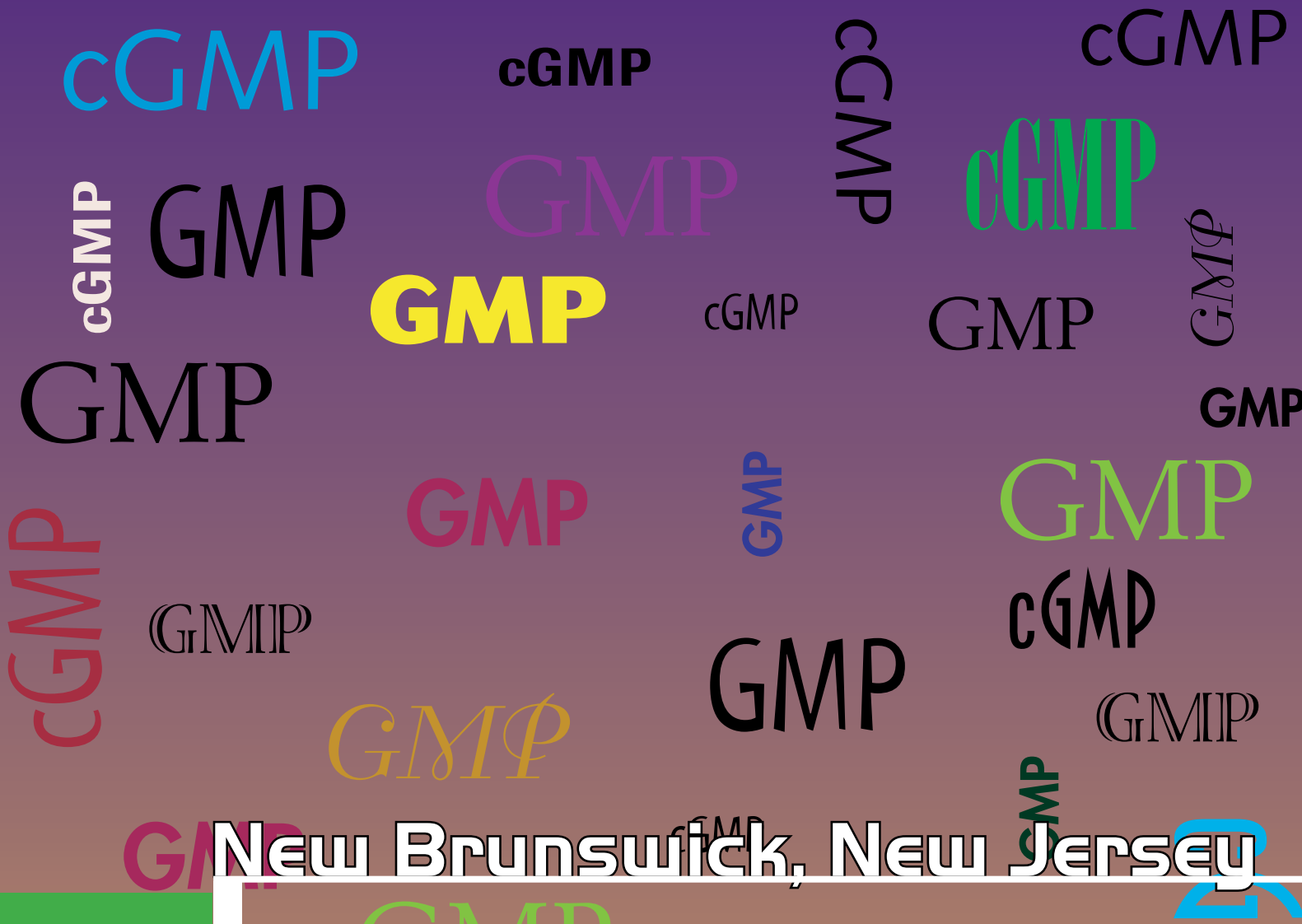


2010 CONFERENCE SERIES



New Brunswick, New Jersey

12th Annual FDA and the Current Challenges of GMPs

May 18 - 19, 2010

Hyatt Regency New Brunswick

Conference produced by



ABOUT THE CONFERENCE

This year's conference focuses on compliance expectations. What is FDA working on? New guidances, recent enforcement actions, 483 issues and many other issues emanating from the Center for Drug Evaluation and Research and the Office of Regulatory Affairs will be covered.

