Maintaining Compliant & Streamlined End-to-End Supply Chain Operations within the Pharmaceutical and Biotechnology Industries Through Comprehensive Understanding of Current Regulations and Operating Processes

PROGRAM OVERVIEW:
The current state of financial environment and the ever-changing conditions within the pharmaceutical and biotechnology industries has placed tremendous pressures on executives to reduce operating expenses, timelines, and overall efficiencies. While certainly this is a top priority within all divisions of these organizations, it is even more critical across the supply chain. A pharmaceutical supply chain is truly unlike any other supply chain for any other type of product, in complexity, cost, and regulation. No other product has such a high risk associated with potential contamination or instability of ingredient, sterilization and stability of packaging, as well as overall transport from factory to consumer, which needs to be strictly monitored and maintained. For that reason, it is absolutely critical for executives from the pharmaceutical and biotech industries to gather to discuss and challenge each other with the problems and hurdles that they face in continuing to produce the most from their supply chains.

With increasing scrutiny and inspections from not only the FDA, but the DEA and other global regulatory bodies, supply chain executives are continually faced with the challenge of streamlining operations while maintaining the highest levels of regulatory compliance. This program will include industry leaders in end-to-end supply chain operations, from procurement through to distribution, who as presenters, will share their experiences and knowledge which will be of great benefit to all attendees.

Industry leaders will be covering a wide range of topics from establishing a supplier network; transitioning supply operations from clinical stage to commercial; instituting supplier quality standards; adhering to global importation and exportation regulations through to distribution strategies and overall supply chain security measures.

This extensive two day program is focused on bringing key industry leaders and executives together to network, knowledge share and openly discusses the challenges and hurdles that they face on a day-to-day basis within supply chain operations. The ability to learn from each other and share new ideas makes this a must attend for all pharmaceutical and biotech supply chain executives.

DISTINGUISHED PRESENTERS INCLUDE:

Charles Forsaith
Director, Supply Chain Security
PURDUE PHARMA
Chairman
PHARMACEUTICAL CARGO SECURITY COALITION
Anthony Flammia
VP, Supply Chain
THE MEDICINES COMPANY
David Kinrade
Director, Supply Chain Planning
ABBOTT
Ian Rosenblum
Associate Director, IT Supply Chain
BIOGEN IDEC
Carlos Castro
Transportation / Cold Chain Project Manager
BAYER HEALTHCARE
Chris Boneham
Director, Trade & Distribution
CHELSEA THERAPEUTICS
Naymisha Patel
Director, Quality Assurance
GERON CORPORATION
Robert Bottome
Director, SSFP Production & Operational Excellence
GENENTECH
Bill Nienburg
Director, Integrated Business Planning
HOSPIRA
Carl Accettura
Senior Director, Supply Chain Operations
SUNOVION PHARMACEUTICALS
Bob DiVasto
VP, Manufacturing & Supply Chain
CADENCE PHARMACEUTICALS
Michael Daly
Director, Supply Chain and International Operations
VALEANT PHARMACEUTICALS
Martha Kliss
US Distribution and Import/Export Manager
UCB
Craig Malzahn
Director, Supply Chain
HUMAN GENOME SCIENCES
Muffie Dalton
Associate Director, Operational Planning
GENENTECH
Dave Malenfant
VP, Global Supply Chain
ALCON
Christina Markus
Partner & Deputy Chair, FDA & Life Science Practice Group
KING & SPALDING LLP
Tony Zook
Supply Chain Security Work-Group
RX-360 CONSORTIUM
David L. Rosen
Partner
FOLEY & LARDNER LLP
Stu Krupnick
Product Manager
THERMOSAFE BRANDS

Conference Sponsors:

Media Partners:
The task of securing the safety of all materials and products that flow through a pharmaceutical supply chain falls primarily on industry executives; however the FDA, EMA, and other international regulatory bodies play a critical role through the implementation of stringent regulations and standard guidelines. It is vital for pharmaceutical supply chain executives to have a full and comprehensive knowledge of all regulations, standards, and guidelines that effect supply chain operations in order to maintain the highest level of overall compliance.

