Session 2: ICH Quality Related Topics

Chair: **Liam Murphy**, Amgen, Ireland

<b>15:00</b>	<b>Best Implementation of ICH Q10</b>	<b>Neil Wilkinson</b> , AstraZeneca, United Kingdom
<b>15:30</b>	<b>ICH Q9 – GMP Related Aspects of EMEA's Implementation Group</b>	<b>Jacques Morénas</b> , AFSSAPS, France
<b>16:00</b>	<b>Concepts of Implementing ICH Q8 for Successful Variations</b>	<b>Liz Coulson</b> , Pfizer, United Kingdom
<b>16:30</b>	<b>Q &amp; A</b>	

### Session 3: Advanced Therapies Regulation

Chair: **Eija Pelkonen**, NAM, Finland

<b>15:00</b>	<b>Revision of EU GMP Annex 2</b>	<b>Ian Rees</b> , MHRA, United Kingdom
<b>15:30</b>	<b>Advanced Therapy Regulation – An Overview</b>	<b>Paula Salmikangas</b> , NAM, Finland
<b>16:00</b>	<b>Industrial Applications of Combination Devices</b>	<b>Achille P. Caputi</b> , University Messina, Italy
<b>16:30</b>	<b>Q &amp; A</b>	

### Session 4: Dedicated Facilities

Chair: **Claudia Nardini**, Kedrion, Italy

<b>15:00</b>	<b>Dedicated Facilities – Regulatory Viewpoint</b>	<b>Sabine Paris</b> , ZLG, Germany
<b>15:30</b>	<b>Dedicated Facilities – Implications for Industry</b>	<b>Paul Wreglesworth</b> , AstraZeneca, United Kingdom
<b>16:00</b>	<b>Case Study – Implementation of Quality Risk Management</b>	<b>Stephan Roenninger</b> , F. Hoffmann - La Roche, Switzerland
<b>16:30</b>	<b>Q &amp; A</b>	
<b>17:00</b>	<b>End Day 1</b>	
<b>19:00</b>	<b>Networking Event</b>	<i>A Gala Dinner will take place at a typical Hungarian restaurant, which offers a wonderful view of the Danube.</i>

**Thursday, 21 February 2008**

**CONCURRENT SESSIONS: Parallel Sessions on Quality and GMP Topics**

The second day of the conference will be divided into four new and extended parallel topical sessions which will allow attendees to learn in detail about specific technical or regulatory subjects. These topics include the relationship between GMP and regulatory quality; the latest developments surrounding starting materials, active substances, excipients and atypical actives; GMP inspections and Investigational Medicinal Products (IMPs).

**Session 5: Regulatory Quality**

*Chair: Tesh Patel,  
Abbott Laboratories, United Kingdom*

- |              |   |   |
|--------------|---|---|
| <b>08:30</b> | <b>Variation Regulation, Certificate of Suitability (CEP) and Registration Procedures in the EU (National, MRP, DCP, Centralised)</b> | <b>Barbara Jentges,</b><br><i>PhACT GmbH, Switzerland</i>             |
| <b>09:15</b> | <b>Changes Foreseen in the Variations Regulation in a Future Revision</b>   | <b>Peter Bachmann,</b> <i>BfArM, Germany</i>                          |
| <b>09:45</b> | <b>How to Achieve and Ensure Regulatory Compliance</b>  | <b>Monica Unger-Bady,</b><br><i>Bayer Schering Pharma AG, Germany</i> |
| <b>10:15</b> | <b>Coffee Break and Exhibition</b>  |   |
| <b>10:30</b> | <b>Dealing with GMP Non-Compliance</b>  | <b>David Cockburn,</b> <i>EMA</i>                                     |
| <b>11:00</b> | <b>Aligning the QP Role to a Modern Pharmaceutical Industry</b>   | <b>John O'Sullivan,</b> <i>Pfizer, Ireland</i>                        |
| <b>11:30</b> | <b>Q &amp; A</b>  |   |

