A MUST ATTEND event for all pharmaceutical companies!

1ST ANNUAL INTERNATIONAL CONFERENCE ON SUPPLY CHAIN SECURITY AND MANAGEMENT

OCTOBER 24 – 26, 2017 | MEMPHIS, TENNESSEE

with Welcome Reception the evening of October 23, 2017

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Special discounts available

Conference produced by

PHARMA CONFERENCE INC

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About the Conference

The **1st Annual International Conference on Supply Chain Security and Management** is a two and a half day intensive and interactive program designed to provide attendees the tools they will need to address the developing area of supply chain security. Thought leaders and industry experts representing major pharmaceutical companies, legal firms, consulting groups, industry organizations, and former FDAers will be providing the most up-to-date and thought-provoking concepts in this rapidly evolving arena.

This program will present the entire supply chain and life cycle of medical products (i.e., raw materials to use by patients) and focuses on developing training programs, processes, procedures, and tools directed at enhancing global medical product quality and supply chain security. This program is intended to focus on efforts to:

- Provide insight into world-wide regulatory trends related to securing the supply chain
- Implement pertinent elements of current Good Manufacturing Practices and Good Distribution Practices
- Provide meaningful information to help companies update their quality management systems
- Implement good import and export practices
- Confirm product authentication and traceability

The **1st Annual International Conference on Supply Chain Security and Management** will allow ample opportunity for individual questions to be answered by the presenters, who are known as some of industry's foremost experts on product security. Like all Pharma Conference programs, it is designed to provide an informal, relaxed learning environment to help improve your performance at work. Information to be presented will be critical to Regulators, Quality Units, Regulatory Affairs, Legal Function, Corporate Security, and Supply Chain Management professionals working in all areas of the pharmaceutical industry. Attendees will receive not only intensive training and regulation information, but practical utilization techniques, as well.

Who Should Attend?

- Anyone involved in ensuring supply controls and effectiveness including quality assurance, quality control, legal, regulatory affairs, or auditing in the pharmaceutical and biopharmaceutical industry, especially those with direct responsibilities for any of these areas.
- Anyone who is not familiar with the requirements for Supply Chain Security and Management

Why Attend?

- To gain a better understanding of how the new supply chain requirements and regulatory initiatives will impact your company activities and operations and how to anticipate problem areas before they create problems for your company
- To take advantage of the knowledge of seasoned experts who are the World's experts on Supply Chain Security
- To understand the potential impact of current concerns in Supply Chain Security on future regulatory directions

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 different agreed guidances.

Timothy Butler, BA, MA, MBA – Mr. Butler is founder and CEO of Tego, Inc., whose technology turns products, components and systems into smart assets. He has a 20-plus year track record taking quantifiable risks to grow market share and achieve profit-generating status for emerging technologies. Tego is Mr. Butler's third technology company; prior to this, he was CEO and founder of SiteScape.

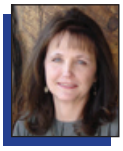
David Elder, BS – Mr. Elder, Executive Vice President, Greenleaf Health, has more than 28 years of extensive regulatory experience. At Greenleaf, he provides strategic guidance and support to pharmaceutical and medical technology companies. Mr. Elder is a 23-year veteran of the FDA where he held the following positions: Investigator, Compliance Branch Director, Director of the FDA Office of Enforcement, and Director of the FDA Office of Regional Operations.

Brad Elrod, BS, MS – Mr. Elrod is the President of Secure Concepts, with 28 years of professional experience to the world of supply chain security and brand protection in the pharmaceutical industry. He has established supply chain security programs for two major pharmaceutical companies globally and has managed government and law enforcement programs to prevent disruption to supply chains. His experience includes managing the Customs-Trade Partnership Against Terrorism at the Tier 3 level, managing the TSA Certified Cargo Screening Program, and working as the lead in several industry associations in the area of cargo protection and supply chain security.

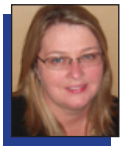
Chuck Forsaith, BS – Mr. Forsaith joined Purdue Pharma LP in 2001 after 21 years of service as both a New Hampshire municipal and State Police officer and also having formally directed security operations for a United States military installation. His responsibilities with Purdue Pharma include managing all domestic and international supply chain security efforts, as well as regulatory compliance with all Federal supply chain security programs. He also acts as the Chairman of the Pharmaceutical Cargo Security Coalition (PCSC), which consists of many individuals, from a wide variety of disciplines, who monitor the security of pharmaceutical goods in both transit and storage all over the world.

