

**THE conference for the newest information coming out of FDA!**

**14<sup>th</sup> Annual  
FDA and the Current  
Challenges of GMPs**



**Bethesda, Maryland  
May 7 – 8, 2012  
Hyatt Regency Bethesda**

Conference produced by



Conference sponsored by

**NIPTE** The National Institute for  
Pharmaceutical Technology and Education  
*Improving quality and lowering costs of pharmaceuticals*

# ABOUT THE CONFERENCE

This year our GMP conference focuses on current and future regulatory expectations regarding the management of a global supply chain. Without question, this is one of the hottest issues in the drug industry and our agenda brings together worldwide regulatory officials from the USA and Europe to explain current and emerging regulatory expectations for supplier oversight. For example, our two keynote speakers have vast experience in managing a global supply chain and compliance with current and future regulatory expectations. These speakers can help you evaluate your current supplier oversight process and to redesign it to meet current and future expectations. Take a look at the speakers and topics for the second day of the conference. These topics will evaluate GMP issues that often appear on lists of observations from worldwide regulatory inspections. The speakers for these topics have significant regulatory inspection and enforcement experience in FDA and other worldwide regulatory departments. For example, you don't see many conferences with a topic on microbiological enforcement issues. Finally, we have identified two additional technical topics for this conference; filter evaluation and testing and electronic data systems. Again the speakers for these subjects have vast experience and technical expertise. This conference is designed to help you return to your department with a new vision of current and emerging regulatory expectations and new ideas to help you build systems that will meet these expectations before you see observations of deficiencies at the end of your next inspection. And, you will return to your department with knowledge and experience that makes you more valuable to your company. We look forward to your attendance at this conference.

## WHO SHOULD ATTEND?

- 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

## 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).



Register online at [www.pharmaconference.com](http://www.pharmaconference.com)

# THE SPEAKERS

Photo Not  
Received  
at Press  
Time

**Anthony Charity** – Mr. Charity's biographical information will be posted as received; please continue to check for updates.



**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.



**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 is a Technical Vice President with PAREXEL Consulting. He joined PAREXEL International in January 2012 after a career that spanned over 23 years with the U.S. Food and Drug Administration. 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. As a senior agency executive in the Office of Regulatory Affairs, he established and/or approved field operational policy and procedures. Mr. Elder has extensive and current experience with agency compliance and enforcement policy. In addition to his recent executive level experience, Mr. Elder served 15 years as an Investigator, Compliance Officer and Director of Compliance at the District Office level.



**Dennis Guilfoyle, PhD** – Dr. Guilfoyle has worked for the FDA for over 38 years and has been classified as a FDA international expert in pharmaceutical microbiology (Sterile and non-sterile products). He serves as an instructor at both national and regional FDA training courses for Pharmaceutical, Medical Device and biotechnology issues. He has assisted on over 150 team inspections that include Team Biologics. He periodically assists FDA Compliance branch and the Office of General Counsel on regulatory interpretation of emerging microbiological problems. He has co-authored 30 scientific publications and co-written/reviewed several FDA field guidelines for microbiological inspections as well as some industry technical baseline documents. He has been involved in the design, construction, and validation of three FDA bioclean rooms as well as a BSL level 3 containment laboratory for the testing of select agents. Dr. Guilfoyle is an FDA liaison to the USP expert committee on Microbiology and Sterility Assurance. He is an active member of the CDER Pharmaceutical Quality Standards Working Group (PQSWG), FDA Field Drug Committee, and presently he is assigned to the USP Monograph modernization task force. Dr. Guilfoyle is an adjunct associate professor for St. John's University in their graduate Pharmacy program. He teaches cGMPs and Process Validation.



**Michael Moussourakis, BS, MS** – Mr. Moussourakis is a Biopharmaceutical Marketing Manager at Pall Life Sciences headquartered in Port Washington, NY. The Biopharm Marketing team provides tactical and product leadership to Pall customers for their processing needs. Mr. Moussourakis has over 10 years experience in the Life Science industry. The last eight years of this have been with Pall where he has provided on site tactical and consultative support, product and technical training, and troubleshooting in various customer process applications.

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at Press  
Time

**Chris Nelson** – Mr. Nelson is currently the Event Frames (Batch) software development lead at OSIssoft, LLC. His previous assignment was leading the development of RtReports, the OSIssoft real-time web-enabled reporting product. Prior to joining OSIssoft, Mr. Nelson worked for Merck & Co., Inc., as a Manager in both Clinical Trial Systems and Manufacturing Process Information Systems. He has over 15 years of experience in software development, having designed several manufacturing information and data analysis systems as well as participating in various control system implementations.

# THE SPEAKERS



**Mary Oates, PhD** – Ms. Oates is Vice President of Global Quality Operations for Pfizer. In this role, she is responsible for GMP oversight of all products made by and for Pfizer for both clinical and commercial use. Ms. Oates joined Pfizer in 1994 as a methods validation scientist. She subsequently held positions of increasing responsibility, including oversight for all post-approval regulatory changes and responsibility for Quality at all manufacturing facilities in North America. Prior to Pfizer, Ms. Oates worked as a chemist supporting clinical trials at Glaxo in Research Triangle Park.



**Debra Pagano, BS, MT(ASCP)** – Ms. Pagano has been a consultant to FDA regulated industry since 2002. In this capacity, she is a compliance consultant to the Pharmaceutical, Biologics and Medical Device Industries conducting mock pre-Approval and CGMP inspections of international and domestic firms. Coverage for CGMP inspections has included the systematic approach with a strong focus in the microbiological laboratory including the review of environmental monitoring programs for aseptic manufacturing and non-sterile manufacturing facilities. Projects have included GAP assessments for critical compliance issues and functions within the FDA regulated industry. She provides CGMP training and presentations on various FDA related topics domestically and internationally. Prior to starting her own company, Ms. Pagano worked for the Food and Drug Administration for 17 years.