- Review of current national and international regulations and guidelines
- Discussion on any upcoming regulatory changes
- How do best deal with different country-to-country regulations when operating a global supply network

Christina Markus, Partner & Deputy Chair, FDA & Life Science Practice Group KING & SPALDING LLP

Anthony Flammia, VP, Global Manufacturing & Supply GENENTECH - NEW PHARMACEUTICAL PRODUCT COMMERCIALIZATION

The increased number of product shortages that occurred throughout 2011 within the pharmaceutical industry has cemented the importance and shown the benefits associated with the utilization of sales, inventory, and operations planning (SIOP) strategies. SIOP processes ensure that the needs and expectations of supply chain, marketing, and sales executives are synchronized, balanced, and realistic. The creation of SIOPs allows for executives to decrease potential inaccuracies within revenue and cost forecasting and also supports more on target inventory management practices.

- Integrate sales planning into SIOP forecasting tools
- Tracking data to determine actual vs. planned 

Craig Malzahn, Director, Supply Chain HUMAN GENOME SCIENCES

Bill Nienburg, Director, Integrated Business Planning HOSPIRA

12:10 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:30 DISCUSSION: ANALYZING THE IMPORTANCE OF OPEN COMMUNICATION IN END-TO-END SUPPLY CHAIN OPERATIONS

The goal for supply chain departments within pharmaceutical organizations is to maintain low inventory counts and shorten product lead times while at the same time maintaining open communication channels between all divisions involved with supply operations is imperative to achieving this objective. There are a multitude of software programs whose capabilities assist in allowing organizations to improve their internal communication strategies and the growing popularity of Cloud computing has advanced file and data sharing between not only divisions but different office locations. All top supply chain executives need to be aware of new communication and information strategies and what technologies are available to assist them in this endeavor to create as much visibility and open information channels between all departments as possible.

Michael Daly, Director Supply Chain and International Operations VALEANT PHARMACEUTICALS

Dave Malenfant, VP, Global Supply Chain ALCON

David Kinrade, Director, Global Supply Planning ABBOTT

Bob DiVasto, VP, Manufacturing & Supply Chain CADENCE PHARMACEUTICALS

2:20 APPLICATION OF OPERATIONAL EXCELLENCE AND LEAN STRATEGIES TO SUPPLY CHAIN PROCESSES

A pharmaceutical supply chain, when you consider the global networks of suppliers, internal employees and contract manufacturers, is quite a large operational division within organizations. As pharmaceutical supply chains, have lacked flexibility and cost-effectiveness in the past, executives are constantly looking for ways to not only streamline processes, but also reduce overall cost and time to market. With multiple efficiency-driven tactics available executives are considering the pro’s and con’s of each theory in order to ascertain which strategy will most efficiently streamline their processes without sacrificing the ability to meet deadlines and product quality standards.

Robert Bottome, Director SSFP Production & Operational Excellence GENENTECH

3:30 WORKSHOP: MPS SIMULATION GAME

Please join us for a hands on, interactive simulation game where you will learn and make tough tradeoffs as a plant master scheduler in a biotech manufacturing plant. You will work in groups to ensure your team does not stock out of life saving drugs while at the same time performing technology transfers within your plant and dealing with manufacturing challenges. Can you keep your plant running? Will you stock out? Can you reach inventory targets? Good luck!

Muffle Dalton, Associate Director, Operational Planning GENENTECH
The importance of maintaining uninterrupted distribution routes is vital for all global organizations, but this significance is amplified for pharmaceutical organizations based upon the fact that a late drug delivery could have serious negative ramifications on patients’ health. A global pharmaceutical distribution chain can face potential disruptions from a number of sources whether environmental, financial, or political. Recent events, such as the Japan tsunami in March 2011, have proven to transportation and distribution executives that organizations need to be prepared to launch alternative strategies and plans to guarantee that their products will reach their end destination without extensive delay.

- Establishing alternative transportation options
- Should pharmaceutical shipments be given special transportation consideration during a crisis
- How do you maintain cold chain operations during a distribution crisis?

