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Worldhotel Bel Air
The Hague, Netherlands
7 – 9 September 2015

1st Annual GMP By The Sea *Europe*

PLUS OPTIONAL 2-DAY PROGRAM:
Inspections of Pharmaceutical – Biopharmaceutical Operations to FDA Standards – Europe

Conference produced by

PHARMA CONFERENCE INC

Conference sponsored by

NIPTE The National Institute for Pharmaceutical Technology and Education
Improving quality and lowering costs of pharmaceuticals

ABOUT THE CONFERENCE

GMP by the Sea has been the preeminent GMP conference in the US for 20 years and is now coming to Europe to provide you the most up-to-date information from leading Regulatory Authorities (EMA, HPRA, MHRA, & FDA) and industry experts. You can expect the same outstanding conference that attendees at the US conference have come to expect; the same networking opportunities with industry colleagues; and the same access to high-ranking Regulators from the world's regulatory authorities. You will be able to attend our networking reception on Monday and our unbelievable Tuesday social where you will be treated to some of the best cuisine Den Haag has to offer.

Being in compliance with cGMPs means more than meeting the stated requirements of the European GMPs or the FDA's 21 CFR 211. It means understanding your manufacturing process well enough to recognize its strengths and weaknesses. It means being aware of what should be done on an ongoing basis to maintain the compliant status. It means understanding that the "c" in "GMP" means "current."

Our conference this year will focus on multiple aspects of cGMPs that will have immediate impact on your business. Our regulatory focus will be on the ongoing harmonization in evidence between the US and Europe and the higher profile role being assumed by PIC-S in the harmonization activities. We will focus on the major reorganization at the Center for Drug Evaluation and Research (CDER) that will affect both the review and inspection of drug product manufacturing sites. We will discuss the high impact data integrity issues so prevalent in the news today. Industry speakers will also address these issues while also focusing on other critical issues such as the recent EFPIA Inspection Survey and the increased concerns regarding Corporate Quality Systems.

Our always popular workshops provide you 10 different opportunities to select technical topics to explore in depth with your colleagues. To afford the greatest learning opportunity, each is offered twice to permit you to customize your learning experience during four different sessions. We encourage your company to send at least three delegates so that all possible workshops may be attended.

This year, as in the past, interaction with the regulatory authorities will be one of our best tools for learning. Besides the usual opportunities to ask questions in plenary sessions, we also offer numerous opportunities for interaction and networking to help you meet others from both Industry and FDA. A formal networking reception on Monday and an evening dinner on Tuesday will provide opportunities to exchange ideas and have your questions addressed by FDA and Industry colleagues.

WHO SHOULD ATTEND?

- Regulatory Affairs Professionals
- Quality Assurance Professionals
- Production Managers and Personnel
- Corporate Officers of Pharmaceutical and Biopharmaceutical Companies
- Financial Analysts Covering Pharmaceuticals

…basically, anyone involved with GMP matters related to pharmaceuticals or biopharmaceuticals

WHY ATTEND?

- To discuss "hot" topics with FDA officials
- To get FDA's latest thoughts on GMP matters
- To ask your questions and receive specific answers
- To interact with your peers on GMP matters
- To take valuable knowledge learned at the conference back to your company
- To network and interact with all regulatory officials present

Register online at www.pharmaconference.com

THE SPEAKERS

Johanna Berberich, PhD – Dr. Berberich is in Global GMP/GDP Audit Management for Bayer HealthCare AG. She has been with Bayer since 1990 in a variety of positions, including Galenical Development Solid Oral Dosage Forms, GMP-Manager for Clinical Supply plant, QA-Manager Contract Manufacturing (Germany), Head of Contract Manufacturing (Germany) and Global QA: GMP/GDP Audit Management.