**Edwin Rivera Martinez, BS, MBA** – Mr. Rivera Martinez's biographical information will be posted as received; please continue to check for updates.

Biographies and photos of speakers will be added as speakers are confirmed and the information is received.

Make sure to join us!  
**17th Annual  
GMP By The Sea**



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August 6 – 8, 2012 • Tampa, Florida  
Grand Hyatt Tampa Bay

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# AGENDA

**Monday, May 7, 2012**

**Morning Session: Moderator – Richard Davis**

8:00 – 9:00 Registration\*

9:00 - 9:45 **Keynote Address** Mary Oates, PhD, Pfizer  
– Building Our Quality Culture in a Global Supply Chain  
– Approaches that Work for Us  
– Focal Points for Success

9:45 - 10:30 **Keynote Regulatory Address** David Elder, Parexel  
– A View of the Next Generation of US Drug Regulation  
– Managing Global Regulatory Audits for Vaccines & Pharmaceuticals  
– Establishing Our Global Quality Culture

10:20 - 10:35 Break\*

10:35 - 11:15 **Drug Shortage Regulatory Oversight** FDA CDER Invited  
– New Legislative Requirements  
– FDA's Approach for Shortage Oversight  
– Industry Activities to Comply

11:15 - 12:00 **Question & Answer Session** Morning Speakers

12:00 – 1:15 Lunch\*

**Afternoon Session: Moderator – David Chesney**

1:00 - 1:35 **International Harmonization** FDA ORA Invited  
– Where Are We & Where Is This Going?  
– Information Exchange  
– PIC

1:35 - 2:10 **EU's Foreign Audit Program** EU Inspector Invited  
– Our Expectations for Supplier/Contractor Oversight  
– EU's USA Inspections (Vaccines & Pharmaceuticals)  
– Annex Updates

2:10 - 2:45 **Contractor/Supply Chain Oversight** Brian Hasselbach, FDA, CDER, invited  
– FDA's Current & Emerging Approaches & Industry Expectations

2:45 - 3:00 Break\*

3:00 - 3:30 **The Future of Foreign Inspections** Anthony Charity, FDA, ORO

3:30 - 4:00 **Electronic Data Systems** Chris Nelson  
– Are They Becoming too Complex  
– Evaluation of Electronic Batch Records  
– Tracking & Trending for CAPA Effectiveness  
– Are Current Systems Adequate & Do They Really Help Us  
– How Do We Implement Best Practices?

4:00 – 4:30 **Question & Answer Session** Afternoon Speakers

4:30 – 5:30 Networking Reception

# AGENDA

**Tuesday, May 8, 2012**

**Morning Session: Moderator – Richard J. Davis**

- 8:30 - 9:45 **Deviation Investigation** Debra Pagano
- FDA Expectations
  - Industry Training
  - Should Investigators & Approvers Be Dedicated Positions & Personnel & Have Compliance Experience?
  - Are There Deviations that Do Not Require Investigations
- 9:45 - 10:30 **PET Drug Manufacturing: Aseptic Processing & Microbial Controls According to cGMP 21 CFR 212** Dennis Guilfoyle, PhD, FDA, ORO
- 10:30 - 10:45 Break\*
- 10:45 - 11:30 **CAPA** Debra Pagano
- CAPAs Must Be Proactive – Are Changes Necessary?
  - CAPA Effectiveness Measures & Metrics
- 11:30 - 12:00 **Question & Answer Session** Morning Speakers
- 12:00 – 1:15 Lunch\*

**Afternoon Session: Moderator – Edwin Rivera Martinez**

- 1:15 - 2:15 **Filter Integrity Testing** Michael Moussourakis
- All About Filters, Their Controls, & Testing
- 2:15 - 2:45 **Process Validation** Edwin Rivera Martinez
- Progress Since The New Guideline Issued
- 2:45 – 3:00 Break\*
- 3:00 – 3:30 **CDER** FDA, CDER, Invited
- Regulatory And Compliance Update
  - Untitled Letters vs. Warning Letters
  - Field Alert Reports (Reporting Guidance)
- 3:30 – 4:30 Conference Wrap Up – Bring your GMP Issues for Panel

\*denotes non-educational activity

**CONTINUING  
EDUCATION**



The University of Maryland School of Pharmacy is accredited by the American Council for Pharmacy Education as a provider of continuing pharmacy education. This activity is eligible for ACPE credit; see final CPE activity announcement for specific details.

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# REGISTRATION

14th Annual FDA and the Current Challenges of GMPs

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## FEES

**Payment Received By March 30, 2012**

\$1795

**Payment Received After March 30, 2012**

\$1995

**Government and Press Rate: \$895**

Includes conference materials, continental breakfast, breaks and lunches per agenda

Cancellation Policy: 30 days or more for a full refund less \$150 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](mailto: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 15 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

### Hyatt Regency Bethesda

One Bethesda Metro Center  
Bethesda, MD 20814  
(301) 657-1234  
\$225 single/double

A limited number of rooms have been blocked at the special rate below per night (single or double). Hotel reservations must be made **on or before April 13, 2012** in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. Be sure to mention the name of the program when making your reservation in order to be properly identified with the program. Please do not use travel agents for reservations.

Hotel is approximately 25 minute METRO ride from DCA airport.

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