**Session 6: Starting Materials**

*Chair: Jacques Morénas,  
AFSSAPS, France*

- |              |  |   |
|--------------|--|---|
| <b>08:30</b> | <b>Starting Materials Regulation and Requirements for Excipients</b> | <b>Sabine Atzor,</b> <i>EU Commission</i>           |
| <b>09:00</b> | <b>Level Playing Field of APIs</b>                                   | <b>Chris Oldenhof,</b> <i>DSM, The Netherlands</i>  |
| <b>09:30</b> | <b>Which GMP Standard Should be Applied for Excipients?</b>          | <b>Janeen Skutnik,</b> <i>Pfizer, Belgium</i>       |
| <b>10:00</b> | <b>Coffee Break and Exhibition</b>                                   |   |
| <b>10:15</b> | <b>Raw Materials (API Starting Materials) for APIs</b>               | <b>Lionel Vionery,</b> <i>AFSSAPS, France</i>       |
| <b>10:40</b> | <b>Starting Materials (APIs, Excipients) for Medicinal Products</b>  | <b>Abdelaali Sarakha,</b> <i>AFSSAPS, France</i>    |
| <b>11:00</b> | <b>Atypical Actives – Which Standard Should be Applied?</b>          | <b>Brian Matthews,</b> <i>Alcon, United Kingdom</i> |
| <b>11:30</b> | <b>Q &amp; A</b>   |   |

## Session 7: GMP Inspections

Chair: **David Cockburn**, EMEA

- 08:30**      **Inspections by EU Authorities**      **Simona Raicu**, ANM, Romania
- 09:00**      **How Does Europe Ensure Consistent Interpretation of GMP Regulations Among the Various Inspectorates?**      **Emer Cooke**, EMEA
- 09:30**      **Inspections Update: Major Observations**      **Tor Gråberg**, MPA, Sweden
- 10:00**      **Coffee Break and Exhibition**
- 10:30**      **Inspectors' Expectations**      **Paul Hargreaves**, MHRA, United Kingdom
- 11:00**      **Industry Perspective of Inspections**      **John Kerridge**, Eli Lilly and Company Ltd., United Kingdom
- 11:30**      **Q & A**

## Session 8: Investigational Medicinal Products (IMPs)

Chair: **Thomas Linz**, Bayer Schering Pharma AG, Germany

- 08:30**      **GMP for IMPs (2003/94)**      **Chris Cullen**, IMB, Ireland
- 09:00**      **Requirements for APIs During Phase I - III**      **Morten Munk**, CMC Biopharmaceuticals, Denmark
- 09:30**      **Labeling and Release Management During IMP Distribution in the EU**      **Michael Djie**, F. Hoffmann - La Roche, Switzerland
- 10:00**      **Coffee Break and Exhibition**
- 10:30**      **Challenges Arising from Conducting Clinical Trials in Europe**      **Hanif Patel**, GSK, United Kingdom
- 11:00**      **Requirements for Medicinal (Drug) Products**      **Karen Ginsbury**, Pharmaceutical Consulting Israel Ltd., Israel
- 11:30**      **Q & A**
- 12:00**      **Lunch Break**

