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*PDA Europe, PIC/S and MFDS present:*

## 2015 Training Course on **GMP for APIs**

*An Experience-Based Training Course for Inspectors and API Industry  
– Applying the Requirements of ICH Q7 Accepted World-Wide*



**Simultaneous  
Korean  
translation will  
be provided**

[europe.pda.org/Seoul2015](http://europe.pda.org/Seoul2015)

**22-23 January 2015**  
Seoul | Republic of Korea

## Scientific Planning Committee

**Sang Bong Kim**, *Director, Ministry of Food and Drug Safety*

**Jeong Yeon Kim**, *Ministry of Food and Drug Safety*

**Jung Hyun Choi**, *Ministry of Food and Drug Safety*

**Kyeore Lee**, *Ministry of Food and Drug Safety*

**Mikael Le Bihan**, *ANSM, France*

**Jeffrey Hodgson**, *PIC/S Secretariat*

**Carmelo Rosa**, *PIC/S API Expert, Circle Chair*

**Stephan Rönninger**, *Amgen Europe*

**Georg Roessling**, *PDA Europe*

**Melanie Decker**, *PDA Europe*

## Contacts

For additional conference information please contact:

<b>Antje Petzholdt</b> Membership Management <b>petzholdt@pda.org</b>	<b>Membership Management</b>
	<b>Interest Group</b>
	<b>General Event Information</b>
<b>Melanie Decker</b> Director Events & Exhibitions <b>decker@pda.org</b>	<b>Presentations</b>
	<b>Speaker Biographies</b>
	<b>Event Agenda</b>
	<b>Committee Information</b>
<b>Creixell Espilla-Gilart</b> Exhibition & Sponsorship Manager Tel: +49 (0) 33056 - 23 77 14 <b>Email: espilla@pda.org</b>	<b>Exhibition Information</b>
	<b>Sponsoring Opportunities</b>

## To Exhibit:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

**Please see the Exhibition Floor Plan on our website:**

<https://europe.pda.org/>

## General Address

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

## Venue

### Courtyard by Marriott Seoul Times Square

15, Yeongjung-ro  
Yeongdeungpo-gu  
Seoul 150-798  
Republic of Korea  
Tel.: + 82-2-2638 3000

<http://www.marriott.com/hotels/travel/selcy-courtyard-seoul-times-square/>



Mobile Tagging:  
Link to PDA website, simply download any QR Code App  
and then scan this code with your Smartphone or Tablet.

API suppliers are subject to regulatory oversight, and you need to know what regulators are looking for. ICH Q7 is the international standard that many regulators use to define GMP requirements for APIs.

Learn from regulatory and industry experts at the **2015 PIC/S-PDA ICH Q7 Training** on how these requirements are being interpreted and enforced. The 2015 PDA PIC/S Q7 Training includes members of the original ICH Expert Work Group (EWG) and current Implementation Working Group (IWG) who are asked to develop Q&As to facilitate implementation.

Participants will have the unique opportunity to discuss:

- How to Implement ICH Q7 and be prepared for Inspections
- Receive Answers from API Manufacturing Site Inspectors
- GMP Principles
- Personnel, Facilities, Equipment, Cleaning
- Materials Management & Distribution
- Biotech API
- Manufacturing Controls
- Process Validation
- Quality System Elements
- Third Party Relationships