Gary Bird, PhD – Dr. Bird is currently President, PharmaConsult-US, LLC, and Managing Partner, PharmaConsult Global, Ltd., an international cooperative supplying GXP quality consulting services. He served as Director of Corporate Quality for GTx, Inc. (Memphis, TN, USA) from 2003 until 2013 and was responsible for confirming all non-clinical (GLP), manufacturing (GMP), and clinical trial (GCP) related activities were conducted in compliance with appropriate laws and regulations. He has held previous positions with Eli Lilly and the FDA where he represented both PhRMA and the FDA in the International Conference on Harmonization negotiations on four (4) different agreed guidances.

Mark Birse, BSc, MSc – Mr. Birse is the Group Manager for the MHRA Inspectorate, which is comprised of over 80 Inspectors covering GCP, GDP, GLP, GMP & GPvP. He is a chemistry graduate with an MSc in pharmaceutical sciences and is a Fellow of the Royal Society of Chemistry. Prior to Mr. Birse joining the MHRA in 2002 as a GMP Inspector, he worked in the pharmaceutical industry for over 10 years in a variety of roles including process technology, technology transfer, new product introduction and quality assurance. He is eligible to be named as a Qualified Person.

Clive Blatchford – Mr. Blatchford is Vice President Quality within GSK Vaccines, responsible for the company's Belgium manufacturing sites. Before joining GSK, he held several Quality positions in biologicals and pharmaceuticals companies (Ipsen, Sanofi Pasteur, Aventis, Rhône-Poulenc Rorer, etc.). Mr. Blatchford has extensive experience in Quality, EHS and Manufacturing Systems for all pharmaceutical dose forms (API and drug product, particularly injectables and biologicals), as well as in the management of UK, European and FDA communications and inspections at corporate and strategic site levels. He is a Microbiologist and an Operational Excellence champion and is also recognized as an EU Qualified Person.

David L. Chesney, BS – Mr. Chesney is the Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting (then known as KMI) in 1995, he served 23 years with the FDA. Since joining PAREXEL, Mr. Chesney has provided compliance consulting and training services to clients worldwide. He presently heads PAREXEL's Strategic Compliance Consulting group, providing services to the pharmaceutical, medical device and biotechnology industries, and the Food and Drug legal community.

Graham Cook, PhD, BPharm – Dr. Cook is the Senior Director, Global Quality Operations and currently the team leader for Pfizer's Global Quality Intelligence and Compendial Affairs group working on regulatory intelligence and external engagement for Quality-CMC topics. He represents Pfizer in Efpia's Technical Development and Operations Committee and is the Efpia lead in the ICH Q12 Product Lifecycle Management Expert Working Group. He is a past chair of Pfizer's QbD Council and has been involved with QbD/ PAT initiatives for 10 years. Dr. Cook was appointed to the British Pharmacopoeia Commission in 2010 and chairs the MC2 Expert Advisory Group and the QbD Working Party. In 2012, he was elected Chairman of the ASTM International E55 Technical Committee developing pharmaceutical manufacturing standards. Previous roles include supporting Wyeth's European manufacturing operations and Director Formulation Development for Wyeth Consumer Healthcare in Richmond, Virginia, USA. He is a pharmacist with a Ph.D. in pharmaceutics.

Robert Darius, BS – Mr. Darius is Head of Quality Advocacy and Stakeholder Engagement in GSK Vaccines. Previously, he was Vice President Quality Unit in GSK Vaccines, responsible for the North American and German manufacturing sites. Prior to joining GSK, he started Radius Biotechnology, LLC, a biotechnology consulting firm. Mr. Darius served in the FDA Center for Biologics Evaluation and Research for 15 years as Lead Reviewer & Inspector, teaching review science and inspection skills to both CBER and Team Biologics personnel. He also served as Special Assistant on Counter Bioterrorism issues, reporting to the CBER Director. Mr. Darius is a Microbiologist by training.