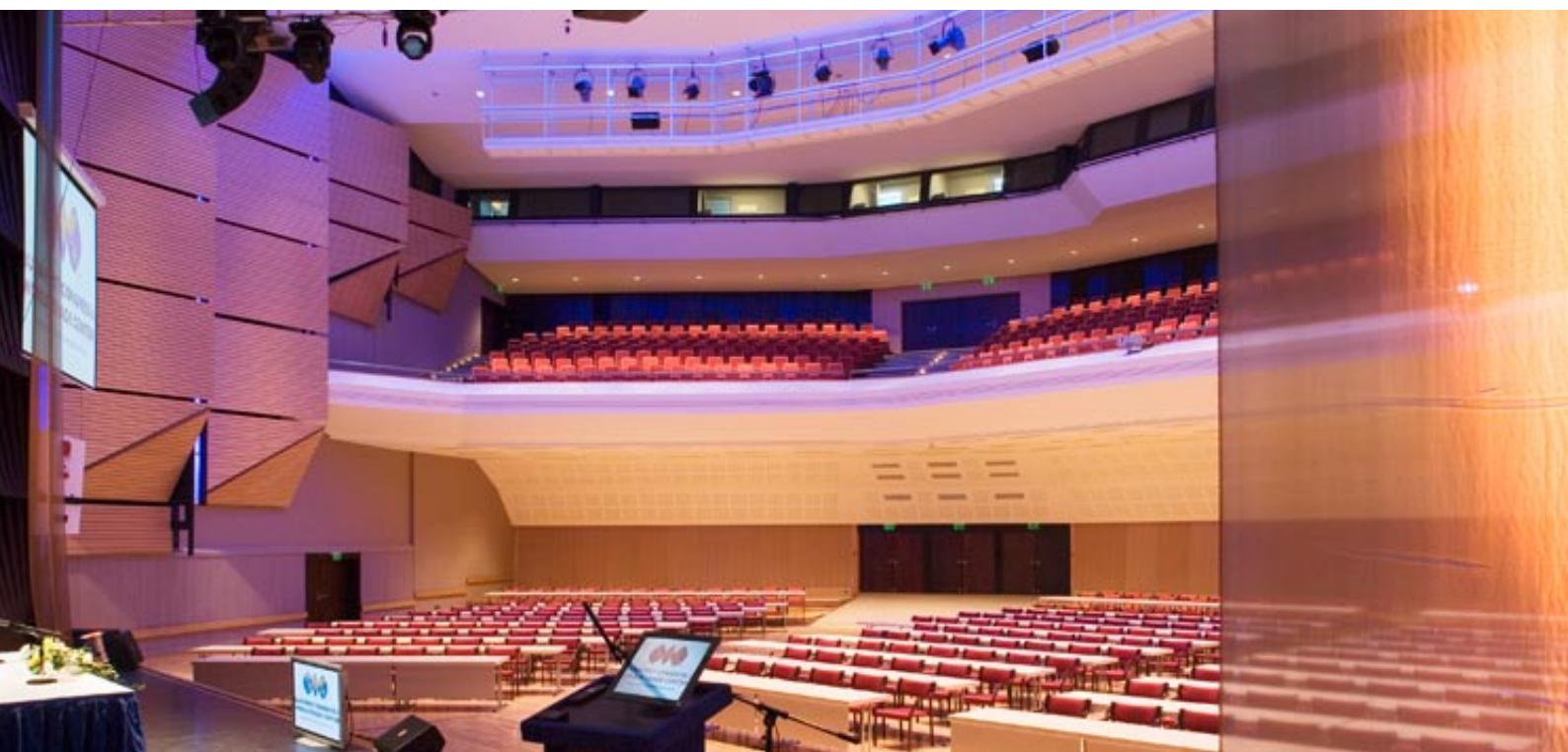
# Conference Agenda

## PLENARY SESSION 3: Looking into the Future

Chair: **Tim Marten**,  
*AstraZeneca, United Kingdom*

The closing plenary session of the conference will take a look into the pharma 'crystal ball'. The session will open with a top level view of the pharmaceutical sector in Europe, it's regulatory oversight, and the how both benefit and serve the citizens, the business and, most importantly, the patient. This will be followed by a presentation on the 'ICH Quality Strategy and Vision' by a leader in this evolving area. Finally, we will hear industry and regulatory views about the future direction and focus of the European Inspection program, and what it may look like in coming years.

