

# 2010 CONFERENCE SERIES

*Celebrating 15 years!*



**NEW  
LOCATION!**

## Savannah, Georgia

Conference produced by



Conference sponsored by

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

## 15<sup>th</sup> Annual GMP By The Sea

**August 16 - 18, 2010  
Hyatt Regency Savannah**

# ABOUT THE CONFERENCE

GMP by the Sea is about change this year. Not the word you want to hear these days? What if the change means an all new and exciting location? A change in scenery during the network reception? How about a change in the menu and structure of the Evening Social to add some more fun? What we didn't change is the quality and the take-home value of the conference. It is still the best known GMP conference around.

This year, the keynote address will be given by the new FDA Chief Counsel. It will be a unique opportunity to learn a legal perspective of GMP compliance. Subjects important to you have been a consistent portion of our plenary sessions- senior CBER, CDER and ORA officials will provide the latest information about their division activities. Industry leaders will also discuss their best practices and reactions to FDA initiatives. And, back by popular demand, you will have the opportunity to bring your issues and questions on inspections and imports direct to ORA management.

The workshop format also remains the same, giving you the opportunity for more interaction and better learning by allowing you to attend four of the eight fascinating sessions offered. The enhanced agenda provides a brief description of each workshop to assist you in planning for your workshop attendance.

In addition to the planned question and answer sessions with the speakers, the networking reception and evening social provide the opportunity for informal discussions with the regulators, industry speakers and conference attendees. You should not leave this conference without having your questions answered!

Pharma Conference Inc celebrates its 15th year of producing GMP by the Sea and is extremely proud of its success. With the many changes facing drug and biologics manufacturers, it is the conference that should not be missed. Register today!

## **Hyatt Regency Savannah**

The hotel is located in historic Savannah and is in the heart of the city's downtown waterfront with plenty to do within walking distance. Experience the River Street by trolley, walking tours or riverboat cruises.

## **About Our New Conference Sponsor**

Pharma Conference is pleased to announce our new conference sponsor, The National Institute of Pharmaceutical Technology and Education (NIPTE). NIPTE is an independent, non-profit organization representing 11 U.S. universities that are leaders in research and education in pharmaceutical science and engineering. The member universities are Duquesne University, Illinois Institute of Technology, Purdue University, Rutgers University, University of Puerto Rico, University of Connecticut, University of Iowa, University of Kansas, University of Kentucky, University of Maryland - Baltimore, and the University of Minnesota. For more information, please visit NIPTE's website: [www.nipte.org](http://www.nipte.org).

## WHO SHOULD ATTEND?

- Regulatory Affairs Professionals
  - Quality Assurance Professionals
  - Production Managers and Personnel
  - Corporate Officers of Pharmaceutical and Biopharmaceutical Companies
- ...basically, anyone involved with GMP matters related to pharmaceuticals or biopharmaceuticals

## WHY ATTEND?

- To discuss "hot" topics with FDA officials
- To get FDA's latest thoughts on GMP matters
- To ask your questions and receive specific answers
- To interact with your peers on GMP matters
- To take valuable knowledge learned at the conference back to your company
- To network and interact with all regulatory officials present

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

# THE PRESENTERS



**Diane Alexander, BS, MT(ASCP)SBB** – Ms. Alexander serves as the Branch Chief of the Biological Drug and Device Compliance Branch in the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research. As the Chief in the Biological Drug and Device Compliance Branch, she is responsible for the review and evaluation of administrative and legal actions for biological drugs and devices regulated by CBER. She began her service with FDA in 1995. Prior to joining FDA, Ms. Alexander was employed as a Medical Technologist in the Washington Hospital Center's Blood Bank.