David Doleski, BS – Mr. Doleski, Acting Deputy Director, OPF, OPQ, has been with FDA for 24 years. He most recently served as director of the Division of Good Manufacturing Practice Assessment, which is responsible for overseeing the pre-approval inspection program for new and generic drugs, and reviews and inspections for biologic products. He was an acting branch chief and team leader in CBER's Division of Manufacturing and Product Quality. As a reviewer and inspector, he performed numerous CMC reviews and pre-approval inspections for biologic drug substances and drug products. He also served as an acting team leader in the Office of Legislation in the Office of the Commissioner.

David Elder, BS – Mr. Elder joined PAREXEL Consulting in January 2012 after a career that spanned over 23 years with the FDA. He is an expert in FDA field operations, including domestic and international inspections and investigations, product recalls, enforcement actions, and imports. He has a thorough and pragmatic understanding of agency law, regulations, policies, and procedures. Since joining PAREXEL, Mr. Elder has helped clients with development and communication of corrective action plans in response to FDA findings. He has audited manufacturing sites around the world – finished pharmaceuticals (including aseptic processing operations), APIs, and medical devices – assessing compliance against regulations and standards, providing recommendations for corrective actions, interviewing site officials and issuing detailed audit reports.

Mark Elengold, BA – Mr. Elengold is President of FDA Strategies LLC, which provides consulting services to FDA regulated industry and the financial community. He retired as the Deputy Director of the FDA's Center for Biologics Evaluation and Research after 34 years of service. He is an expert and frequent speaker on regulatory and compliance activities, Good Manufacturing Practices (GMPs), and FDA application review procedures, including electronic submissions.

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THE SPEAKERS

Nigel Hamilton, BSc – Mr. Hamilton is Head of Global Quality External Affairs for Sanofi in Paris. He works within Sanofi's Global Quality function focusing on external affairs and strategic projects. He has more than 40 years experience working within the Pharmacaeutical Industry. He has held a number of site and corporate management positions within Manufacturing and Quality Operations. He was a member of the EFPIA team at the ICH Implementation Working Group for ICH Q8, Q9, and Q10, and was also a member of the EFPIA ICH Q9 Risk Management working group. In addition, he is a member of the EFPIA Technical Development and Operations Committee.

Paul Hargreaves, MSc – Mr. Hargreaves is an Expert Medicines Inspector who spent 12 years in the pharmaceutical industry prior to joining MHRA in 1986. He has inspected most types of medicines, from herbals to biotechnology medicines both in the UK and overseas. For the past two years, Mr. Hargreaves has worked as liaison manager between the Inspection Group and the Enforcement Group.

John Hyde, BS, BBA, MS – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. The company has operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. From 1982 to 1992, Mr. Hyde was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.

John DR Jolley, FR Pharm S, FCQI CQP.RSC. – Mr. Jolley is a Pharmaceutical Consultant providing technical consultancy and training in European countries, the Middle East, South Africa and the USA. He is a practicing pharmacist who has held positions in Clinical Research, Product Registration, Manufacturing, Quality Assurance, and General Management. He is a practicing Qualified Person (QP) for pharmaceutical manufacturing, Distribution and Clinical Research organizations and is an Industry representative on the EMA advisory committees for GMP/GCP. He has a degree in Pharmacy and has been awarded fellowships with the Royal Pharmaceutical Society and is Registered as a Senior Consultant to carry out GXP audits and deliver training for candidates wishing to qualify for the Diploma in Quality Management and membership of The Chartered Quality Institute.

Declan Kelly, BSc, MSc, MBA – Mr. Kelly joined Alexion in December 2013 and was promoted to Senior VP of Quality/Chief Quality Officer in June 2014. He has global responsibility for Corporate Quality, R&D/Clinical Quality and Operational Quality. Mr. Kelly has more than 25 years of quality management experience, including leadership positions at Genzyme and Aventis. Prior to joining Alexion, he was VP of Quality for Genzyme in Europe, leading quality initiatives at five European manufacturing plants and directing quality functions throughout the EU to ensure product safety and efficacy. He also assumed additional responsibility as Interim Head of Quality at Genzyme Allston Landing site in Massachusetts to help upgrade quality systems and operations, and implement culture change within the facility during their Consent Decree remediation.