- |              |  |   |
|--------------|--|---|
| <b>13:00</b> | <b>The Expectations of the Society Towards the Pharmaceutical Business</b>                               | <b>Christian Siebert</b> , <i>European Commission, DG Enterprise &amp; Industry</i> |
| <b>13:30</b> | <b>ICH Quality Strategy and Vision</b>   | <b>Jacques Morénas</b> , <i>AFSSAPS, France</i>                                     |
| <b>14:00</b> | <b>Coffee Break and Exhibition</b>   |   |
| <b>14:30</b> | <b>Future Inspections and Assessment – Industry Expectations</b>   | <b>Tim Marten</b> , <i>AstraZeneca, United Kingdom</i>                              |
| <b>15:00</b> | <b>Future Inspections and Assessment – Regulatory Discussions</b>  | <b>Regulatory Speaker from EMEA</b> ( <i>invited</i> )                              |
| <b>15:30</b> | <b>Panel Discussion:<br/>Harmonisation and Communication Efforts<br/>– Is Europe on the Right Track?</b> |   |
| <b>16:30</b> | <b>Closing Remarks</b>   | <b>Emer Cooke</b> , <i>EMA</i><br><b>Georg Roessling</b> , <i>PDA Europe</i>        |
| <b>16:45</b> | <b>End of Conference</b>   |   |



Patria Hall

Preceding the 2008 PDA/EMEA Joint Conference, the PDA Training and Research Institute (PDA TRI) is offering six training courses geared toward your professional and career development. Course topics include Drug Registration in Europe, ICH Q10 and its Impact on the Pharmaceutical Industry, and Quality System Strategies for Investigational Drugs. Please visit the Conference site for additional course listings.

## **ICH Q10 and its Potential Impact on the Pharmaceutical Industry – NEW COURSE!**

**18 February 2008** PDA #172

**09:00 – 16:30** Room: Liszt I-II

**Gabriele Gori**, *Compliance Director Europe, Bausch & Lomb SpA*

This training course focuses on the content and comments of the ICH Draft Q10 Guideline. The course will evaluate whether or not the document can be turned into practical solutions for the pharmaceutical industry. The training will provide in-depth information regarding global regulatory expectations for the design, management and inspection of modern quality systems expressed in this document. Focus will be on the challenges faced by virtual, small and large companies in developing and implementing robust quality systems compliant with this Draft Guideline. Application to drug substance and drug product – including biotechnology facilities – will be discussed.

## **Drug Registration in Europe – An Insight View – NEW COURSE!**

**18 February 2008** PDA #104

**09:00 – 16:30** Room: Lehár III

**Barbara Jentges**, *Managing Director, PhACT GmbH*

This course will provide participants with an overview of the European Registration Procedures. Particularly, the course will focus on regulatory milestones during drug development (clinical trial application, marketing authorization application), registration procedures and application types, alternative ways to submit quality data for drug substance (Certification of Suitability and Active Substance Master File), and post-authorization surveillance (handling variations, applying for an extension, renewal application, pharmacovigilance).

## **Preparing for and Passing a European or United States GMP Inspection**

**18-19 February 2008** PDA #263

**09:00 – 16:30** Room: Lehár I-II

**Michael H. Anisfeld**, *Globepharm Consulting*

GMP inspectorates from EU nations (EMEA) and from the United States (FDA) have developed tough inspection programs to assure GMP compliance in operations and laboratory testing. This course is designed to provide background and insight into the inspection processes of the EMEA and FDA, and to provide practical strategies and tactics that a company must know and implement in order to have the potential to pass an inspection the first time through. EMEA and FDA inspections have many similarities but also substantial differences. Companies need to be intimately familiar with these differences and how they impact the handling of an inspection. The course will touch on everything, and we do mean everything, you need to know to have a smooth and successful inspection.

## **Quality System Strategies for Investigational Drugs**

**18-19 February 2008** PDA #149

**09:00 – 16:30** Room: Liszt III

**Karen Ginsbury**, *President, Pharmaceutical Consulting Israel Ltd.*

This two-day course will address the FDA draft Guidance for the manufacture of drugs for Phase I trials and compare its recommendations with Annex 13 of the EU GMPs. It will equip attendees with tactics for addressing “how much” quality is necessary at each stage of the development process and how to introduce quality without antagonizing the Chief Scientific Officer and without paralyzing the system or impeding creativity. Development of a methodical, ordered but efficient and flexible system will ensure safety while allowing the company to move forward fast. The course is designed to be highly interactive with the opportunity for the audience to ask questions and to exchange views with other participants struggling with similar conundrums.