The topics in this year's conference are taken from some of the most frequently listed regulatory observations following FDA inspections and presenting the subjects in a manner that will help you adopt measures to comply with regulatory expectations and prevent your being cited for similar violations of the GMPs. FDA speakers will address their latest quality and compliance initiatives. There is a wide range of topics on this year's agenda and there is an impressive group of speakers with vast quality, GMP, and enforcement experience to present these topics. We hope that you will take advantage of the opportunity to have your questions addressed by this impressive list of speakers.

The location is the same, but the information is always new and accurate. Don't miss this opportunity to hear the newest information coming out of CDER and ORA that directly affects every aspect of your organization.

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- Regulatory Affairs Professionals
- Quality and Compliance Personnel
- Production Managers and Personnel
- Directors and Corporate Officers of Pharmaceutical Companies
- Research and Development Personnel Involved with GMPs

WHY ATTEND?

- To receive current information regarding FDA's new programs and initiatives
- To have the opportunity to ask questions of FDA and receive answers
- To network with your peers
- To gain useful information to use and enhance your day to day operations

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Participants will receive 1.0 CEUs (10.00 contact hours) for **12th Annual FDA and the Current Challenges of GMPs** conference attendance. The University of Rhode Island College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This is a knowledge type of activity. Attendance and completion of evaluation forms and self-assessment tools at the conclusion of the program are required for issuance of a statement of credit. Statements will be mailed within six to eight weeks of program completion. ACPE universal program number 060-999-10-053-L04-P.

Register online at www.pharmaconference.com

THE PRESENTERS



Ali Afnan, PhD – Dr. Afnan joined the FDA's PAT policy team, in the Office of Pharmaceutical Science at CDER, in 2003. His responsibilities include developing agency policy and training, coordinating submissions and discussions with the pharmaceutical industry, and collaborating in research ventures with industry and academia. In addition to his responsibilities to PAT, he is involved in the implementation of initiatives at the OPS-IO, where he works as an advisor to the office director. At the beginning of his career, he was with the On-Line Analysis and Measurement Group at ICI Engineering. In 1993, he joined the International Technology Development Group within the Pharmaceuticals Engineering Group of AstraZeneca. He was responsible for the development and implementation of Process Analytical Technology that led to the design, construction and implementation of a solid dosage facility capable of exercising total control over manufacturing during the production operations. This was the first such facility implemented within AstraZeneca and is believed to have been the first in industry.



Diana Amador-Toro, BS – Ms. Amador-Toro currently serves as the New Jersey District Director in FDA's Office of Regulatory Affairs (ORA). As the District Director she provides executive leadership in directing and managing all the programs of FDA within the state of New Jersey and has operational and administrative responsibility for a professional and technical field staff. Prior to assuming her current position in November 2008, Ms. Amador-Toro served 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.



Michael Bruckheimer, BS, RPh – Mr. Bruckheimer is Executive Director, Group Quality Assurance of Novartis Pharmaceuticals Corporation, East Hanover, NJ. His responsibilities include oversight of compliance activities relating to FDA regulatory requirements in GMPs, GLPs and GCPs. He plays a key role in Novartis' inspection management operations, pre-approval readiness, internal audits and verification of corrective actions. Prior to the formation of Novartis, he had responsibilities for GLP/GCP Quality Assurance at the former Sandoz Pharmaceuticals Corporation. The majority of his career was with the U.S. Food and Drug Administration as both a Compliance Officer and Field Investigator. During his many years at FDA he conducted local, national and international inspections/investigations and represented FDA at meetings with domestic and foreign government officials.



H. Gregg Claycamp, PhD – Dr. Claycamp joined CDER's Office of Compliance as the Associate Director for Risk Analysis and Strategic Policy Assessment in early 2007. He was appointed as permanent Director of the Division of Compliance Risk Management and Surveillance in 2008. Dr. Claycamp directs a division working on a portfolio of risk problems, risk management systems, strategic policy analysis and surveillance inspections.



Richard J. Davis, BS – Mr. Davis operates Richard Davis & Associates LLC, providing quality assurance and supply chain services to the international pharmaceutical industry. He was formerly employed by Bristol Myers Squibb and the DuPont Pharmaceutical Company as Senior Vice President for Quality Assurance and Regulatory Compliance. At DuPont he was responsible for worldwide quality assurance and regulatory compliance. Prior to this, Mr. Davis was the Regional Director for the Mid-Atlantic Region of the FDA from 1977 to 1994. He joined the FDA in 1961 and served in a number of positions before his appointment to Regional Food and Drug Director.