Anabela Luis De Lima Marçal, Pharm S – Ms. Marçal has been with the European Medicines Agency (EMA) since 1999 and currently serves as the Head of Compliance and Inspections (2013-present). Previously, she was Head of Community Procedures, European Medicines Agency (2009-2013) and Specialised Group Leader for Post-Authorisation Safety and Efficacy Central Nervous System / Endocrinology, European Medicines Agency (2001-2009). Her first role with the Agency was as a Scientific Administrator (1999-2001). Prior to joining the EMA, Ms. Marçal was the Scientific Administrator, Infarmed, Lisbon, Portugal (1995-1999).

Janet Mas, BA, MS – Ms. Mas is Executive Director, Medical Devices and Combination Products Quality for Merck in support of Quality and GMP compliance activities relating to the manufacture of pharmaceutical, biologic, and vaccine combination products and pure medical devices. These responsibilities span development and in-line product support. She has 31 years' pharmaceutical industry experience in regulatory, medical device compliance, device development, specification development and scientific review in support of global regulatory inspections and approvals for medicinal, medical device, and combination products.

Ann McGee, BSc, MSc – Ms. McGee, a former Senior Regulator with the HPRA, is the Principal Consultant and Managing Director of McGee Pharma International (MPI), a multi award winning consultancy. MPI's team of 40 consultants, including former EU regulators, delivers quality, compliance, technical and training advice and solutions across the product lifceycle (GxP).

Kevin O'Donnell, PhD – Dr. O'Donnell is Market Compliance Manager at the Health Products Regulatory Authority (HPRA) in Ireland. He is responsible for a number of compliance-related and market-surveillance programs at HPRA, such as the quality defect and recall program and the IMB's sampling and analysis activities. Dr. O'Donnell is also a Senior GMP Inspector at the HPRA.

Mark Petrich, PhD – Dr. Petrich is Director, Component Engineering at Merck & Co. and serves as second vice chair of the Bio-Process Systems Alliance (BPSA). His current role emphasizes design and deployment of single use technologies in vaccine and biologics manufacturing. Prior roles at Merck included technical support for commercial manufacturing, clinical supplies production, process development, and management of laboratory engineering. Prior to joining Merck, Dr. Petrich was Assistant Professor of Chemical Engineering at Northwestern University where he held the M.E. Fine Junior Professor in Materials and Manufacturing chair.

THE SPEAKERS

Simone Pitts, BS, MS – Ms. Pitts is an Investigator with Team Biologics, USFDA, specializing in biopharmaceuticals. At FDA, she has held the position of Laboratory Microbiologist and Investigator. As a Dedicated Drug Cadre Investigator, she specialized in Active Pharmaceuticals Ingredients and cGMPs. In addition, she provided cGMP training to new FDA Investigators and industry.

Donald Prater, DVM – Dr. Prater is the Director of FDA's Europe Office in Brussels, Belgium. He is responsible for coordinating FDA's global engagement within a European regulatory and public health context to ensure the safety and quality of FDA-regulated products, including medical products, biologics, medical devices, tobacco, and food/feed. Dr. Prater facilitates contact and collaboration between FDA scientific, technical and policy experts in the United States and their counterparts in Europe.

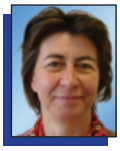
Declan Quinlan, BSc, MSc, Qualified Person – Mr. Quinlan is currently the Director of Quality Operations at Merck, Sharp & Dohme's Biologics & Vaccines facility in Carlow, Ireland. During the past 20 years, he has worked in the start-up and operation of drug substance, parenteral and oral dose facilities in Ireland and the United States. He performed a variety of roles in Quality Control, Quality Assurance, Validation, Regulatory Affairs and Metrology.