# PDA TRI Training Courses

## **Risk-Based Approach and Risk Management in Pharmaceutical Manufacturing Processes**

**19 February 2008** PDA #133

**09:00 – 16:30** Room: Liszt I-II

**Trevor Deeks**, *Director of Development, Product Development - UK, Emergent BioSolutions*

The FDA is keen to encourage companies to adopt risk management techniques in their manufacturing operations. The initiative *GMP in the 21st Century – A Risk-Based Approach* advocates the use of these techniques. This course will provide participants with a regulatory and historical background to pharmaceutical risk assessment and the use of risk assessment and risk management tools. It will be comprised of a combination of formal presentations, group exercises and group discussion sessions. Group exercises will allow attendees to learn about risk assessment tools by using them to solve hypothetical problems based on real life experiences of the course tutor. Following the risk assessment exercise, each group will be asked to develop a control philosophy to manage the risks identified.

## **Briefing Meetings, Scientific Advice / Protocol Assistance, Pre-Submission Meetings with EMEA - When to Do What and How to Prepare – NEW COURSE!**

**19 February 2008** PDA #173

**09:00 – 16:30** Room: Lehár III

**Barbara Jentges**, *Managing Director, PhACT GmbH*

This course will provide participants with an insight into the different forms of pre-submission meetings with the EMEA prior to the submission of a marketing authorization application within the centralized procedure. How and when to apply for what kind of meeting, as well as how to prepare for it will be the basis of much discussion. Scientific Advice and Protocol Assistance meetings will also be topics of focus, and participants will be able to discuss the concepts as well as differences between the two.



Connecting People, Science and Regulation®

# 2008 PDA Virus & TSE Safety Forum

In Cooperation with Paul-Ehrlich-Institut, FDA and European Health Authorities

This international conference will create a platform for discussion about the latest regulatory guidances, critical issues and new technologies in virus and TSE safety. Representatives from European Health Authorities, FDA, technology providers and the pharmaceutical industry will share their experiences and knowledge. Scientific and practical information will be presented.

**3-5 June 2008**  
**Berlin, Germany**

Conference and Exhibition

See the complete program at:

[www.pda.org/europe](http://www.pda.org/europe)

Register by  
3 April 2008  
and SAVE!

# PDA Advanced Workshop on Cleaning and Disinfection

## Cleaning and Disinfection – An Advanced Workshop

18-19 February 2008

Room: Brahms I-II

Learn how to control contamination within your classified environments with a successful cleaning and disinfection program. Attendees will discuss and learn how to choose and apply cleaners and disinfectants properly depending on the surface, environment and product, which will reduce labour costs and commodity usage. The wide range of lectures include sanitization of a Class 100/10,000 pharmaceutical cleanroom and other classified environment when performing aseptic processes, proper equipment cleaning/disinfection procedures, and validation of disinfectant performance and application. In the end, participants will gain a profound understanding that will allow them to develop validation protocols and a proper cleaning and disinfection program to suit their professional and business needs.

DAY 1	
10:00 – 11:00	<b>Registration</b>
11:00 – 11:45	<b>Basics Overview</b> Cleaning Chemistry and Cleaning Physics Cleaning Targets Designing an Effective Cleaning Cycle <b>Dusko Filipovic</b> , <i>Partikel-Messtechnik AG</i>
11:45 – 12:30	<b>Basics Overview (cont.)</b> Regulatory Requirements Documentation Issues Sampling Techniques and Analytical Methods/Residues and Limits <b>Esmail Ektefaie</b> , <i>Baxter BioScience</i>
12:30 – 13:30	<b>Lunch Break</b>
13:30 – 14:30	<b>CIP-Technology</b> <b>Stephen Trombetta</b> , <i>Veltek</i>
14:30 – 15:40	<b>Spray Applications</b> <b>Kent Milton</b> , <i>Alfa-Laval</i>
15:40 – 16:00	<b>Coffee Break</b>
16:00 – 17:30	<b>Derouging and Passivation</b> <b>Florian Andre</b> , <i>Henkel Beiz- und Elektropolier-technik GmbH &amp; Co. KG</i>
17:30 – 18:30	<b>Ask the Inspector/Ask the Consultant</b> Chair: <b>Volker Eck</b> , <i>PDA Europe</i> <b>Herbert Syrowatka</b> , <i>QSC<sup>1</sup> (Consultant)</i>