Gregg Goneconto, BA – Mr. Goneconto is a consultant with Baymar Consulting LLC. Prior to this, he spent many years in federal law enforcement, including 15 years with FDA's Office of Criminal Investigations, where he also served as Senior Operations Manager for drug investigations at OCI headquarters. Over a 10-year span at OCI headquarters, Mr. Goneconto witnessed the changing landscape of pharmaceutical supply chain threats and had the unique opportunity to oversee many of this country's most significant supply chain investigations involving prescription drug diversion and counterfeiting. He played a pivotal role in the development and implementation of FDA's widely successful pharmaceutical cargo theft strategy, as well as the agency's response to the counterfeit Avastin and Altuzan incidents.

About the Speakers



Susan Griggs, BS² – Ms. Griggs, Advisor, Eli Lilly and Company, has spent the last 17 years in security, emergency response, and environmental consulting, both in manufacturing and corporate roles. Her current focus is in facilities and logistics security, assisting Lilly sites and personnel in over 70 countries. Prior to joining Lilly, Ms. Griggs spent 13 years in the specialty chemical and environmental industries with positions in sales, operations management, and senior leadership roles.



Charlotte Hicks, BA, MBA – Ms. Hicks is a Chemical Supply Chain Professional with extensive experience in supply chain risk mitigation. She has worked for distributors VWR and ThermoFisher managing their production chemical portfolios and is the founder of SupplyChainRiskMitigation.com. While she has developed a commercial database to anticipate issues in the supply chain, her passion is to use common Google and Microsoft tools to develop systems that map and score risks for materials and suppliers to predict impacts in the supply chain.

Michael R. Loveless, BS, MBA – Mr. Loveless is Founder and CEO of RAAD360, maker of a game-changing SCRM software platform called RAAD™. Previously, he spent two decades in Enterprise Resource Planning solutions, including six years at SAP. He worked in venture capital and software marketing in the early 90s and has held positions ranging from boardrooms to technical development rooms.

Eric Marshall, BA, JD – Mr. Marshall is a senior director at Leavitt Partners, a health intelligence firm founded by former Secretary of Health and Human Services, Mike Leavitt. Mr. Marshall advises complex health care coalitions and provides consulting services in the areas of domestic and international supply chain security; drug, device, and diagnostics regulation; and health care compliance. Prior to joining Leavitt Partners, he practiced law, counseling health care and life science clients on regulatory, compliance, and transactional matters.

Charles Morton, BS – Mr. Morton is an Associate Director in Global Security at Merck where he leads supply chain security initiatives to enable the secure and efficient movement of Merck products and materials worldwide. He has over 20 years of combined experience in law enforcement, homeland security, supply chain security, and corporate security management. Mr. Morton is a former Vice President and North America Security Manager at Panalpina and served at the Transportation Security Administration (TSA) as Director of the HAZMAT Threat Assessment Program and is the former TSA Branch Chief for Highway Cargo Security.

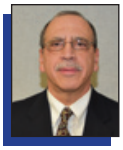
Mark Paxton – Photo and bio coming soon

About the Speakers

Vito Pirrera, BS – Mr. Pirrera, a co-founder and Executive Vice President at Vantage Consulting Group, is responsible for engineering and operations. He has 30 years of pharmaceutical manufacturing and compliance experience, specializing in manufacturing automation and validation. For the last six years, he has focused on expanding Vantage's serialization implementation and qualification team. Mr. Pirrera and his team work alongside serialization vendors and equipment OEMs to provide clients with the engineering design, installation, start-up and validation needed for a successful project.

Matthew Sample – Photo and bio coming soon

Gregory L. Schlegel, BS – Mr. Schlegel is Founder of The Supply Chain Risk Management Consortium, 19 companies that bring skills, solutions and methodologies that identify, assess, mitigate and manage enterprise risk. He has been a Supply Chain Executive for several Fortune 100's, has been a Supply Chain Executive Consultant for IBM, is Executive-in-Residence at Lehigh University teaching Supply Chain Risk Management, Adjunct Professor teaching Enterprise Risk Management for Villanova University's EMBA program and VP/Principal at SherTrack LLC. Mr. Schlegel is also past president of APICS.



Pete Scilla, BA – Mr. Scilla is Vice President, Supply Chain Innovation at RAAD360 LLC, where he helps fulfill the mission of uninterrupted, secure delivery of goods by successfully navigating the increasing risks in complex Global Supply Chains. In his current role, he guides the development of RAAD360 LLC's cutting edge integrated Supply Chain Risk Management (SCRM) Platform, RAAD™. Mr. Scilla has spent 40 years establishing and leading supply chains, including 20 years with Johnson and Johnson Pharma and six years as VP at start-up Pharma companies.

Jennifer Zachary, JD – Ms. Zachary is a partner in Covington & Burling's Washington, DC office, where she advises on compliance with FDA requirements for the development, manufacture, and sale of drugs and biologics, and assists clients with issues relating to GMP and GCP requirements, inspections, warning letters, recalls, import detentions, and compliance with the DSCSA. Before joining Covington, she served for six years as an Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel.