Sylvie Raule Rasmussen, PharmD – Ms. Rauel Rasmussen is Vice President, Head of Quality Assurance at UCB. She first joined the Pharmaceutical industry in 1989 and has held positions of increasing responsibility. In 2000, Ms. Rauel Rasmussen joined Eli Lilly & Company in Belgium as Quality Manager and Qualified person of the Belgian manufacturing site for Lilly Clinical supplies in Europe. In 2005, she was promoted to Director of European Development Quality with oversight in Germany and Belgium and in 2007, she expanded her responsibilities to Japan and was appointed Director of out of US Development QA. In 2009, Ms. Rauel Rasmussen became Director for Global Quality Auditing and Compliance. In May 2010, she joined UCB as a Senior Director, Corporate Quality. Ms. Rauel Rasmussen was promoted Vice President, Product Supply Quality in January 2012 and has since then held several positions with increasing responsibilities in the areas of Quality Assurance. She was appointed Vice President, Head of Quality Assurance in 2015.

Oscar-Werner Reif, PhD – Prof. Dr. Reif is the Executive Vice President of R&D and Member of the Board of Directors of Sartorius Stedim Biotech S.A. He studied chemistry and molecular biology at the University of Hanover in Germany and Vanderbilt University, USA and earned his doctorate degree in chemical engineering at the Technical University of Hanover. In addition to his active commitments in several industry-related professional associations, Prof. Dr. Reif is a member of the board of the DECHEMA Society for Chemical Engineering and Biotechnology and honorary professor at the Institute for Chemical Engineering of the University of Hanover.

Mark Schwartz, LLM, LLB, BSc – Mr. Schwartz has been Deputy Director of the Office of Compliance and Biologics Quality, at the Center for Biologics Evaluation and Research, FDA, for over two years. In this capacity, he advises the Center Director and the various Office Directors within CBER, as well as various other components of FDA, and the Department of Health and Human Services, regarding a variety of inspection, surveillance, compliance and enforcement matters. Prior to this position, Mr. Schwartz was Associate Chief Counsel at FDA for 10 years, primarily for drugs and biologics.

Sharon Thoma, PharmD, RPh – Dr. Thoma is a National Expert Pharmaceutical Investigator with the USFDA Office of Regulatory Affairs. She has been with the FDA since 1989 and has held various positions within the organization, including Pre-Approval Inspection Manager and Senior Drug Investigator. Domestically, she travels to help FDA field offices conduct pre-approval and CGMP inspections of pharmaceutical facilities. Internationally, she has inspected firms in India, France, Germany, Sweden, Belgium and Canada. Inspections include sterile, solid oral dosage form, topical, and active pharmaceutical ingredient manufacturers, contract testing laboratories, Clinical Investigators, etc. for human and/or animal drug facilities.



Stephanie Wibaux, Pharm – Mrs. Wibaux has been part of Global Quality Supply Chain for Sanofi Group since 2010. She coordinates the compliance of Good Distribution Practices of both internal distribution centers and external distribution partners. She also develops Risk Management processes and tools related to storage and transportation. She began her career with a French wholesaler company and gained experience when she joined the Quality Operation of International Customer Service of the company, then transitioned to the Quality Risk Management department. Mrs. Wibaux is pharmacist.

Lawrence Yu, PhD – Dr. Yu is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for eight years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, Division Director, Deputy Office Director, and Office Director. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal. He has authored/co-authored over 130 papers, presented over 100 abstracts, and given over 200 invited presentations.

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THE VENUES

The Hague

The Hague is one of the most extraordinary cities in Holland, not only because it is the seat of government in the Netherlands, but also because of its many monuments, historic districts and its location near the beautiful North Sea coastline. The Hague is also known as the 'Royal City by the Sea' and is called 'the residence city' because of the many members of the Dutch Royal Family who reside in its chic neighbourhoods.

