PIC/S and PDA Europe present...

GMP for APIs

in co-operation with MCC / South Africa

An Experienced Based Training Course for Inspectors and API Industry Applying the World Wide Accepted Requirements of ICH Q7

18-19 March 2014
Johannesburg
South Africa

TRAINING COURSE 18-19 March

https://europe.pda.org/GMP2014

Information

Core Team

Joey Gouws, *PIC/S Chair person, MCC / South Africa*
Stephan Rönninger, *Amgen*
Patrizia Tosetti, *European Commission*
Carmelo Rosa, *US FDA / USA*
Oege (Sjef) Jellema, *IGZ / The Netherlands*
Henry Martin John Leng, *MCC / South Africa*
Mikael Le Bihan, *ANSM / France*
Jeffrey Hodgson, *PIC/S Secretariat*
Miranda Viljoen, *PSSA, South Africa*
Georg Roessling, *PDA Europe*
Melanie Decker, *PDA Europe*

Who Should Attend

Regulators: New API Inspectors or Inspectors wishing to familiarise with API Inspections
Industry: Manufacturer of APIs and support functions – QC | QA Engineering | Development and Production Functions Audit functions | Purchasing
Overall: It´s for people who deal with APIs

Venue

Radisson Blu Gautrain Hotel
Sandton Johannesburg
Cnr Rivonia Road and West Street
Johannesburg
South Africa
Phone +27 (11) 286 1000
www.radissonblu.com

Special rates

Double room for single use **Rand 1850***
* Rates per room and night
Buffet breakfast and VAT included.

Room Reservations

PDA has secured a limited number of rooms at a special group rate until **31 January 2014.**
Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

Contacts

For additional conference information please contact:
PDA Europe gGmbH
Adalbertstr. 9
16548 Glienicke/ Berlin, Germany
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Fax: +49 (0) 33056 - 23 77 77
info-europe@pda.org

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For exhibition information please contact:
Elke von Laufenberg
Exhibition & Sponsorship Manager PDA Europe
Tel: +49 (0) 33056 - 23 77 14
Email: laufenberg@pda.org

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3. The data requested will be displayed on your screen

Facilitator Biographies

Joey Gouws, *PhD, PIC/S Chairperson*
National Medicines Regulatory Authority, Medicines Control Council (MCC) and Department of Health, South Africa

Joey Gouws is appointed as the Deputy Registrar of Medicines by the Minister of Health to support the work of the Medicines Control Council on the registration of medicines. In addition, she services as a councilee on the South African Pharmacy Council to oversee the provision of quality pharmaceutical services and care to the public. Within the the National Depratment of Health, Cluster Medicines Regulatory Affairs she is appointed as the Director: Inspectorate and Law Enforcement heading the national medicines inspectorate. Within the international pharmaceutical industry she holds the portfolio of Deputy Chair of the Pharmaceutical Inspection Cooperation Scheme (PIC/S); an association for national medicine inspectorates world-wide, with head office, Geneva, Switzerland. Since 2001 she represents South Africa at the Wold Health Organisation's (WHO) Developing Country Vaccine Regulatory Network.
Her academictions include:
MBA (GIBS, University of Pretoria)
PhD (University of Potchefstroom)
MPharm (University of Potchefstroom)
Honns BSc, Pharmacology (University of Potchefstroom)
Bachelor of Pharmacy (University of Potchefstroom)
Bachelor of Science, Zoology & Physiology ((University of Potchefstroom)
Her working experience includes all sectors of pharmacy across both the private and public sectors. She joined the Department of Health, Medicines Inspectorate in 1993 with her current responsibilities managing the medicine inspectorate relating to Good Manufacturing, Wholesaling, and Clinical trials inspections, licencing of medicine manufactueres and wholesalers and overseeing compliances with the Medicines and Related Substances Act, 1965 including border control, counterfeit and sub standard and falsified medicine investigations, advertising enforcement and medicine quality control relating to medicine recalls, post marketing pharmacovigilence and control over South Africa's use of narcotic and phycotropic substances.

Stephan Rönninger, *PhD, Amgen*

Stephan Rönninger holds a PhD and 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 he provides leadership, support and represent of external activities impacting Amgen's operations functions. He 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-chairs several international conferences and training events (e.g. with PIC/S). He is one of the founders and co-chair of the PCMO project. He also represents Amgen in 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.

Oege (Sjef) Jellema,
MScPharm Coordinating/Special Senior Inspector at the Dutch Health Care Inspectorate (IGZ), The Netherlands

In his present position at the Dutch Health Care Inspectorate (Inspectie voor de Gezondheidszorg (IGZ)) as Coordinating/Special Senior Inspector, he is conducting GMP inspections at pharmaceutical companies with a focus on biotechnological companies and Active Pharmaceutical Ingredients (API) manufacturers. Due to the internationalization of the pharmaceutical industry, IGZ carries out GMP inspections both in the Netherlands and increasingly abroad, like the USA, China and India. Apart from holding inspections, an important task is the handling and coordination, if needed, of notifications taken in by the central Information Office (Meldpunt IGZ). These notifications have a very diverse nature such as complaints/recalls of pharmaceutical products, counterfeit medicines, etc. From 1988 onwards, he held various positions in the field of Quality Assurance/Quality Control and Production of both human and veterinary medicines and medical devices. Working for a number of innovative, world-wide operating pharmaceutical companies, he gained a lot of experience in the deployment of Quality Management Systems (Good Manufacturing Practices, Good Laboratory Practices, ISO/IEC 17025, ISO 9001, ISO 14001).