**Bob DiVasto**

VP Manufacturing & Supply Chain

**CADEENCE PHARMACEUTICALS**

**9:50** COFFEE & NETWORKING BREAK

**10:10** STRENGTHENING SUPPLY SECURITY THROUGH PROACTIVE SECURITY PROCEDURES

Supply chain security has become a highlighted issue within the pharmaceutical industry, due to the increased counterfeiting and cargo theft occurrences, as a result pharmaceutical companies have begun to concentrate on enhancing security measures to protect their supply chain from materials to finalized products. Industry executives and FDA officials are concerned about the possibility that products taken during cargo thefts will be introduced on finalized products. Industry executives and FDA officials are concerned about the possibility that products taken during cargo thefts will be introduced on finalized products. Industry executives and FDA officials are concerned about the possibility that products taken during cargo thefts will be introduced on finalized products. Industry executives and FDA officials are concerned about the possibility that products taken during cargo thefts will be introduced on finalized products. Industry executives and FDA officials are concerned about the possibility that products taken during cargo thefts will be introduced on finalized products.

- Analyze and evaluate security gaps
- Trends in counterfeiting prevention
- Response protocols to cargo thefts or tainted materials

**Chuck Forsaith**

Director, Supply Chain Security

**PURDUE PHARMA**

**11:00** PANEL DISCUSSION: TRANSPORTATION EFFICIENCY: ENHANCING TRANSPORTATION LOGISTICS AND DISTRIBUTION ROUTES

- Implementing thorough analysis’s to determine the most efficient route and mode of transportation that while being cost-efficient guarantees products arrival by shipment deadlines
- Evaluate external influences on the cost of shipping and transportation
- Compensate for the decrease of available storage space on airlines by implementing better consolidation of product shipments
- Analyze packaging options that will ensure product sterility while en-route

**Stu Krupnick**

Product Manager

**THERMOSAFE BRANDS**

**Carlos Castro**

Transportation / Cold Chain Project Manager

**BAYER HEALTHCARE**

**Chris Boneham**

Director, Trade & Distribution

**CHELSEA THERAPEUTICS**

**Martha Kliss**

US Distribution and Import/Export Manager

**UCB**

**11:50** LUNCHEON FROM ALL ATTENDEES, SPEAKERS & SPONSORS

**1:00** QUALITY COMPLIANCE STANDARDS THROUGH ESTABLISHMENT OF GOOD SUPPLIER AUDITING PRACTICES

Following a year plagued by quality compliance troubles that were linked to improperly stored or transported raw material and APIs, the importance of vendor quality screenings within the pharmaceutical industry has been amplified. The FDA’s increased regulatory scrutiny on these material procurement issues has many organizations implementing more frequent and stringent quality audits on their supplier companies. Implementing thorough external supplier and vendor quality management initiatives serves to mitigate any possible regulatory risk that organizations may face due to lack of quality standards at vendor facilities.

- Documentation and analysis methods
- Strategies for addressing deficiencies uncovered during audits
- Counteracting vendor’s hesitancy to allow audits to take place
- Possible benefits of Rx-360’s audit-sharing program

**Naymisha Patel**

Director QA

**GERON CORPORATION**

**1:50** DECODING THE INTRACACIES COMPREHENSIVE COLD CHAIN MANAGEMENT PRACTICE

Cold chain management procedures are a vital aspect within the distribution and transportation divisions of a pharmaceutical organization’s supply chain. As supply chain networks become more advanced and complex, cold chain and temperature management procedures concurrently become more complicated from wholesaler security, transportation and storage temperature control through to maintaining compliance with all distribution regulations. Pharmaceutical organizations need to analyze their current cold chain operations to discern if there are any gaps in all current procedures and monitor all activities to certify that products remain compliant and reach the public with its quality intact.

- What temperature monitoring technologies are available?
- Troubleshooting temperature deviations
- Implementation of CRT strategies

**Carlos Castro**

Transportation / Cold Chain Project Manager

**BAYER HEALTHCARE**

**2:40** COFFEE & NETWORKING BREAK

**3:00** RX-360 – ADVANCING SUPPLY CHAIN SECURITY

Rx360 is a non-profit consortium of pharmaceutical supply chain partners with a mission to enhance patient safety by developing a global quality system that helps members ensure product quality and authenticity throughout the pharmaceutical supply chain. A workgroup was recently formed to develop and share best practices on key supply chain security processes and enhance collaboration among stakeholders on issues of supply chain security.