The Plein and Grote Markt squares abound with great restaurants, eateries, coffee houses and night clubs and are lively and welcoming places every day of the week. The Hague's shopping is as varied as the city itself, ranging from luxury department stores and international top brands to cosy little streets filled with boutiques and specialty shops. It also has a lot of internationally renowned art and culture to offer.

Last but not least, The Hague proves that a modern skyline and a historic city centre are perfect partners. Scheveningen, the best known seaside resort on the Dutch coast, is a great place to go for a suntan and water sports in summer and a bracing walk in winter.

Headquarters Hotel

Worldhotel Bel Air

Worldhotel Bel Air is 4-star hotel in The Hague, Netherlands, in the middle of the Statenkwartier area across the Catshuis, within walking distance of the Gemeente Museum, the Peace Palace and the World Forum Convention Center. The rooms and suites on the west side offer a view of the sea, the rooms facing eastward a view of the skyline of The Hague. The location of Worldhotel Bel Air between city and sea makes it stand out among the hotels in The Hague, and also makes the hotel easily accessible. The hotel is 45 minutes from the Amsterdam Schiphol and Rotterdam/ The Hague airports. Den Haag HS and Centraal stations are easily reachable by public transport.

Conference Venue

Zuiderstrandtheater

The Zuiderstrandtheater/South Beach Theater is the only theater on the Dutch coast. Located next to Scheveningen Harbor, Zuiderstrandtheater offers unsurpassed views of the North Sea.

The theater is three minutes from the headquarters hotel by shuttlebus, which will be provided.

AGENDA

1st Annual GMP By The Sea Europe

Monday, 7 September 2015

Morning Session: Plenary Session

Moderator – Sylvie Raule Rassmussen – Focus on International GMPs and Cooperation

7:30 – 8:50	Registration and check-in	
8:50 – 9:00	Welcome – Conference Chair	Gary Bird, PhD
9:00 – 9:35	**The Evolving Environment: An Update on EU GMP Initiatives including the Newly Issued GMPs**	Anabela Marçal, EMA
9:35 – 10:10	**The International Inspection Discussion: PIC-S Initiatives to Harmonize Inspection Activities and Standards**	Paul Hargreaves, MHRA
10:10 – 10:30	Break*	
10:30 – 11:05	**The International Inspection Discussion: Mutual Reliance Initiative from the EMA's Perspective**	Anabela Marçal, EMA
11:05 – 11:40	**The International Inspection Discussion: Mutual Reliance Initiative from the USFDA Perspective**	Donald Prater, USFDA
11:40 – 12:10	**Question and Answer Session**	Morning Speakers
12:10 – 13:10	Lunch*	

Afternoon Session: Plenary Session

Moderator – Declan Kelley – Focus on International GMPs and Cooperation

13:10 – 13:15	Reconvene	
13:15 – 13:50	**2014 EFPIA Inspection Survey**	Johanna Berberich, PhD
13:50 – 14:25	**An Industry Perspective on GMP Harmonization Initiatives**	Clive Blatchford
14:25 – 14:45	Break*	
14:45- 15:20	**USFDA Update on the Creation, Roles, and Responsibilities of the New Office of Pharmaceutical Quality**	Lawrence Yu, USFDA
15:20 – 15:55	**GMP Failures in Quality Risk Management Indicative of Poor Knowledge Management**	Kevin O'Donnell, PhD
15:55 – 16:30	**Question and Answer session**	Afternoon Speakers
17:00 – 18:00	Networking Reception* (hors d'oeuvres and drinks) at headquarters hotel	

Tuesday, 8 September 2015

Morning Session: Moderator – Declan Quinlan

9:00 – 9:10	Introduction and Moderator Comments	
9:10 – 9:40	**Critical Issues in Data Integrity – MHRA**	Mark Birse, MHRA
9:40 – 10:10	**Implementing a Comprehensive, Corporate Data Integrity System**	Ann McGee
10:10 – 10:30	Break*	
10:30 – 11:00	**Combination Product Filing and Expectations in the US and EU**	Janet Mas
11:00 – 11:30	**FDA's New "Integrated Quality Assessment" Approach: Application Reviews & Process/Facility Inspections in the New OPQ**	David Doleski, USFDA
11:30 – 12:00	**Question and Answer Session**	Morning Speakers
12:00 – 13:00	Lunch*	

