



Meeting the Challenges: FDA Inspections

An Interactive Two-Day Program

Morristown, New Jersey | April 12 – 13, 2016
Hyatt Regency Morristown

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EARLY!**
Limited seats
available

Program produced by



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NIPTE The National Institute for
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About the Program

Ten 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

Continuing Education

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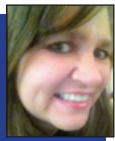
The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This knowledge-based activity meets the ACPE criteria for continuing education credit. Statements of credit will be mailed within 60 days to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

Register online at www.pharmaconference.com

About 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.



Marlene Bobka, BS, MLS – Ms. Bobka is Senior Vice-President and member of the Board of Directors at FOI Services, Inc., a privately-held firm she joined in 1985. She is responsible for functions facilitating access to FDA records acquired using the Freedom of Information Act as well as producing teleconferences which interpret FDA regulations, actions, and expectations. She is a frequent author and speaker on topics offering insight into finding and using fugitive drug, device and biologic regulatory information and has addressed audiences worldwide for organizations including the Drug Information Association, AdvaMed, the Regulatory Affairs Professional Society, the Special Libraries Association, the American Chemical Society, the Association of Food and Drug Officials and many others. Before joining FOI, Ms. Bobka taught online searching strategy, conducted extensive medical, chemical, and government literature research and designed and documented databases at Bibliographic Retrieval Services and the National Cancer Institute.



Robert Coleman, BA – Mr. Coleman has been a Senior Compliance Expert Consultant in Pharmaceuticals with IHL Consulting Group, Inc. since he retired from the FDA in 2008. He began his FDA career in 1972 and served as an Investigator, a Drug Specialist Investigator, Drug Pre-Approval Manager, and finally National Drug Expert Investigator. During the course of his FDA career, Mr. Coleman conducted over 1,000 inspections across the diverse array of FDA regulatory responsibilities.



Robert Darius, BS – Mr. Darius is Head Quality Advocacy Liaison at GSK Vaccines. He served for 15 years in FDA/CBER as a Microbiologist, Reviewer, Lead Inspector for all CBER regulated products, and lastly as Acting Senior Advisory on Counter bioterrorism products. In 2005, he joined BCG as a Senior Consultant, then formed Radius Biotechnology, a consulting company. He joined ID Biomedical in 2006 as VP Quality and Validation. When IDB was purchased by GSK, Mr. Darius served for 10 years in an expanding role as Quality Unit Head of the Dresden and North American GSK Vaccine Operations.



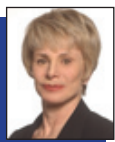
David Doleski, BS – Mr. Doleski, Acting Deputy Director, OPF, OPQ, has been with FDA for 24 years. He most recently served as director of the Division of Good Manufacturing Practice Assessment, which is responsible for overseeing the pre-approval inspection program for new and generic drugs, and reviews 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 K. Elder, BS – Mr. Elder is Vice President of PAREXEL Consulting, which he joined in 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 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.



Debra Pagano, BS – Ms. Pagano is an independent consultant who operates her own company under an LLC in Pennsylvania. She has been a consultant to FDA regulated industry since 2002. In this capacity, she is a compliance consultant to the Pharmaceutical, Biologics, Combination Products and Medical Device Industries conducting mock pre-Approval and CGMP inspections of international and domestic firms. Ms. Pagano previously worked for the Food and Drug Administration for 17 years. She was the Pre-Approval Program Manager from October 1994 to October 2002 and held positions as drug specialist and investigator.



Nancy Singer, BS, JD, LL.M – Ms. Singer founded Compliance-Alliance LLC to specialize in the professional development for FDA and industry employees. She is an instructor at FDA's Staff College, and she has taught good documentation practices to the investigators and compliance officers in ten FDA District Offices. Previously she served as AdvaMed's Special Counsel for FDA compliance and enforcement matters. Ms. Singer began her career as an attorney with the United States Department of Justice where she did litigation for the Food and Drug Administration. Subsequently, she was a partner at the law firm of Kleinfeld, Kaplan and Becker.

Agenda

April 12, 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	David Elder
9:20 – 9:55	Impact of a Violative Investigation	Debra Pagano
9:55 – 10:15	Break*	
10:15 – 10:50	The Changing Environment of National and International Inspections	Helen Verdel, FDA
10:50 – 11:25	Interaction Between OPQ and ORA: Who Leads and Who Inspects?	David Doleski, FDA
11:25 – 12:00	Recent Findings Nationally and Internationally from FDA 483s	Paul Bellamy, FDA
12:00 – 1:30	Lunch*	

Afternoon Session Moderator – Gary Bird, PhD

1:30 – 2:05	Writing for Effective Communication with FDA – Part 1	Nancy Singer Marlene Bobka
2:05 – 2:40	Quality by Design: What Does It Mean During an Inspection?	Robert Darius
2:40 – 3:00	Break*	
3:00 – 3:35	Data Integrity: Identifying and Resolving the Issues	Gary Bird, PhD
3:35 – 4:10	Deviations and CAPA from the FDA Perspective	Gary Bird, PhD
4:10 – 5:00	Case Study #1: Preparation for the Inspection	Team

Agenda

April 13, 2016

Morning Session Moderator – David Elder

8:30 – 9:15	API Inspections	Robert Coleman
9:15 – 10:00	Biologic Inspections and What They Find	FDA – Team Biologics Investigator Invited
10:00 – 10:20	Break*	
10:20 – 10:55	Preparing for an Inspection When “I’m Not Ready”	Gary Bird
10:55 – 11:30	Change Control Expectations from a Former Investigator’s Point of View	Debra Pagano
11:30 – 12:00	Evidence Development	Robert Coleman
12:00 – 1:30	Lunch*	

Afternoon Session Moderator – Gary Bird, PhD

1:30 – 2:05	Writing for Effective Communication with FDA – Part 2	Nancy Singer Marlene Bobka David Elder
2:05 – 2:40	Compliance Actions Including 483s, Warning Letters, Seizures, and Consent Decrees	
2:40 – 3:00	Break*	
3:00 – 3:35	Meeting with the FDA to Resolve Inspectional Issues	David Elder
3:35 – 4:10	Case Study #2: Company Position Papers to Support Inspection Processes, Techniques, and Responses	Robert Darius
4:10 – 4:55	Group Discussion – Bring Your Own GMP Questions for Open Discussions	Team
4:55 – 5:00	Meeting Adjournment	

*Denotes non-educational activity

Register

Meeting the Challenges: FDA Inspections

Fees

 *Register early and SAVE!*

Payment Received By January 15, 2016

☐ \$1895

Payment Received After January 15, 2016

☐ \$2095

Includes program materials, continental breakfasts, coffee breaks, and lunches per agenda

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.

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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.

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

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\$219* single/double

*Rate available three days either side of conference

A limited number of rooms have been blocked at the special rates listed per night. **Hotel reservations must be made on or before March 11, 2016, in order to guarantee the special rate.** 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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