**Tony Zook**, Supply Chain Security Work-Group of Rx360

**RX-360 CONSORTIUM**

**3:50** EVALUATION OF THE REGULATORY ENVIRONMENT FOR PHARMACEUTICAL IMPORTATION AND EXPORTATION

As pharmaceutical supply chains become more globalized, executives need to increase their knowledge surrounding the current regulations that pertain to the importation and exportation of pharmaceutical products. When importation and exportation guidelines, such as proper supporting documentation, aren’t fulfilled it can cause a severe delay in finished products reaching their designated markets due to customs and DEA investigations. It is essential for supply chain executives to stay current on these customs’ regulations to ensure uninterrupted and timely product distribution.

- Key red flags customs and DEA representatives are the looking for before shipments are subjected to inspections
- Review of current importation and exportation restrictions
- How can companies work the customs and the DEA to facilitate quicker importing and exporting timelines

**David L. Rosen**

Partner

**FOLEY & LARDNER LLP**

**4:40** CLOSING REMARKS & CONFERENCE CONCLUDES
Executives that will find this program of greatest relevance are those currently working to enhance the supply chain processes and operations within pharmaceutical and biotechnology corporations. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Supply Chain Planning
- Supply Chain Operations
- Procurement
- Transportation
- Distribution
- Supplier Quality
- Brand Protection & Supply Chain Security
- Global Logistic

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Distribution Service
- Cold Chain Management and Temperature Monitoring
- RFID and Barcoding Technologies
- Raw Materials/API Providers
- Communication IT Solutions
- Import/Export Regulatory Consultants

PREVIOUS ATTENDEE COMPANIES INCLUDE:

- Abbott Biotherapeutics
- Abbot Laboratories
- Acorda Therapeutics
- Alcon Laboratories
- Alkermes
- Alseres
- Amgen
- Amplimmune
- Amylin Pharmaceuticals
- Arno Therapeutics
- AstraZeneca
- Auxilium Pharmaceuticals
- Avanir Pharmaceuticals
- Baush & Lomb
- Baxter Biosciences
- Bayer Healthcare
- Biogen Idec
- Biophtigen
- BioVail
- Bristol Myers Squibb
- Celgene
- Cephalon
- Cornerstone Pharmaceuticals
- Covidien
- CR Bard
- Daiichi Sankyo
- Elsil Pharmaceuticals
- Eli Lilly
- EMD Serono
- Endo Pharmaceuticals
- Enzon Pharmaceuticals
- Ferring Pharmaceuticals
- Forest Laboratories
- Genentech
- Gen-Probe
- Genzyme
- Genelid Pharmaceuticals
- GlaxoSmithKline
- Globelimmune
- Grifols
- H.Lundbeck
- I-Flow
- ImClone Systems, Inc
- Jazz Pharmaceuticals
- Johnson & Johnson
- King Pharmaceuticals
- LEO Pharma
- Lux Biosciences
- MAP Pharmaceuticals
- Meda Pharmaceuticals
- Merck
- Merrimack Pharmaceuticals
- Millennium Pharmaceuticals
- Mitsubishi Tanabe
- Mylan Laboratories
- Nephron Pharmaceuticals
- Novartis Pharmaceuticals
- Noven Pharmaceuticals
- NPS Pharmaceuticals
- Osiris Therapeutics
- Otsuka Pharmaceuticals
- Pfizer
- Prolong Pharmaceuticals
- Purdue
- Qualitest Pharmaceuticals
- Regeneron Pharmaceuticals
- Salusair
- Sanofi-Aventis
- Schering Plough
- Shire Pharmaceuticals
- Sigma Tau
- Sorin Group
- Solvay Pharmaceuticals
- Spectrum Pharmaceuticals
- Takeda Pharmaceuticals
- Teleris Pharmaceuticals
- Teva Pharmaceuticals
- The Medicines Company
- Tiber Labs
- Tibotec Therapeutics
- TissueGene
- UCB Pharma
- URL Pharma
- Vertex Pharmaceuticals
- Viro Pharmaceuticals
- Vicus Therapeutics
- Watson Pharmaceuticals
- ZARS Pharma