About the Venue

With a style and tradition befitting one of Memphis' grandest, most legendary hotels, The Peabody Memphis offers a magnificent bridge between the "Blues City's" celebrated past and cosmopolitan present.

Nestled in the heart of downtown, our historic Forbes Four-Star, AAA Four-Diamond hotel offers a one-of-a-kind experience just blocks from Beale Street, the Memphis Rock 'n Soul Museum, the Gibson Guitar Factory, Fed-Ex Forum, Sun Studio, the Orpheum Theatre and the Memphis Cook Convention Center.

Of course, The Peabody itself is also one of Memphis' most beloved attractions with the world-famous Peabody Ducks marching to and from the Grand Lobby fountain each day at 11 a.m. and again at 5 p.m. in a time-honored tradition that dates back to 1933.

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

Agenda

Monday, October 23, 2017

5:00 – 7:00	Registration	
6:00 – 8:00	Evening Welcome Reception*	

Tuesday, October 24, 2017
Morning Session: Moderator – Gary Bird, PhD, Conference Chair

7:30 – 8:30	Registration	
8:30 – 8:40	Welcome*	
8:40 – 9:10	**The Critical Issues of Supply Chain Management and Security**	Gregory Schlegel
9:10 – 9:40	**The Design Space (or Defining the Problem) – Supply Chain Management and Product Security**	Chuck Forsaith
9:40 – 10:10	**FDA Initiatives to Protect the Nation's Drug Supply**	David Elder
10:10 – 10:30	Break*	
10:30 – 11:00	**How Will the Drug Supply Chain Security Act Impact Manufacturing Activities?**	Jennifer Zachary
11:00 – 11:30	**Rising Drug Diversion and Counterfeiting Threats and the Role of Due Diligence to Protect Patients and Enhance Supply Chain Security**	Gregg Goneconto
11:30 – 12:00	**Question and Answer Session**	Morning Speakers
12:00 – 1:15	Lunch*	

Afternoon Workshops

1:15 – 2:45 **1. The Impact of the DSCSA (Drug Supply Chain Security Act) on Manufacturers** — Jennifer Zachary, Eric Marshall

The DSCSA is intended to enhance supply chain security through a series of new obligations phased in over the ten-year period. Many of these obligations must first be implemented by or are uniquely borne by manufacturers. For instance, beginning in November manufacturers must serialize their products and determine how they will designate "grandfathered" product for downstream trading partners. Manufacturers are the only trading partners responsible for submitting notifications to FDA of products at "high risk of illegitimacy." The building blocks for achieving unit level traceability, which must be in place in 2023, are being designed, developed, and implemented now and that process is raising a number of challenging regulatory questions for manufacturers. These questions range from the obligations of each trading partner to help compile traceability information to the role of FDA's increased emphasis on data integrity to the governance and ownership of data and shared resources. This workshop will explore a number of these issues.

Agenda

2. Case Studies – Criminal Intent and Lessons Learned in Supply Chain Diversion and Counterfeiting — To be determined

3. Zero Budget Supply Chain Mapping and Risk Mitigation — Charlotte Hicks

This workshop is designed for operations personnel who need a quick tool to anticipate and mitigate supply chain risk, but do not have a budget to outsource the project. In this course, the attendee will walk out with the skills to create:

- a heat map of their suppliers
- location risk and a method to create scores
- metrics to tease out risk
- monitoring of the supply chain
- predictive analytics

Attendees can bring their own data and computers to the workshop and walk out with a supply chain map and metrics to begin their risk mitigation journey.

4. Validation of Serialization Systems — Vito Pirrera

Participants will learn about and discuss developing IQ/OQ/PQ (Installation Qualification/ Operational Qualification/Performance Qualification) documentation for serialization solutions and how "on-site, off-line" testing reduces line downtime attributed to validation. This workshop will also take a different look at Factory Acceptance Testing and how to make it customer, rather than OEM (Original Equipment Manufacturer), driven.

2:45 – 3:05 Break*

3:05 – 4:35 **Workshops Repeated - the above workshops will be repeated**

Wednesday, October 25, 2017
Morning Session: Moderator – Chuck Forsaith

8:30 – 9:00	**The Global Serialization Regulatory Landscape – Pharmaceutical Online December 2016**	Eric Marshall
9:00 – 9:30	**Building a Proactive Supply Chain Security Program**	Brad Elrod
9:30 – 10:00	**Supply Chain Risk Management Strategies**	Charles Morton
10:00 – 10:20	Break*	
10:20 – 10:50	**Analyzing the Supply Chain Using Available Data**	Michael Loveless
10:50 – 11:20	**The Joint Audit Program: Confirming Product Quality in the Upstream Supply Chain**	Mark Paxton
11:20 – 11:50	**Visibility, the Key to Securing Your Supply Chain**	Pete Scilla
11:50 – 12:20	**Question and Answer Session**	Morning Speakers
12:20 – 1:35	Lunch*	

Agenda

Afternoon Workshops

1:35 – 3:05

1. Integrating Supply Chain Management and Security into Your QMS (Quality Management System) — Charles Morton

This workshop will focus on recommended practices to integrate supply chain security into a Quality Management System (QMS). Maintaining product integrity is a shared goal of quality and security management. The objective of this workshop is to provide attendees with an open forum to learn about and discuss how security risk management promotes quality management functions that seemingly operate in silos.