**Simultaneous Korean translation will be provided**

Simultaneous Korean translation will be provided during the workshop

12 Dec 2014

## Thursday, 22 January 2015

9:00	Welcome and Introduction	Sang Bong KIM, <i>Director, MFDS</i> Carmelo Rosa, <i>PIC/S API Expert</i> Circle Chair, <i>FDA USA</i> Georg Roessling, <i>PDA Europe</i>
Opening Plenary		Moderator: <b>Georg Roessling</b> , <i>PDA Europe</i>
09:15	South Korean Regulations How they apply to API	Jeong Yeon KIM, <i>MFDS</i>
	International Regulations on API and its Supply	Stephan Rönninger, <i>Amgen</i>
	Background, History and the Link to the ICH Quality Paradigm	Stephan Rönninger, <i>Amgen</i>
	Discussion and Expectations from the Participants	Carmelo Rosa, <i>FDA USA</i>
	Mapping of Important Sections in ICH Q7	Stephan Rönninger, <i>Amgen</i>
10:30	Coffee Break	
11:00	Commonly Identified Non-Compliance of (API) Manufacturing Sites	Carmelo Rosa, <i>FDA USA</i> Graeme McKilligan, <i>MHRA</i>
	Perspectives from API Manufacturers	Kwan Jong KIM, <i>JW Pharmaceutical</i> Cormac Dalton, <i>AbbVie</i>
	Key Messages on the Chapters Section 1: Introduction	Graeme McKilligan, <i>MHRA</i>
	Questions & Answers	
13:00	Lunch Break	
GMP Principles		
14:00	Section 2: Quality Management	Carmelo Rosa, <i>FDA USA</i>
	Section 6: Documentation and Records	Carmelo Rosa, <i>FDA USA</i>
	Questions & Answers	

## Personal, Facilities, Equipment, Cleaning

<b>Section 3: Personnel</b>	Georg Roessling, <i>PDA Europe</i>
<b>Section 4: Buildings and Facilities</b>	Georg Roessling, <i>PDA Europe</i>
<b>Section 5: Process Equipment and Cleaning</b>	Graeme McKilligan, <i>MHRA</i>

**15:30**      **Coffee Break**

## Materials Management & Distribution

<b>16:00</b>	<b>Section 7: Materials Management</b>	Graeme McKilligan, <i>MHRA</i>
	<b>Section 10: Storage and Distribution</b>	Carmelo Rosa, <i>FDA USA</i>
	<b>Questions &amp; Answers</b>	
<b>17:00</b>	<b>Implementing the FMD: Changes to the EU Regulatory Framework for APIs &amp; Questions</b>	Patrizia Tosetti, <i>European Commission</i>

**17:30**      **End of First Day**

## Friday, 23 January 2015

### Biotech API

<b>9:00</b>	<b>Section 18: Specific Additional Guidance for APIs by Cell Culture/Fermentation</b>	Cormac Dalton, <i>AbbVie</i>
	<b>Questions &amp; Answers</b>	

### GMP for Clinical Trials

<b>9:30</b>	<b>Section 19: APIs for Use in Clinical Trials</b>	Stephan Rönninger, <i>Amgen</i>
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### Manufacturing Controls

<b>10:00</b>	<b>Section 8: Production and In-Process Controls</b>	Cormac Dalton, <i>AbbVie</i>
	<b>Section 9: Packaging and Labeling</b>	Georg Roessling, <i>PDA Europe</i>
	<b>Section 11: Laboratory Controls</b>	Cormac Dalton, <i>AbbVie</i>
	<b>Questions &amp; Answers</b>	

**11:00**      **Coffee Break**

# TRAINING COURSE AGENDA

## Quality System Elements

11:30	<b>Section 14: Rejection, Reuse, Reprocessing</b>	Graeme McKilligan, <i>MHRA</i>
	<b>Section 15: Complaints and Recalls</b>	Carmelo Rosa, <i>FDA USA</i>
	<b>Questions &amp; Answers</b>	
	<b>Section 12: Process Validation</b>	Stephan Rönninger, <i>Amgen</i>
	<b>Section 13: Change Control</b>	Stephan Rönninger, <i>Amgen</i>
	<b>Questions &amp; Answers</b>	

## 13:30 Lunch Break

## Third Party Relationships

14:15	<b>Section 16: Contract Manufacturing</b>	Carmelo Rosa, <i>FDA USA</i>
	<b>Section 17: Agents, Brokers, Traders, Distributors, Repackers and Relabellers</b>	Graeme McKilligan, <i>MHRA</i>
	<b>Questions &amp; Answers</b>	