**Edward Allera, BS, JD** – Mr. Allera is a managing shareholder of the Washington, D.C., office of Buchanan Ingersoll & Rooney PC, as well as chairman of the firm's FDA/Biotechnology Section. He began his career at the FDA, where he served as associate chief counsel. As a pharmacist, one of Mr. Allera's strengths is the ability to integrate science into the law to combat ill-considered FDA actions. He also has a cadre of experts with whom he works that enables him to create rapid, sophisticated legal/scientific rebuttals to FDA actions. He has worked extensively in the product life cycle management area and with almost every dosage form. Because he has a background in the science surrounding dosage forms and pharmacokinetics, he has filed a large number of Citizen Petitions in the product life cycle management process.



**Maria Anderson, BS, MS** – Mrs. Anderson has served as a Consumer Safety Officer in the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (CBER) since 2005. She is responsible for the review and evaluation of administrative and legal actions for biological drugs and devices regulated by CBER. Prior to joining FDA, Mrs. Anderson worked as a Biologist with the National Institutes of Health (NIH).



**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.



**Michael Cipriano, BS** – Mr. Cipriano has 12 years of experience at Genentech leading numerous automation projects and plant startups. During the last three years he has been the lead system engineer for four automated inspection lines at Genentech's Hillsboro Fill/Finish facility overseeing all phases of the AIM implementation including specifications, design, installation, engineering development of vision tuning and supporting qualification strategies and plans. He is responsible for all aspects of Automated Visual Inspection including defect set specifications, ongoing performance monitoring, and implementation of inspection action limits.



**Jon Clark, BS, MS** – Mr. Clark is the Associate Director for Policy Development and GMP in the CDER Office of Pharmaceutical Science. He joined the FDA in 1992 after 12 years experience working in industry. He has experience reviewing chemistry submissions, developing electronic submission technology, and helping to shape the future of drug product quality regulation in the FDA. He is engaged in the Pharmaceutical Quality CGMPs for the 21st Century program, the Product Quality Research Institute (PQRI) and ICH. He frequently represents CDER's drug quality policy in public speaking engagements and working groups.



**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.

# THE PRESENTERS



**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.



**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.



**Joseph George** – Mr. George has been with FDA/CBER since 2003. Starting in the Office of Vaccines Research and Review, he was involved in research related to rapid microbiological methods and their application in sterility and mycoplasma testing. He was also a reviewer as the LAL product specialist. In 2007, he joined the Division of Manufacturing Product Quality in CBER's Office of Compliance as a Consumer Safety Officer, his current position. There he performs CMC reviews and inspections for BLAs and licensed product supplements. His areas of expertise include cGMP related to facilities and equipment, aseptic processing and sterility assurance.

PHOTO  
NOT  
AVAILABLE  
AT PRESS  
TIME

**LT Tara Goen, BS, MS** – LT Goen is a Commissioned Corps Officer who began her career with FDA in the New Jersey District Office as an investigator. As an investigator in New Jersey, she conducted domestic and foreign inspections of drug manufacturing facilities for compliance with Current Good Manufacturing Practices. In 2007, she transferred to FDA/CDER, Office of Compliance, Division of Manufacturing and Product Quality as a Chemical Engineer within the Guidance and Policy Development Team. She is currently a Team Leader in the New and Generic Drug Manufacturing Team. This Team handles the evaluation of establishments named in applications and the pre-approval inspection program. Prior to FDA, she spent time in small-scale and pilot scale pharmaceutical manufacturing facilities and academic research related to biotech manufacturing.



**Gerald W. Heddell, BSc, MiBiol, CBiol, MRSC, DMS** – Mr. Heddell joined the MHRA as Director of the Inspection & Standards Division in 2005. His responsibilities focus on the quality of medicines in the UK and include a comprehensive surveillance, inspection and enforcement program, the licensing of pharmaceutical manufacturers and wholesalers, defective medicines reporting, unlicensed imports, borderline products, medicines testing and the British Pharmacopoeia.