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AGENDA

Afternoon Session: Workshops

13:00 – 14:30	Workshop Session #1	
	• **Inside the FDA – Why They Do The Things They Do**	Mark Elengold
	• **QbD: Designing and Implementing Robust Processes for Transfer and Scale-Up**	To Be Announced
	• **Audit Techniques to Identify Data Integrity Issues**	Ann McGee
	• **Supplier Qualification of Single-Use Production Systems and Processes**	Mark Petrich, PhD Oscar Reif, PhD
	• **Cleaning Validation and Cross-Contamination: The Potential Impact on Product Safety**	John Hyde
14:30 – 14:50	Break*	
14:50 – 16:20	**Workshops Session #2: The above workshops will be repeated**	
17:00 – 20:00	Evening Social* – drinks and dinner away from hotel	

Wednesday, 9 September 2015

Morning Session: Moderator – Nigel Hamilton

9:00 – 9:10	Introduction and Moderator Comments	
9:10 – 9:40	**FDA Center for Biologics Compliance Update**	Mark Schwartz, USFDA
9:40 – 10:10	**The New ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management**	Graham Cook , PhD
10:10 – 10:30	**Overview of International Biologics Inspections 483 Issues for 2014 and 2015**	Simone Pitts, USFDA
10:30 – 10:50	Break*	
10:50 – 11:10	**Findings and Inspection Results from FDA-ORA Inspections**	Sharon Thoma, USFDA
11:10 – 11:30	**Compliance Management and Supply Chain Management: A Primer to Prevent a Company's Future Product Shortages**	Mark Birse, MHRA
11:30 – 12:00	**Good Distribution Practices to Address Critical Supply Chain Issues including Product Falsification and Counterfeiting**	Stephanie Wibaux
12:00 – 12:30	**Question and Answer Session**	
12:30 – 13:30	Lunch*	

Afternoon Session: Workshops

13:30 – 15:00	Workshop Session #3	
	• **The GMPs of Combination Products**	David Elder
	• **Update on FDA/OPQ-Related Guidance**	David Doleski, USFDA Lawrence Yu, USFDA
	• **All You Need to Know About Consent Decrees**	David Chesney
	• **Industry Actions for Supply Chain Shortages Due to Quality Issues**	Mairead Goetz
	• **Good Distribution Practices: The New Guidances and How to Implement Them**	John Jolley
15:00 – 15:20	Break*	
15:20 – 16:50	**Workshop Session #4: The above workshops will be repeated**	
16:50 – 17:00	**Conference Wrap-Up**	

*denotes non-educational activity

AGENDA

Optional 2-Day Program: Inspections of Pharmaceutical-Biopharmaceutical Operations to FDA Standards – Europe

Thursday, 10 September 2015

Morning Session: Moderator – David Elder

8:00 – 9:00	Registration	
9:00 – 9:05	Welcome	JW Smith
9:05 – 9:45	**Regulatory Inspections – A New Game with More Players**	David Chesney
9:45 – 10:30	**Introduction to the FDA Inspection Process: An Overview to Set the Tone**	Mark Elengold
10:30 – 10:50	Break*	
10:50 – 11:35	**The Corporate Culture of Quality**	David Chesney
11:35 – 12:00	**Surviving FDA System Inspections (Focusing on the Six Systems)**	Mark Elengold
12:00 – 13:15	Lunch*	

