An Interactive Two-Day Program

Auditing Pharmaceutical and Biotechnology Drug Product Systems for Business and Regulatory Compliance

Washington D.C. Area/Bethesda, Maryland
June 15 – 16, 2015
Hyatt Regency Bethesda

REGISTER EARLY!
Limited seats available
Audits are critical to companies that are trying to maintain high quality, efficient, and economical business systems and that are required to meet the standards of established Regulatory Authorities such as the US-FDA, Europe’s EMA, and the new emerging authorities such as ANVISA (Brazil), ANMAT (Argentina), and the SFDA (Saudi Arabia). The benefits of a properly designed audit program go far beyond satisfying the simple “check list” to meet regulatory requirements.

- When properly developed, the audit system acts as an early warning system to alert the company to problems with vendors and internal systems and production.
- The audit system can be used to provide intelligence regarding issues developing in the industry and to create a best practices system to improve business capabilities within your own company.
- Preparation for a Regulatory Authority inspection begins far sooner than when the Investigator/Inspector shows up at the front door with the "Notice of Inspection" in hand. The presence of a strong audit program designed to identify and correct problems is critical to confirming that all products (raw materials, excipients, utilities, API, and drug products) meet the requirements of the pharmacopoeia, guidances, and guidelines/regulations.
- With the focus of many companies now turned to marketing in as many countries as possible, the issues of becoming internationally compliant multiply.

Auditing Pharmaceutical and Biotechnology Drug Product Systems for Business and Regulatory Compliance is a highly interactive, two-day program designed to provide quality, production, regulatory affairs, and auditing professionals in both biotechnology and mainstream pharmaceutical development and commercialization a basic to advanced understanding of the auditing requirements every company should have in place. The benefits of such a program will become evident by the time this program is complete.

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 GMP matters. Like all Pharma Conference programs, this program will be an informal, relaxed learning session to help improve your performance at work. Attendees will receive not only basic regulation information, but practical utilization techniques, as well.

Register early – 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 audit requirements and the importance of utilizing and considering audit activities in all of their day-to-day operations.

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
- To take advantage of the knowledge of seasoned experts who have “been there, done that, got the T-shirt”
- To obtain current information about FDA activities
- To get those audit questions that cause you sleepless nights answered by the experts

Register online at www.pharmaconference.com
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 Lowry, BS, MBA – Mr. Lowry is President of cGMP Consulting Services, which specializes in assisting clients in their compliance needs. Previously, he was a Vice President at PAREXEL Consulting. Mr. Lowry has more than 48 years of experience in pharmaceutical, medical device and biologic Quality Assurance/Quality Control management. He has expertise in all phases of plant QA/QC and is particularly experienced in the development and implementation of Quality Management Systems and in the management of facility microbiological functions. Prior to his roles as Director and Vice President at PAREXEL Consulting, Mr. Lowry held numerous positions as Director of Quality Assurance and Regulatory Compliance for the Biomedical Services Division of the American Red Cross and companies including: Ciba Vision Corporation, Pharmaceutical Basics, Inc., and Delmed, Inc. Mr. Lowry began his career as a Biologist at Baxter Healthcare Inc., eventually serving as a QA Manager in the Baxter Corporate Office, developing and implementing quality policies and programs both internally and for joint ventures.

John McCann, BS – Mr. McCann is President of North End Group. He is a former FDA investigator, biotechnology specialist, and regulatory chemist who has an intimate knowledge of current FDA regulatory and enforcement priorities, practices and policies. During his eight years as an FDA inspector, Mr. McCann handled some of the largest cases in the Boston district, including the Barr case. He is a nationally recognized expert in FDA laws, regulations, policies, and procedures and has a broad experience in presenting quality systems and FDA inspectional readiness training to FDA-regulated firms.

Bruce Miller, BS – Mr. Miller is President of Miller Consulting Inc., which assists clients with compliance issues and operational improvements. His career and experience spans more than 36 years in the pharmaceutical industry, with 20 years providing consulting services. He has spent much time in remediation activities with multiple companies occurring as a result of FDA inspections, having worked on some of the largest consent decrees and Official Action Indicated remediation efforts mandated by FDA. He frequently performs gap analyses and has developed quality systems from the ground up. His background includes both generics and Innovators companies. He provides consulting services to the pharmaceutical and health industry in the quality, regulatory and operations areas, including the development of standard operating procedures, auditing, functional and GMP training and the evaluation and optimization of operating systems and controls and compliance corrective action plans.

ABOUT THE VENUE

Bethesda, Maryland, is a thriving urban district that is part of the Washington, DC Metro Area. Access to the national monuments is less than 30 minutes away on the Metro Red Line. Bethesda is also the home of the Bethesda Naval Hospital (Bethesda Naval Medical Center) and the National Institutes of Health (NIH).
Monday, June 15, 2015
Morning Session Moderator – John McCann

8:00 – 9:00  Registration
9:00 – 9:10  Welcome
9:10 – 9:45  Business and International Regulatory Requirements for a Strong Audit Program including Quality System Requirements  Gary Bird, PhD
9:45 – 10:30  Tools of the Auditor  John McCann and David Lowry

10:30 – 10:50  Break*

10:50 – 11:30  Goals and Strategies to Meet Audit Requirements  Bruce Miller and Gary Bird, PhD

11:30 – 12:00  Conducting the Audit  Bruce Miller

Afternoon Session Moderator – Bruce Miller

1:30 – 2:20  Auditing Deviations, Product Complaints, and CAPA Systems  Gary Bird, PhD
2:20 – 3:00  The Audit Report  John McCann
3:00 – 3:20  Break*

3:20 – 4:00  Audit Follow-up and Finalization  David Lowry
4:00 – 4:35  Revisiting the Audit Program to Confirm Effectiveness  Gary Bird, PhD
4:30 – 5:00  Q&A Session  All Presenters

Register online at www.pharmaconference.com
Tuesday June 16, 2015
Morning Session Moderator – Gary Bird, PhD

9:00 – 10:20  System Audits (Part 1)  
• Quality Systems  
• Material Management  
• Laboratory Control System  

David Lowry

10:20- 10:40  Break*

10:40 – 12:00  System Audits (Part 2)  
• Production Systems  
• Facilities and Equipment  
• Packaging and Labeling System  

Gary Bird, PhD

12:00 – 1:30  Lunch*

Afternoon Session Moderator – David Lowry

1:30 – 2:00  Creating a Vendor Certification Program  

David Lowry

2:00 – 2:45  Case Studies  

Gary Bird, PhD and David Lowry

2:45 – 3:05  Break*

3:05 – 4:30  Case Studies  

David Lowry and Gary Bird, PhD

4:30 – 5:00  Q&A Session  

David Lowry and Gary Bird, PhD

*Denotes non-educational activity

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.
CLICK HERE TO REGISTER ON OUR SECURE SERVER

Payment Received By April 15, 2015

$1695

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

Payment Received After April 15, 2015

$1895

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 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):

Airmail to: P.O. Box 291386, Kerrville, Texas 78029 USA
Express to: 819 Water Street, Suite 350, Kerrville, Texas 78028 USA

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

CLICK HERE TO REGISTER ON OUR SECURE SERVER

Register online at www.pharmaconference.com