**John Hyde, BS, MS** – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 100+ engineers and scientists founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. For nearly two years prior to the formation of JM Hyde Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company located in Boulder, CO. His work at Synergen included design, start-up and validation of key process systems and the overall responsibility for the cleaning validation programs for the firm's large scale and clinical manufacturing facilities. From 1982 to 1992, John was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of hygienic process systems and the application of CIP technology.



**Christopher Joneckis, PhD** – Dr. Joneckis serves as the Senior Advisor for Chemistry, Manufacturing and Control (CMC) Issues at the FDA. In this position, he advises on a variety of CMC issues for the Center's regulatory, review, scientific programs and activities. He is also involved in several Agency groups drafting CMC and cGMP policy, and is currently a member of the FDA Pharmaceutical Quality Council and the Quality Lead for CBER in ICH activities. He is involved in the development and implementation of several Center and Agency programs, policies and standards for CMC and review issues in the Center, including Standards Activities, Quality Systems and Bioinformatics.

# THE PRESENTERS



**Richard Jushchyshyn, BS, MBA** – Mr. Jushchyshyn, a Principal Consultant with Hyde Engineering + Consulting, Inc., has over 35 years of food and bio/pharmaceutical industry experience in various engineering, operations management and consulting roles. He began his career in the food industry with Whitman's Chocolates as an industrial engineer. He then spent 20 years with the predecessors to GlaxoSmithKline providing compliance, validation, engineering, engineering management and operations management support. His expertise includes projects at GSK's North American manufacturing sites, particularly the Philadelphia based solids, liquids, sterile dosage form manufacturing plant, and the Upper Merion based small and large volume parenteral antibiotic manufacturing site. Mr. Jushchyshyn has been with Hyde Engineering + Consulting, Inc. since 2004 providing compliance, cleaning and sterilization technology subject matter expertise the firm's client base.



**Daniel Lobato, BS** – Mr. Lobato is leader of the Quality Control function for all aspects of vaccine production at Emergent's site in Lansing, MI. Before joining Emergent BioSolutions, he was a consultant with Shadle Consulting Services implementing quality systems, GMP auditing, and providing training to a variety of clients. He was Director of Quality Control at Genitope Corp. maker of MyVax® personalized cancer therapy; patient-specific monoclonal antibodies. Prior to that, he was vice president of Quality at Micro-Virology Laboratories, Inc. (MVL), a contract laboratory where he implemented quality systems to service biotechnology and pharmaceutical companies on the west coast, and had 2 successful FDA inspections. Before joining MVL, he was associate director of QC at Onyx Pharmaceuticals overseeing testing of a novel oncolytic virus product in clinical development. He has more than 20 years of experience in QA and QC, with a strong emphasis on biopharmaceuticals and raw materials. Mr. Lobato has held positions at other leading pharmaceutical companies such as SmithKline Beecham biopharmaceutical development, Synergen, Inc.; and Geneva Pharmaceuticals.



**Mary Malarkey, BS** – Ms. Malarkey is the Director, Office of Compliance and Biologics Quality (OCBQ), at FDA's Center for Biologics Evaluation and Research (CBER). From 2000 through 2004, she was the Director, Division of Case Management (DCM), OCBQ, CBER. Prior to that, Ms. Malarkey was a Branch Chief in the Division of Manufacturing and Product Quality (DMPQ), CBER. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989.



**Marion Michaelis, BA, MT(ASCP)** – Ms. Michaelis has been a Consumer Safety Officer at FDA/CBER's Division of Manufacturing and Product Quality (DMPQ) since 2007. Her duties include: reviewing Chemistry, Manufacturing and Controls (CMC) section of biologics license applications and supplements; conducting pre-approval and pre-license inspections for biologics; participating in industry meetings and, various policy groups addressing CGMP issues for biologics products. Before joining the FDA, she spent 28 years as a Clinical Medical Technologist. Her clinical experience focused mostly in the discipline of Microbiology and Infectious Diseases. She also worked for a number of years in the area of risk management and regulatory compliance oversight for the Department of the Army's North Atlantic Medical Command Pathology Laboratories.