David K. Elder, BS – Mr. Elder has been with FDA since 1988 and has been the Director of the Office of Regional Operations (ORO) within the Office of Regulatory Affairs (ORA) since January 2009. From September 2003 – January 2009, Mr. Elder was Director of the Office of Enforcement (OE) within ORA. Prior to assuming this position in September 2003, Mr. Elder spent the previous 15 years with FDA's New England District Office.



Richard L. Friedman, BS, MS – Mr. Friedman is the Director of the Division of Manufacturing & Product Quality in the Center for Drug Evaluation and Research (CDER), Office of Compliance. In this position, he directs the interpretation and development of CGMP policy, review of inspectional recommendations, and determination of manufacturing site acceptability. He has been employed by FDA since 1990, including prior positions as New Jersey District Drug Specialist, CDER Senior Compliance Officer, and Team Leader of Guidance and Policy.

THE PRESENTERS



Joseph McGinnis, RPh – Mr. McGinnis is a Captain in the U.S. Public Health Service whose current Duty Station is the New Jersey District Office of the Food and Drug Administration. He began his FDA career in 1994 as an Investigator in New Jersey's North Brunswick Resident Post and was promoted to Compliance Officer in June 2000 where he specializes in pharmaceutical industry and pharmacy compounding cases. Captain McGinnis also serves as a member of the Secretary's Emergency Response Team, is a graduate of the agency's Leadership Development Program and also recently completed a four month detail in Rockville as the Special Assistant to the ACRA.



Debra L. Pagano, BS, MT(ASCP) – Ms. Pagano is an independent consultant with Debra L. Pagano, FDA Consultants, LLC. Prior to this, she worked for the Food and Drug Administration for 17 years. She was the Pre-Approval Program Manager from October 1994 to October 2002 and previously held positions as drug specialist and investigator. She has provided the Pharmaceutical Industry as well as FDA investigators and chemists, training in various drug program areas. She was a course advisory member and teacher for FDA's Pre-Approval Inspection Training Course for Investigators and Chemists; FDA's Pre-Approval Manager Update session and FDA's Basic Drug School. In addition, Ms. Pagano is an adjunct professor for Temple University's Quality Assurance/Regulatory Affairs Masters Program. She has conducted numerous inspections in the pre-approval program and pharmaceutical areas and was on FDA's Foreign International Inspection cadre.



Michael Simeone, RPh, MBA – Mr. Simeone is the Director of Continuing Education, College of Pharmacy, University of Rhode Island. He has an extensive background in developing and implementing continuing pharmaceutical education programs. Prior to joining the College of Pharmacy, he practiced hospital pharmacy for over twenty years. Mr. Simeone is also a Certified Diabetes Outpatient Educator in the state of Rhode Island.



Peter D. Smith, BS – Mr. Smith, Vice-President Pharmaceutical Compliance, PAREXEL Consulting (formerly KMI), spent 22 years in various FDA field and headquarter positions, including heading the foreign drug inspection program. Since joining KMI in 1994 he has been working with clients domestically and internationally regarding regulatory and GMP compliance issues. His primary areas of expertise include active pharmaceutical ingredients (API's); Pre-approval inspections (PAIs); sterile and non-sterile dosage forms; FDA foreign inspections; GMP/quality systems, and FDA and international regulatory requirements.



Myriam M. Sosa, BS, MS – Ms. Sosa is the Director of Investigations Branch for the FDA in Parsippany, New Jersey.



CDR Domenic J. Veneziano, BS – CDR Veneziano has been the Director of the Division of Import Operations and Policy, FDA, since March 2005. He is responsible for providing direction, guidance, and leadership to all FDA district offices and senior agency official related to the importation of FDA regulated commodities. He began his FDA career in 1992 as an Investigator in the New England District Office, where he conducted both foreign and domestic inspections and investigations.



D. Christopher Watts, PhD – Dr. Watts is the Team Leader for Standards and Technology in the Office of Pharmaceutical Science at the FDA's Center for Drug Evaluation and Research. His current responsibilities include developing Agency policy and training programs, managing standards efforts, and collaborating in research ventures with industry and academia. Prior to joining the FDA, his industrial experience involved product and process development, as well as the scale-up and manufacture of inhalation and oral drug products.