DAY 2	
08:30 – 09:15	<b>Directives and Guidelines in Relation to the Different Types of Contamination in an APA</b> <b>Peter Koger</b> , <i>Veltek</i>
09:15 – 10:00	<b>Environmental Monitoring, Viables</b> <b>Stephen Trombetta</b> , <i>Veltek</i>
10:00 – 10:30	<b>Coffee Break</b>
10:30 – 11:15	<b>Environmental Monitoring, Non-Viables</b> <b>Joerg Dressler</b> , <i>Partikel-Messtechnik AG</i>
11:15 – 12:30	<b>Aseptic Manufacturing, the Strands of the Rope</b> <b>John Lindsay</b> , <i>Aseptic Solutions</i>
12:30 – 13:30	<b>Lunch Break</b>
13:30 – 14:30	<b>Smoke Studies, Air Made Visible</b> <b>John Lindsay</b> , <i>Aseptic Solutions</i>
14:30 – 15:30	<b>People in an APA</b> <b>Peter Koger</b> , <i>Veltek</i>
15:30 – 16:00	<b>Coffee Break</b>
16:00 – 17:30	<b>Ask the Inspector/Ask the Consultant</b> Chair: <b>Volker Eck</b> , <i>PDA Europe</i> and <b>Herbert Syrowatka</b> , <i>QSC<sup>1</sup> (Consultant)</i>

<sup>1</sup>Quality Systems Consulting GmbH



## 2008

### **PDA Compendial Conference in cooperation with Ph.Eur., JP and USP**

**Conference/Exhibition: 1 - 2 April – Frankfurt, Germany**  
**Training Course: 31 March**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **2008 PDA Virus & TSE Safety Forum**

**Conference/Exhibition: 3 - 5 June – Berlin, Germany**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **2008 PDA/EBE**

#### **Biopharmaceutical Development and Manufacturing**

**Conference/Exhibition: 24 - 25 June – Dublin, Ireland**

**Training Courses: 26 - 27 June**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **2008 Pharmaceutical Freeze Drying Technology**

**Conference/Exhibition: 23 - 24 Sept – Brussels/Wavre, Belgium**

**Training Course: 25 September**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **Quality by Design**

**Conference/Exhibition: 7 - 8 October – Berlin, Germany**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **2008 PDA Visual Inspection Forum**

**Conference/Exhibition: 14 - 15 October – Berlin, Germany**

**Training Courses: 16 - 17 October**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **Pharmaceutical Cold Chain Management**

**Conference/Exhibition: 4 - 5 November – Berlin, Germany**

**Training Courses: 6 - 7 November**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **PDA/ISPE Workshop with PIC/S**

**Workshop: 13 November – Geneva, Switzerland**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

### **Mircobiology: Implementation of RMM**

**Conference/Exhibition: 18 - 19 November – Berlin, Germany**

**Training Courses: 20 - 21 November**

Contact: [info-europe@pda.org](mailto:info-europe@pda.org)

**FOR LATEST INFO: [www.pda.org/europe](http://www.pda.org/europe)**

*Subject to change*

## 2008 PDA Compendial Forum

# Future Directions of the Pharmacopoeias

**In Cooperation with Ph.Eur., JP and USP**

**1-2 April 2008**  
**Frankfurt, Germany**

Conference, Exhibition

See the complete program at:

[www.pda.org/europe](http://www.pda.org/europe)