**Sharon O'Callaghan, BS** – Ms. O'Callaghan is a Consumer Safety Officer with the Division of Inspections and Surveillance, Office of Compliance, Center for Biologics Evaluation and Research (CBER). She joined FDA in 1988 as a medical technologist and has managed the Biological Product Deviation (formerly Error and Accident) Reporting System since 1990. Ms. O'Callaghan was instrumental in developing the final rule on reporting Biological Product Deviations, published November 7, 2000.



**Timothy Oswald, BS** – Mr. Oswald is the Manager of Project Services for The Quantic Group, Ltd., a consulting firm focused on compliance and manufacturing issues for the Pharmaceutical and related industries. In 15 years with Quantic, Mr. Oswald's client work includes Consent Decree assessments and Quality System remediation projects.

# THE PRESENTERS



**Christopher Petroski, BS, MS** – Mr. Petroski is Executive Director, West Point Quality Operations, with Merck Sharp & Dohme Corp., Manufacturing Division. His responsibilities include directing all quality related functions at the West Point, Pennsylvania site including QC release and stability testing, auditing, product release activities, environmental monitoring, and GMP compliance. He has been with Merck since 1987 and has held leadership roles in Biological Quality Control, Biological Quality Assurance, and CMC for vaccines.



**Emma Ramnarine, BS, MS** – Ms. Ramnarine started with Genentech in 2005 and is currently Head of Global Quality Risk Management for Roche. She is responsible for leadership and governance of Roche's QRM program throughout the product lifecycle including integration of QRM into the Quality System. Ms. Ramnarine has extensive practical risk management experience as a trainer/facilitator in leading complex risk assessments using Fault Tree Analysis, Failure Modes and Effects Analysis, Preliminary Hazard Analysis, Hazard Analysis & Critical Control Points, etc. She also led the development and implementation of Genentech's risk based validation program for manufacturing, laboratory and computer systems. Her prior experience includes developing Quality Systems in device, combination product and pharmaceutical companies with emphasis on Risk Management, Laboratory Systems, Change Control and Validation.



**Edwin Rivera-Martinez, BS, MBA** – Mr. Rivera-Martínez is Chief of the newly created International Compliance Branch, which serves as the compliance branch for all human drug and API inspections conducted by FDA abroad. From July 1990 to November 2002, he served as compliance officer in DMPQ where he reviewed proposed regulatory actions for conclusiveness and acceptability of evidence, nature and extent of deviations from cGMP's, and appropriate regulatory action strategy. Prior to transferring to CDER, he was an investigator in FDA's San Juan district office for 14 years where he specialized in the inspection, auditing, and investigation of complex, state-of-the-art active pharmaceutical ingredient and drug product production facilities.



**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.



**Ralph Tyler, BA, JD, LL.M.** – Mr. Tyler became Chief Counsel to the Food and Drug Administration (FDA) in January 2010. Immediately prior to joining the FDA, Mr. Tyler was the Maryland Insurance Commissioner. Mr. Tyler has worked as a lawyer for more than 35 years. His governmental law positions include serving as Counsel to the Governor of Maryland, Baltimore City Solicitor, and Maryland Deputy Attorney General. He was also a partner in the law firm of Hogan & Hartson, L.L.P. His legal practice has focused on civil litigation and administrative law.



**David Willis, PhD** – Dr. Willis is Senior Manager of Regulatory Affairs for Emergent BioDefense. The primary focus of this company is BioThrax® (Anthrax Vaccine Adsorbed), the only licensed anthrax vaccine in the U.S. Dr. Willis is responsible for FDA interactions related to manufacturing operations at the Lansing, Michigan facility. He has over 20 years of experience in the biologics, pharmaceutical and device industries, including R&D, pre-clinical, clinical, manufacturing and Regulatory Affairs (domestic and international). This experience allowed him to successfully interact with a variety of teams in the design, planning and implementation of Quality Systems consistent with FDA's new inspection guidance.

