An Optional Two-Day Companion Program to GMP By The Sea Europe

Inspections of Pharmaceutical – Biopharmaceutical Operations to FDA Standards – Europe

Worldhotel Bel Air
The Hague, Netherlands
10–11 September 2015

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 PROGRAM

Inspections of Pharmaceutical and Biopharmaceutical Operations to FDA Standards – Europe for Biotech Drug Products is a highly interactive, two-day program designed to provide quality, production, regulatory affairs, and auditing professionals in both the pharmaceutical and biotechnology drug product industries an in-depth understanding of the inspectional practices of the FDA.

The program will allow ample opportunity for individual questions to be answered by the presenters, all of whom are either current or former staff members at FDA and are known as experts on GMP matters. Like all Pharma Conference GMP programs, it is designed to be an informal, relaxed learning session to help improve your performance at work. You will receive not only basic regulation information, but practical utilization techniques, as well.

Our program will enforce your basic knowledge by presenting required information on FDA inspection programs conducted by ORA and CBER, and then dive into more advanced topics. It will address preparing companies for upcoming inspections; present advanced information related to company culture and its impact on GMP compliance; go into detail on FDA inspection strategies; and teach you new ways to utilize company audit programs to act as early warning systems for inspections. We will show you how SOPs can be your best friend in an inspection and how they can provide the investigator all the information needed to write a 483 observation. In addition, two current FDA inspectors will present recent observations from some of their inspections. We will then address the proper ways to respond to the 483 observations by truly correcting the issues that led to them, not merely by saying "we will retrain our operators." And finally, we will teach you how to use intelligence resources to stay abreast of the trends in regulatory inspections.

Our goal is to help you "thrive" in an inspection, not "survive" as so many would have you do.

Register early, since this program is limited in size and always fills up.

WHO SHOULD ATTEND?

Anyone involved in production, quality assurance, quality control, regulatory affairs, or auditing in the pharmaceutical and biopharmaceutical industry.

Supervisory personnel and managers can enhance GMP performance by sending production, quality, and regulatory personnel to this learning experience. They will gain a significant appreciation of GMP requirements and the importance of utilizing and considering GMP matters in all of their day-to-day operations.

WHY ATTEND?

- To gain a better understanding of how the FDA looks at your operations and how to anticipate problem areas before they create problems for your company
- To take advantage of the knowledge of seasoned experts who have over a century of combined experience with FDA issues
- To obtain current information about FDA activities
- To get those cGMP questions that cause you sleepless nights answered by the experts

THE SPEAKERS

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.

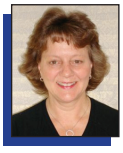
David L. Chesney, BS – Mr. Chesney is the Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting (then known as KMI) in 1995, he served 23 years with the FDA. Since joining PAREXEL, Mr. Chesney has provided compliance consulting and training services 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.

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 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.

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.



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.

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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.

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.

AGENDA

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

CONTINUING EDUCATION

ACPE®

The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Statements of credit will be mailed within 60 days to those participants who successfully complete the activity. Successful completion requires participation at the entire activity and completion of an activity evaluation form. No partial credit will be awarded. This activity is co-sponsored by NIPTE.

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	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, continental breakfast, breaks, lunches, networking reception and evening events per agenda.

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

Cancellation Policy: 30 days or more for a full refund less $250 cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

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.

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