Henry Martin John Leng, *M.Pharm, PhD, MBA, Medicines Control Council (MCC), South Africa*

Henry M. J. Leng is a senior research scientist in the School of Public Health at the University of the Western Cape and is registered as pharmacist with the South African Pharmacy Council. He serves on the Medicines Control Council (MCC) and the Executive Committee of the Academy of Pharmaceutical Sciences. He is also an expert member of the Pharmaceutical & Analytical Committee and Biological Medicines Committee of the MCC. He holds undergraduate degrees in Science and Pharmacy from the University of the Western Cape, and postgraduate degrees from the University of Stellenbosch and the University of Cape Town. His postdoctoral work was done at the Katholieke University of Leuven in Belgium. He has published papers in international journals in areas such as anaemia, inflammation and thrombosis and has also presented his research at both national and international conferences. His current research interest is in the area of medicines regulation and access to medicines in developing countries and he is a collaborating member of a research group funded by the European Union Seventh Framework Programme under the title 'Access to Medicines in Africa and South Asia [AMASA]'. The project team includes partners at the University of Edinburgh (UK), Foundation for Research in Community Health (India), University of Ghent (Belgium), Mbarara University of Science and Technology (Uganda), Makerere University (Uganda), Queen Mary University London (UK), Swiss Tropical and Public Health Institute at the University of Basel (Switzerland) and the University of the Western Cape (South Africa).

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

Patrizia Tosetti, PhD, 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*

Dr. 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.

Tuesday, 18 March 2014

9:00	**Welcome & Introduction**	Joey Gouws, *PIC/S Chair, MCC, South Africa* Georg Roessling, *PDA Europe*
Opening Plenary		*Moderator:* **Georg Roessling**, *PDA Europe*
9:15	**International Regulations an API´s and its supply Falsified Medicines and API import, ICH, WHO**	Stephan Rönninger, *Amgen*
	Europeen Regulations an APIs presented by the EU Commission	Patrizia Tosetti, *Europeen Commission*
	Regulations of South Africa and the South African nations regarding APIs	Joey Gouws, *PIC/S Chair, MCC, South Africa*
	Mapping of important Sections in ICH Q7	
10:30	Coffee Break	
	Commonly Identified Non-Compliances of (API) Manufacturing Sites	Carmelo Rosa, *US / FDA, USA* Sjef Jellema, *IGZ, The Netherlands*
	Discussion and Expectations from the Participants	
	Background, History and the Link to the ICH Quality Paradigm	Stephan Rönninger, *Amgen*
	Key Messages on the Chapters Section 1: Introduction	Stephan Rönninger, *Amgen*
	Q&A	
13:00	Lunch Break	
GMP Principles		
14:00	**Section 2: Quality Management Section 6: Documentation and Records**	Carmelo Rosa, *US / FDA, USA*
	Q&A	
Personal, Facilities, Equipment, Cleaning		
	Section 3: Personnel Section 4: Buildings and Facilities Section 5: Process Equipment and Cleaning	Georg Roessling, *PDA Europe*
	Q&A	
15:30	Coffee Break	
Materials Management & Distribution		
16:00	**Section 7: Materials Management Section 10: Storage and Distribution**	Carmelo Rosa, *US / FDA, USA*
	Q&A	
	Short Break- **Attendees not involved in Biotech APIs may leave**	
Biotech API		
17:00	**Section 18: Specific Additional Guidance for APIs by Cell Culture/Fermentation**	Henry Leng, *MCC, South Africa*
	Q&A	
18:00	End of First Day	

Wednesday, 19 March 2014

Manufacturing Controls:		
9:00	Section 8: Production and In-Process Controls Section 9 :Packaging and Labeling Section 11: Laboratory Controls	Georg Roessling, *PDA Europe*
	Q&A	
10:00	Coffee Break	
Quality System Elements:		
10:30	Section 14: Rejection, Reuse, Reprocessing Section 15: Complaints and Recalls	Sjef Jellema, *IGZ, The Netherlands*
	Q&A	
	Section 12: Process Validation Section 13: Change Control	Stephan Rönninger, *Amgen*
	Q&A	
12:30	Lunch Break	
Third Party Relationssships:		
13:15	Section 16 : Manufacturing Section 17 : Agents, Brokers, Traders, Distributors, Repackers and Relabellers	Sjef Jellema, *IGZ, The Netherlands*
	Q&A	
Closing Plenary:		
14:00	Panel Discussion	All Speakers
15:00	Closing Key Messages, Summary	Stephan Rönninger, *Amgen*
15:15	Closing Plenary: Future of Implementation	All Speakers
15:50	Closing Remarks	Georg Roessling, *PDA Europe*
16:00	End of Conference – Networking Coffee /Tea	

PDA Parenteral Drug Association

2014 PDA Europe-PIC/S Training Course
GMP for APIs
18-19 March 2014 | Johannesburg | South Africa

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1. **ONLINE: https://europe.pda.org/GMP2014**
2. **FAX: +49 33056 23 77 77**
3. **EMAIL: petzholdt@pda.org**
4. **MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany**

Your Contact Person is Antje Petzholdt at PDA Europe

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- 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 Conference Registration

All fees given in Euro and excluding VAT (14 %)

Training Course (18-19 March 2014)

Regulators	☐ **150**
Industry Delegates	☐ **495**

(No PDA membership included)

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9 Substitutions

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10 For assistance contact: Antje Petzholdt, PDA Europe

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

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