## Closing Plenary

15:00	<b>Panel Discussion</b>	All Speakers
15:50	<b>Closing Remarks</b>	Georg Roessling, <i>PDA Europe</i>
16:00	<b>End of Training Course – Networking Coffee /Tea</b>	

Co-funded by the European Commission





**Sang Bong Kim**, *Director, Ministry of Food and Drug Safety (MFDS)*

Sang Bong Kim is the Director of Pharmaceutical Quality Division of Pharmaceutical Safety Bureau in Ministry of Food and Drug Safety (MFDS). He has been working at the Ministry of Food and Drug Safety since 1996. He got his Bachelor's Degree in Manufacturing Pharmacy and Master's Degree in Pharmacy from Seoul National University.



**Jeong Yeon Kim**, *PhD, Senior GMP Inspector and Deputy Director Ministry of Food and Drug Safety (MFDS)*

Jeong Yeon Kim is Senior GMP inspector and Deputy Director for Pharmaceutical Quality Division in Ministry of Food and Drug Safety (MFDS). She has been working for MFDS since 1999. Her education background is Pharmacy and Biology (Bachelor degrees), as well as Business (MBA) and Public Health (MPH). She has a doctorate degree in Pharmacy (Ph.D).



**Kwan Jong Kim**, *Senior Manager, Chief of QA Department II, APIs Production Division, JW Pharmaceutical*

Kwan Jong KIM got his Bachelor's Degree of Chemistry from Korea University in February 1993. He joined JW Pharmaceutical Corporation in 1994 and has approximately a 20-year experience since then. He has 9-year experience in troubleshooting and technology transfer from laboratory to sites of new products (mainly cephalosporin and penem APIs), 3-year experience in national license and approval, Qualification and Validation in a QA team, and 3-year experience in general GMP-related tasks as a QA Manager. He was a manager and a director of the Aseptic Synthesis Team for 2 years since 2009 and a senior manager and director at the same time of the Quality Technology Team for 3 years since 2011, and is currently working as a senior manager at the Shihwa site of JW Pharmaceutical since 2014.



**Cormac Dalton**, *PhD, Director of Quality and Compliance AbbVie Pharmaceuticals*

Cormac Dalton graduated from University College Dublin with a PhD in Organic Chemistry. His PhD was based upon the catalytic asymmetric synthesis using organometallic Chromium complexes. He worked in the pharmaceutical industry over a period of 5 years prior to joining the Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board. Whilst working at HPRA, Cormac acted as an inspector of manufacturers and distributors of active pharmaceutical ingredients (APIs) and medicinal products. He was a member of the Steering Committee of the PICS Expert Circle on APIs responsible for the planning and execution of training programs to regulatory agencies worldwide. In August 2014, Cormac joined AbbVie Pharmaceuticals as Director of Quality and Compliance. He continues to work with PIC/S and PDA in the delivery of training on APIs to global audiences.



**Graeme McKilligan**, *Senior GMDP Inspector, UK Medicines and Healthcare Products Regulatory Agency (MHRA)*

Graeme McKilligan is a Senior GMDP Inspector within the Inspection Enforcement and Standards Division at the UK Medicines and Healthcare Products Regulatory Agency (MHRA) having joined the agency in 2005. Graeme performs inspections in the UK and overseas across a wide range of pharmaceutical manufacturing and import activities, but specialises in Active Pharmaceutical Ingredient inspections and chairs the MHRA starting materials specialist group. Graeme was a member of the PIC/S team that produced a Q&A document on PIC/S GMP Part II and is representing PIC/S on the ICH IWG preparing a Q&A document on ICH Q7. Graeme has also recently represented MHRA on the revision of EU GMP chapters 3 & 5. He has a degree in chemistry and is a Chartered Chemist. Before joining MHRA he worked in the active pharmaceutical industry and the medical device industry in a variety of Quality Assurance and Quality Control management roles.