AGENDA

May 18, 2010

Morning Session: Moderator – Richard J. Davis

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|---------------|---|---|
| 8:00 – 9:00 | Registration | |
| 9:00 – 9:05 | Welcome | Michael Simeone, URI College of Pharmacy Gregg Claycamp, PhD, CDER |
| 9:05 – 9:45 | Deviation Management – FDA Perspective Root Cause and Deviation Event Trending (Biologic and Drug Products) – COMPLIANCE EXPECTATIONS <ul style="list-style-type: none">• Statistical Analysis of Data• Repeated Deviation Events and Root Causes• Impact on CAPA Effectiveness• How to Ensure You Comply with Expectations | |
| 9:45 – 10:25 | Process Validation-COMPLIANCE EXPECTATIONS FDA's New Process Validation Guidance Emphasizes Life Cycle Monitoring and Continuous Improvement <ul style="list-style-type: none">• FDA Inspections to Monitor State of Manufacturing and Quality System Control• Internal Evaluations (Audits) of Quality Systems• How to Ensure You Comply with Expectations | Rick Friedman, CDER |
| 10:25 – 10:45 | Break | |
| 10:45 – 11:25 | Deviation Management – Industry Perspective OOS Test Results –COMPLIANCE EXPECTATIONS <ul style="list-style-type: none">• FD483 & Warning Letter Citations• When is Averaging Permitted• When is Averaging Not Permitted• Replicate Injections | Peter Smith |
| 11:25 – 12:00 | Question and Answer Session | Morning Speakers |
| 12:00 – 1:15 | Lunch | |

Afternoon Session: Moderator – Michael Bruckheimer

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|-------------|--|----------------------|
| 1:15 – 2:00 | Keynote Address Focus of Commissioner's Enforcement Initiatives Changes Within Field Office <ul style="list-style-type: none">• Impact of New Personnel• Import & Export Activities• Foreign Inspection Program• Foreign Offices and Their Impact on Risk Management | David Elder, ORA |
| 2:00 – 2:45 | FDA CDER Update <ul style="list-style-type: none">• Learnings from 2009• Compliance Concerns and Initiatives for 2010• Latest on Laboratory Computer Systems• Supply Chains• OOS• Upcoming Guidances | Rick Friedman, CDER |
| 2:45 – 3:05 | Break | |
| 3:05 – 3:50 | FDA's Drive to Quality | Ali Afnan, PhD, CDER |
| 3:50 – 4:20 | Proposed Regulations to Clarify GMPs for Co-Packaged Drug and Device Components <ul style="list-style-type: none">• Impact on GMP Compliance Systems• How Should Plants React to These Proposed Regulations? | Richard Davis |
| 4:20 – 4:45 | Question and Answer Session | Afternoon Speakers |

AGENDA

May 19, 2010

Morning Session: Moderator – Peter Smith

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|---------------|---|--------------------------------|
| 9:00 – 9:35 | Import Overview and Update | Domenic Veneziano, ORA |
| 9:35 – 10:10 | Foreign Matter in Parenterals A Practical Discussion of Foreign Matter and Particulates in Parenteral Products | Debra Pagano |
| 10:10 – 10:30 | Break | |
| 10:30 – 11:10 | Supply Chain Risk Assessment and Risk Management Expectations <ul style="list-style-type: none">• Systems that Impress FDA Investigators• Quality Agreements• Processes That Do Not Meet FDA Expectations• Suggested Elements for Supplier Qualification Program• How Do I Know I Comply with Expectations | Myriam Sosa, FDA |
| 11:10 – 11:45 | Office of Pharmaceutical Science Update | D. Christopher Watts, PhD, FDA |
| 11:45 – 12:15 | Question and Answer Session | Morning Speakers |
| 12:15 – 1:30 | Lunch | |

Afternoon Session: Moderator – Richard J. Davis

| | | |
|-------------|--|--|
| 1:30 – 2:00 | Enforcement Update New FDA Policy on Warning Letters <ul style="list-style-type: none">• Feedback on Program Implementation• Summary of Warning Letters Issued New Consent Decrees Product Seizures Criminal Actions Trends in FD483 Citations | Joseph McGinnis, FDA |
| 2:00 – 3:30 | Bring Your Own Issues and Question and Answer Session | Joseph McGinnis, FDA Myriam Sosa, FDA Diana Amador-Toro, FDA Morning Speakers |



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For additional information, contact Pharma Conference Inc (830) 896-0027 Fax: (830) 896-0029 or e-mail: contactus@pharmaconference.com.
Our office hours are 8:00 a.m. to 4:00 p.m. Monday through Thursday and 8:00 a.m. to 1:00 p.m. Friday central USA time.

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