## Monday, August 16, 2010

### Morning Session: Moderator – Mark Elengold, Program Chairman

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	J.W. Smith Pharma Conference Inc Ralph Tyler, JD, FDA Chief Counsel Edward Allera, JD
9:10 – 9:55	Keynote Address: FDA Enforcement of GMPs – A Legal Perspective	
9:55 – 10:40	SubKeynote Address: FDA's Enforcement of GMPs – A View from the Private Bar	
10:40 – 11:00	Break	
11:00 – 11:40	FAQs - Direction to Existing Guidance and Parametric Release, USP New Process Validation Concepts and Comparability Protocols	Jon Clark, FDA Christopher Joneckis, PhD, FDA Edwin Rivera-Martinez, FDA Morning Speakers
11:40 – 12:15	Question and Answer Session	
12:15 – 1:30	Lunch	

### Afternoon Session: Workshops

1:30 – 3:00	<b>1. Quality Agreements</b> This workshop will provide a hands-on opportunity to develop the elements of a Quality Agreement for various types of Quality relationships, pitfalls to avoid in developing a Quality Agreement, and what actions should follow the approval of a Quality Agreement.	Christopher Petroski Maria Anderson, FDA
	<b>2. Technology Transfer/Change Control</b> An interactive workshop to address compliance with change control and technology requirements listed in the GMPs. The objective of this workshop is to address compliance with change control and technology transfer requirements listed in the statutes and GMPs. Change control and Technology Transfer are important functions in the life cycle approach to process validation addressed in FDA's latest process validation guidance. Both have been mentioned in recent CDER process validation presentations – change is mentioned nine times in the FDA's newest guidance on process validation	Richard Davis Peter Smith
	<b>3. Risk Based Cleaning Design</b> Learning objectives are to understand and utilize risk based and science based approaches to cleaning process development, engineering, qualification and ongoing monitoring the result in effective and efficient cleaning operations for pharmaceutical and biopharmaceutical manufacturing.	John Hyde
	<b>4. Biological Product Deviation Reporting</b> Not just a requirement, it's a process. The "nuts and bolts" of the reporting process, including investigations and CAPA.	Sharon O'Callaghan, FDA Diane Alexander, FDA
3:00 – 3:20	Break	
3:20 – 4:50	Workshops Repeated	
5:30 – 7:00	<b>Networking Reception – hors d'oeuvres and drinks</b>	

# AGENDA

**Tuesday, August 17, 2010**

**Morning Session: Moderator – Richard Davis**

9:00 – 9:30 A Foreign Regulator's Perspective on Current Quality Issues  
9:30 – 10:00 CBER Compliance Update  
10:00 – 10:30 Office of Enforcement (OE) Compliance Update

Gerald Heddell, MHRA  
Mary Malarkey, FDA  
Director, Office of Enforcement,  
FDA

10:30 – 10:50 Break  
10:50 – 11:20 CDER Update  
11:20 – 11:50 ORO Inspection Update - An Interactive Discussion with FDA About  
YOUR Questions  
*(This is a session where you should come prepared with questions from your  
office or site.)*  
11:50 – 12:30 Question and Answer Session  
12:30 – 1:45 Lunch

Edwin Rivera-Martinez, FDA  
David Elder, FDA

Morning Speakers

**Afternoon Session: Moderator – Workshops**

1:45 – 3:15 **1. Issues in Vaccine Manufacturing**

This workshop will be hosted by representatives from CBER and Industry with hands-on experience in vaccine manufacture and regulation. Participants will review practical case studies and discuss appropriate strategies for short term and durable corrective actions, Regulatory notifications and Quality System impact. The focus of the workshop will be on achieving compliance while finding opportunities for improvement using real-world situations. The workshop will include both team activities, role play, and presentations. Audience participation through question and answer will further expand the scope of discussions.