2. The Joint Audit Program: Securing Raw Materials, Excipients, and APIs (Active Pharmaceutical Ingredients) — Mark Paxton

3. Cross-Functional Solutions to Supply Chain Issues — Brad Elrod

Industry has long struggled with the security aspect of supply chain processes. This workshop will discuss the impact of conducting supply chain security programs business when measured against other essential programs in pharmaceutical supply chain. When considering the needs of your transportation and logistics personnel, supply chain planners, quality, and insurance/risk management teams, there is no reason that security functions cannot be integrated and even enhance the needs and concerns of these other vital functions.

4. Supply Chain Risk Management: A Scenario-Based Exercise in Identifying, Assessing, Mitigating, & Managing Enterprise Risk — Gregory Schlegel, Pete Scilla

This interactive session will cover new techniques for pharmaceuticals to better Identify, Assess, Mitigate, and Manage enterprise-wide supply chain risks, utilizing a Case-based, Scenario Analysis and Simulation methodology. This workshop will walk through pharmaceutical supply chain disruptions such as raw material issues, product theft/counterfeiting, manufacturing issues, delivery issues, natural disasters, port stoppages and more.

3:05 – 3:25 Break*

3:25 – 4:55 **Workshops Repeated - the above workshops will be repeated**

6:00 – 8:00 **Evening Social*** – An informal gathering for drinks and dinner. Included in the price of your registration fee. Dress Casual.

Agenda

Thursday, October 26, 2017
Morning Session: Moderator – Charles Morton

8:30 – 8:40	**Introduction and Moderator Comments***	
8:40 – 9:10	**In the Aftermath of the Largest Pharmaceutical Theft…**	Susan Griggs
9:10 – 9:40	**Government Based Trade Security Compliance Programs (C-TPAT (Customs-Trade Partnership Against Terrorism), AEO (Authorized Economic Operator), PIP (Partners in Protection), etc.)**	U.S. Customs – invited
9:40 – 10:10	**Counterfeits on the Move – How the Digitization of Drugs Can Help Manage Supply Chain Risk**	Timothy Butler
10:10 – 10:30	Break*	
10:30 – 11:00	**DSCSA (Drug Supply Chain Security Act), How Serialization Changes Supply Chain Management, Compliance, and Creates Opportunities**	Matthew Sample
11:00 – 11:30	**The Potential Future of Supply Chain Security: Regulatory Inspections**	David Elder
11:30 – 12:00	**Question and Answer Session**	Morning Speakers

*Denotes non-educational activity

Continuing Education

This conference qualifies for 15.0 hours of continuing education credit.

Register

1st Annual International Conference on Supply Chain Security and Management

Fees

	Industry	U.S. Gov't & Press
EXTRA EARLY DISCOUNT: Payment Received By June 1, 2017	❑ $2095	❑ $1395
EARLY DISCOUNT: Payment Received By August 7, 2017	❑ $2295	❑ $1395
NO DISCOUNT: Payment Received After August 7, 2017	❑ $2495	❑ $1395

Includes conference materials, continental breakfasts, breaks, lunches, welcome reception and evening social per agenda

Cancellation Policy: 30 days or more for a full refund less $250 USD 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

- All credit card transactions are processed in US Dollars (your bank will convert to your local exchange rate when billing)
- You will receive a confirmation via email as soon as the registration is processed. In order to receive the early registration price, payment must be made by the deadline specified in the brochure. (Taxpayer ID #27-1438344)
- Registrations must be accompanied by full payment.

Payment Terms: Conference attendees must be paid in full prior to conference start date.

Hotel

The Peabody Memphis Hotel
149 Union Avenue
Memphis, Tennessee 38103
(901) 529-4000
$199 single/double

A limited number of rooms have been blocked at the special rate listed per night. Rate is available 3 nights either side of the conferences dates, based upon availability of rooms. **Hotel reservations must be made on or before October 2, 2017, 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.**

Reservations:
Please call 1-800-PEABODY (1-800-732-2639)

Online:
https://reservations.travelclick.com/95096?groupID=1780668#/guestsandrooms

For additional information, contact Pharma Conference Inc:
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