Afternoon Session: Moderator – Gary Bird, PhD

13:15 – 14:00	**The Difference Between CBER Inspections and Other Inspections**	Robert Darius
14:00 – 14:45	**How I Inspect Your Pharmaceutical Establishment**	Sharon Thoma, FDA
14:45 – 15:05	Break*	
15:05 – 15:50	**What FDA Inspectors Will Look for in Your Biologic Establishment**	Simone Pitts, FDA
15:50 – 17:00	**Question and Answer Session**	Thursday Speakers

Friday, 11 September 2015

Morning Session: Moderator – David Chesney

9:00 – 9:45	**Details Make a Difference for Successfully Managing an FDA Inspection from the Company Perspective**	Mark Elengold
9:45 – 10:30	**Proper Auditing is Your Early Warning System Before an Inspection**	Gary Bird, PhD
10:30 – 10:50	Break*	
10:50 – 11:40	**SOP Pitfalls That Can Jeopardize Your Inspection**	Robert Darius
11:40 – 12:00	**The Intelligent Response to a 483**	David Elder
12:00 – 13:15	Lunch*	

Afternoon Session: Moderator – Gary Bird, PhD

13:15 – 14:00	**The Warning Letter Dilemma: What Does It Mean?**	David Elder
14:00 – 14:45	**Effective Remediation: An Acceptable Response is Not the End of the Inspection**	Gary Bird, PhD
14:45 – 15:05	Break*	
15:05 – 16:05	**Necessary Intelligence: What is Out There That Can Affect Your Company in the Near Future? (Inspection Related)**	David Chesney
16:05 – 17:00	**Question and Answer Session**	Friday Speakers

*denotes non-educational activity

Click here to view the full 2-day program brochure

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REGISTRATION

1st Annual GMP By The Sea Europe *and optional 2-day program* Inspections of Pharmaceutical-Biopharmaceutical Operations to FDA Standards – Europe

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FEES

Register early and SAVE!

	Conference Only	Optional 2-Day Program (see page 9)	BEST VALUE! Both Programs
Payment Received By 26 June 2015	❑ $2795 US	❑ $1995 US	❑ $4390 US
Payment Received After 26 June 2015	❑ $2995 US	❑ $2195 US	❑ $4590 US

Includes conference, full buffet breakfast at the hotel, breaks, lunches, networking reception and evening events per agenda.

	Either Program	Both Programs
Gov't/Press Rate	❑ $1595 US	❑ $2595 US

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PAYMENT

Full payment may be made by credit card or company check

- Checks must be received within 15 days of receipt of registration form.
- Checks should be made payable to Pharma Conference Inc, in U.S. dollars and drawn on a U.S. bank.
- Registrations will be confirmed when full payment has been received. Taxpayer ID #27-1438344.
- **Registrations made within 60 days of conference start date must be accompanied by full payment.**

Checks should be sent to Pharma Conference Inc at the following addresses (see check instructions above):

Airmail to: P.O. Box 291386, Kerrville, Texas 78029 USA

Express to: 819 Water Street, Suite 350, Kerrville, Texas 78028 USA

HOTEL

Headquarters Hotel
Worldhotel Bel Air
Johan de Wittlaan 30
2517 JR The Hague
Netherlands
+31 (0)70 3525354

Single/Double rate 125€
(if reserved by 31 May)

Single/Double rate 145€
(if reserved after 31 May)

Both rates are incl. breakfast and excl. city tax at EUR 4,60 per person per night.

A limited number of rooms have been blocked at the special rate shown per night (single or double). Hotel reservations must be made **on or before 31 May 2015** in order to guarantee the discounted rate. Individuals are responsible for making their own hotel reservations. Be sure to mention the name of the conference and Pharma Conference Inc when making your reservation in order to be properly identified with the conference. **Please do not use travel agents for reservations.**

Book hotel online here:
http://tinyurl.com/GMPbytheSeaEU

For additional information, contact Pharma Conference Inc
Voice: (830) 896-0027 Fax: (830) 896-0029 or e-mail: contactus@pharmaconference.com.

CLICK HERE TO REGISTER ON OUR SECURE SERVER