Meeting the Challenges: FDA Inspections – Europe

An Interactive Two-Day Program

Vienna, Austria | 19 – 20 July, 2016
Hotel Intercontinental Wien/Vienna

REGISTER EARLY! Limited seats available
Current and former FDAers will help guide you and your company through the process of preparing for, hosting, participating in, and responding to FDA inspections. This highly interactive, two-day program is designed to provide quality, production, regulatory affairs, and auditing professionals an extensive exposure to the FDA inspection process and the investigators responsible for executing it. It will move from basic concepts to advanced applications that will help your company “meet the challenges” of FDA inspections from the war rooms to the final responses to 483. It will help you avoid the mistakes of communication that can lead to significant issues that could potentially lead to Warning Letters or worse.

The program will allow ample opportunity for individual questions to be answered by the presenters, who are known as some of the nation’s foremost experts on inspectional issues. Like all Pharma Conference programs, it is designed to be an informal, relaxed learning session to help improve your performance at work. Attendees will receive not only basic regulatory information, but practical implementation techniques, as well.

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

Who Should Attend?

- Anyone involved in FDA inspection preparation, hosting, or responses including production, quality assurance, quality control, regulatory affairs, or auditing in the pharmaceutical and biopharmaceutical industry in Regulatory and GMP matters.
- Supervisory personnel and managers can enhance Regulatory and GMP performance by sending production, quality, and regulatory personnel to this learning experience. They will gain a significant appreciation of FDA’s inspectional approach, and they will learn the critical skills needed to prepare for and properly host inspections.

Why Attend?

- To gain a better understanding of how the Regulatory Authorities look at your operations and how to anticipate problem areas before they create problems for your company during the inspection
- To take advantage of the knowledge of seasoned FDA experts who have “been there and done that”
- To obtain current information about FDA activities
- To get those cGMP questions that cause you sleepless nights answered by the experts

Register online at www.pharmaconference.com
To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

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 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.

Peter Smith, BS – Mr. Smith is Vice President, Strategic Compliance, for PAREXEL. He joined PAREXEL (then KMI) in 1994 following a 22-year FDA career. At the FDA, Mr. Smith worked as an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections, later serving as Associate Director, International and Technical Operations Branch, Division of Field Investigations. In this capacity, he managed the FDA’s Foreign Inspection Program. During his FDA career, he conducted inspections of pharmaceutical plants in Europe, Asia, South America and Australia. Mr. Smith has primary expertise in GMP for Active Pharmaceutical Ingredients and non-sterile dosage forms, management of Pre-Approval Inspections, management of foreign inspections, GMP quality systems and FDA regulatory issues.

Diana Amador-Toro, BS – Ms. Amador-Toro currently serves as Central Region Food and Drug Director in FDA’s Office of Regulatory Affairs (ORA) and is responsible for over 700 field employees in seven Districts and three Laboratories. She has served as the Chair of the Field Drug Committee and as the Drug Program Manager for ORA since 2008 and has held various positions within FDA. She served seven years as the District Director in New Jersey and six years as the Director of Investigations providing leadership in directing and managing the district’s inspectional activities in New Jersey. She also served four years as the Science Branch Director in the San Juan District Office. Ms. Amador-Toro has over 33 years of field experience in investigations and compliance activities, has contributed to ICH and FDA Guidance documents and has conducted international GMP and Pharmaceutical Quality training in Argentina, Estonia and England, among other countries.

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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In its 21st year, the top pharmaceutical conference in the U.S. features top leaders from the most impactful organizations – FDA, CBER, and CDER/OPQ. A total of 10 FDA speakers will be present to share FDA’s converging approach to quality and what it means for GMP’s and your organization.

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19 July 2016
Morning Session Moderator – Gary Bird, PhD

7:30 – 8:30  Registration*

8:30 - 8:35  Welcome and Introductions

8:35 – 9:20  The Basic FDA Investigation Approach Including the Legal Basis of FDA Activities  Peter Smith

9:20 – 9:55  Impact of a Violative Investigation  Mark Elengold

9:55 – 10:15  Break*


11:25 – 12:00  Recent Findings Nationally and Internationally from FDA 483s  Diana Amador-Toro, FDA

12:00 – 13:30  Lunch*

Afternoon Session Moderator – Mark Elengold

13:30 – 14:40  Effective Communication and Meetings with FDA  Mark Elengold

14:40 – 15:00  Break*

15:00 – 15:35  Data Integrity: Identifying and Resolving the Issues  Gary Bird, PhD

15:35 – 16:10  Deviations and CAPA from the FDA Perspective  Gary Bird, PhD

16:10 – 17:00  Preparation for the Inspection  Team

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20 July 2016
Morning Session Moderator – Mark Elengold

8:35 – 9:15  API Inspections  
Peter Smith

9:15 – 10:00  Biologic Inspections and What They Find  
Mark Elengold

10:00 – 10:20  Break

10:20 – 10:55  Preparing for an Inspection When “I’m Not Ready”  
Gary Bird, PhD

10:55 – 11:30  Responding to FDA Inspection Observations (483s)  
Gary Bird, PhD

11:30 – 12:00  Evidence Development  
Peter Smith

12:00 – 13:30  Lunch

Afternoon Session Moderator – Gary Bird, PhD

13:30 – 14:05  Quality by Design:  
What Does It Mean During an Inspection?  
Gary Bird, PhD

14:05 – 14:40  Compliance Actions Including 483s, Warning Letters, Seizures, and Consent Decrees  
Peter Smith

14:40 – 15:00  Break

15:00 – 15:35  Meeting with the FDA to Resolve Inspectional Issues  
Peter Smith

15:35 – 16:10  Company Position Papers to Support Inspection Processes, Techniques, and Responses  
Gary Bird, PhD

16:10 – 16:55  Group Discussion – Bring Your Own GMP Questions for Open Discussions  
Team

16:55 – 17:00  Meeting Adjournment

*Denotes non-educational activity
Meeting the Challenges: FDA Inspections – Europe

Fees

Payment Received By 11 March 2016

☐ $1895 USD
  Includes program materials, full buffet breakfasts, coffee breaks, and lunches per agenda

Payment Received After 11 March 2016

☐ $2095 USD

Cancellation Policy: 30 days or more for a full refund less $250 USD 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.

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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 30 days of conference start date must be accompanied by full payment.

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A limited number of rooms have been blocked at the special rates listed per night. Individuals are responsible for making their own hotel reservations. You must mention the title of the program AND Pharma Conference when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.

For additional information, contact Pharma Conference Inc:
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