**Stephan Rönninger**, *PhD, Amgen Europe*

Stephan Rönninger holds a PhD and an engineering degree in organic chemistry. After his postdoctoral studies he worked for F. Hoffmann-La Roche 1992 - 2013 in an API manufacturing site and in the Global Quality organization. Since 2013 he is with Amgen providing leadership, support and representation of external activities impacting Amgen's operations functions. Stephan works with associations in the EU, Japan and Emerging Markets. He is responsible for advocacy in various external organizations and provides assessment and communication to Amgen. In PDA he is a member of the Board of Directors, past chair of the RAQAB, leader of the PDA-Europe Inspections Trends Interest Group and co-chair of several international conferences and training courses (e.g. with PIC/S). Stephan is one of the founders and co-chair of the PCMO project. He also represents Amgen in the industry trade association EFPIA and the European Industry on GMP/GDP topics as well as at ICH working groups such as ICH Q9, Q-IWG, and the ICH Q7-IWG.



**Carmelo Rosa**, *PsyD, PIC/S API Expert Circle Chair and Director, Division of International Drug Quality, United States Food and Drug Administration (US FDA), USA*

Carmelo Rosa has a B.S., M.S., Psy.D. He started with the FDA in May 1990 as an Investigator for the Los Angeles District. Mr. Rosa later transferred to the San Juan District, where for 13 years he served as a pharmaceutical drug Investigator and 6 years as a Compliance Officer. He is member of the foreign drug inspection cadre. He has conducted many inspections of complex pharmaceutical inspections and other commodities regulated by the FDA that have resulted in significant regulatory actions initiated by the FDA. In August 2008 relocated to Maryland to work for CDER as Compliance Officer. In 2009 he was promoted to Team Leader at CDER/DMPQ/OC/ICB, and then to Branch Chief for the International Compliance Branch. He currently serves as the Director for the Division of International Drug Quality. Mr. Rosa is also an invited Professor at the University of Puerto Rico, School of Law, where he teaches a course on Federal Regulations Enforced by FDA and a General Overview to the FD&C Act. He works very closely with International Regulatory Authorities in different collaboration initiatives, and is also responsible for the evaluation of all GMP inspection reports of foreign pharmaceutical manufacturers and testing facilities. He is also one of FDA's representatives at PIC/S.



**Patrizia Tosetti**, *PhD, Policy Officer, European Commission, DG Health and Consumers, Unit D6 Medicinal Products – Quality, Safety and Efficacy*

Patrizia Tosetti works as Policy Officer in the Directorate General for Health and Consumers of the European Commission. Her duties include the regulatory supervision of issues related to quality and safety of medicines, such as the implementation of the Falsified Medicines Directive, as well as contributing to European health policy. Before joining the European Commission in 2005, Tosetti received her degree in Pharmaceutical Chemistry and a PhD in Neurophysiology from the University of Pavia, Italy. After her studies, she worked at Tufts University, Boston (USA), and at the INMED Institute, Marseilles (France), before becoming a principal investigator for the French Medical Research Institute (INSERM) in Montpellier, France.



**Georg Roessling**, *PhD, Senior Vice President, PDA Europe*

Georg Roessling is a trained Chemist who graduated from the University of Karlsruhe, Germany. After he had received his PhD, he went to Berkeley, USA to work as a post-doc in Chemical Engineering. After that, he held different positions at Schering AG, Germany. As Head of Pharmaceutical Development of Parenterals, Georg was responsible for formulation and process development, clinical trial material preparation as well as transfer to production. Prior to this, Georg was in charge of the Global CMC Technology Office and during this time, he was granted more than 50 patents. Of these, more than ten products went into development and reached the market. Georg joined PDA as Senior Vice President of the European office in 2006. Since then, he has been leading the team of PDA Europe.