David Willis, PhD  
Diane Alexander, FDA

**2. Moist Heat, Sterilization, Sanitization and Decontamination**

The learning objectives of this workshop are to understand regulatory expectations and concerns around the application of steam technology and to understand how to apply best practices in good engineering and qualification principles to prevent issues within pharmaceutical and biopharmaceutical manufacturing operations.

Richard Jushchyshyn  
Marion Michaelis, FDA

**3. Avoiding Warning Letters**

A facilitated workshop in short and long term approaches to maintain compliance. How can you prepare for inspections to reduce the likelihood of receiving a Warning Letter from FDA? How can sustainable quality systems be implemented to prevent significant compliance issues in the first place?

Timothy Oswald  
David Chesney

**4. Quality Issues for Releasing Final Vials**

This workshop will discuss two issues that are important to pharmaceutical manufacturers that use glass vials: what to do about glass vial breakage events and how to validate automated/semi automated visual inspection instruments. Broken or cracked vials can lead to products complaints and potentially submission of BPDRs to the Agency. Validation of automated systems has its own unique challenges that will be discussed during this session.

Mike Cipriano  
Joseph George, FDA

3:15 – 3:35 Break  
3:35 – 5:05 Workshops Repeated  
6:00 – 8:00 **Evening Social – dinner, drinks, and fun, etc.**

# AGENDA

Wednesday, August 18, 2010

**Morning Session: Moderator – Timothy Oswald**

9:00 – 9:45	Joint Regulatory Inspection	CDER TBD
9:45 – 10:45	Supplier Management Perspectives - Industry - FDA	Daniel Lobato Joseph George, FDA
10:45 – 11:05	Break	
10:30 – 11:30	Risk Assessment-Expectations and Inspection Outcomes - Industry - FDA	Emma Ramnarine Tara Gooen, FDA
11:30 – 12:00	Question & Answer Session	

**CONTINUING  
EDUCATION**



Participants will receive 1.5 CEUs (15.00 contact hours) for **15th Annual GMP By The Sea** conference attendance. The University Of Maryland School Of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Statements of credit will be mailed to participants within six to eight weeks of program completion. Attendance at the entire program and the completion of evaluation forms and self-assessment tools at the conclusion of the program are required for issuance of a statement of credit. ACPE Universal Activity Number 0025-9999-10-052-L04-P.

**Learning Objectives**

1. Explain the legal perspectives of compliance with the Food and Drug Administration's (FDA's) current Good Manufacturing Practice (GMP's).
2. Describe the recent activities of the various divisions within the FDA, including the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER).
3. Apply current guidelines to achieve regulatory compliance in the manufacturing of drugs and biologics.
4. Identify the key points of emphasis in preparing for regulatory inspections.

## ABOUT THE VENUE

Savannah's architecture and history are internationally known, as is its reputation for Southern charm and hospitality. Each year, Savannah attracts millions of visitors from across the country and around the world. Savannah's downtown area is one of the largest National Historic Landmark Districts in the United States. The city was founded in 1733 by James Oglethorpe.



# REGISTRATION 15<sup>th</sup> Annual GMP By The Sea

**CLICK HERE TO REGISTER ON OUR SECURE SERVER**

## FEES

Payment Received By June 3, 2010

☐ \$1795

Payment Received After June 3, 2010

☐ \$1945

Includes conference materials, continental breakfast, breaks, lunches, networking reception and evening social 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 Inc (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 Inc 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

### NEW ADDRESSES!

Please note that these addresses are new as of March 1, 2010. Please make sure that your accounting office is aware of this change of address.

## HOTEL

**Hyatt Regency Savannah**  
Two W Bay St  
Savannah, Georgia 31401  
(912) 238-1234  
(800) 233-1234  
\$149 Single or 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 July 14, 2010 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 and Pharma Conference Inc when making your reservation in order to be properly identified with the program. Please do not use travel agents for reservations.**

**\*Rate includes complimentary fitness center use and complimentary internet in all guest rooms**

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