# PIC/S-PDA Training Course GMP for APIs (ICHQ7)

22-23 January 2015 | Seoul | Republic of Korea

Your Contact Person is  
Antje Petzholdt at PDA Europe  
[petzholdt@pda.org](mailto:petzholdt@pda.org)

## 4 WAYS TO REGISTER

- 1 **ONLINE:** [europe.pda.org/Seoul2015](http://europe.pda.org/Seoul2015)
- 2 **FAX:** +49 33056 23 77 77
- 3 **EMAIL:** [petzholdt@pda.org](mailto:petzholdt@pda.org)
- 4 **MAIL:** PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

## 1 Your Contact Information

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

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

## Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

## 2 Registration

No PDA membership included

A limited number of **free registrations for regulators** will be made available to regulators on a first come, first served basis, thanks to support from the EU Commission. For inquiries, please contact [petzholdt@pda.org](mailto:petzholdt@pda.org).

All fees given in Euro

### Training Course (22-23 January)

All Participants

☐ 500

Regulators

☐ 250

The fee includes course documentation as well as mid-session refreshments and lunch. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

## 3 Payment Options

☐ By Credit Card (one week prior to event)

☐ American Express

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For your credit card information safety:

Please send your details by fax only (+49-33056-23 77 77) or register online.

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Address:

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Date

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**CONFIRMATION:** Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** You must have a written confirmation (including invoice) to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. Payment must be received or guaranteed by Purchase Order or credit card details on 1st day of event, at the very latest. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **22 December 2014**, 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. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe work PCI-Compliant. **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](mailto:info-europe@pda.org) or fax to +49 (33056) 23 77 77. **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.



# Helpful Hints When Registering for PDA Europe Events

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### 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 Do not 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 VAT ID number if European-based Company

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. Changes in the billing address (if induced by participating company) will be charged 25,- € if imposed 3 weeks prior to the start of the event.

### 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 if payment had been done by credit card and details are available. Refunds to bank accounts can be done if payment had been done by bank transfer and the following details are provided:

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

### 9 Substitutions

If a participant is unable to attend, substitutions are welcome at any time. Changes are free of charge until 3 weeks prior to the start of the event. After this date, there will be a charge of € 50 per name change.

### 10 For assistance contact: Antje Petzholdt, PDA Europe

**Tel: +49 (0)33056 2377-10**

**Email: petzholdt@pda.org**

## THANK YOU FOR YOUR COOPERATION!

*The Parenteral Drug Association presents...*

# PDA Europe Upcoming Activities and Events

## 2015

22-23 January	Extractables & Leachables	Workshop	Seoul Republic of Korea
22-23 January	GMP for APIs (ICHQ7)	Training Course	Seoul Republic of Korea
17-18 February	Pharmaceutical Microbiology	Conference, Exhibition	Berlin Germany
3-4 March	Parenteral Packaging	Conference, Exhibition	Frankfurt/Main - Bad Soden Germany
14-15 April	Aseptic Manufacturing	Conference, Exhibition	Berlin Germany
2-3 June	Advanced Therapy Medicinal Products	Conference, Exhibition	Amsterdam The Netherlands
9-11 June	Virus/ TSE Safety Forum	Conference, Exhibition	Lisbon (Cascais) Portugal
23-24 June	Quality & Regulation Conference	Conference, Exhibition	Brussels Belgium
15-16 September	Pharmaceutical Freeze Drying Technology	Conference, Exhibition	Munich Germany
22-23 September	8 <sup>th</sup> Workshop on Monoclonal Antibodies	Workshop, Exhibition	Berlin Germany
6-7 October	Pharmaceutical Cold & Supply Chain Logistics	Conference, Exhibition	Amsterdam The Netherlands
3-4 November	The Universe of Pre-filled Syringes & Injection Devices	Conference, Exhibition	Vienna Austria

For latest info: <https://europe.pda.org>

Subject to change

Shortlist 12 Dec 2014

**Additional training courses will accompany most conferences. For details, please use the QR-Code or go to [www.europe.pda.org](http://www.europe.pda.org)**

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**For general information  
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PDA Europe, Adalbertstr. 9  
16548 Glienicke / Berlin, Germany  
Tel: +49 (0) 33056 - 23 77 10  
Fax: +49 (0) 33056 - 23 77 77  
Email: [info-europe@pda.org](mailto:info-europe@pda.org)

**For exhibition information  
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