American Conference Institute's

Drug Safety, Pharmacovigilance and Risk Management Forum

Managing product risks and complying with FDAAA safety regulations

October 22 – 24, 2012 | The Union League | Philadelphia, PA

Practical, Real-World Solutions From:

AMAG Pharmaceuticals, Inc.
Baxter Healthcare Corporation
BioMarin Pharmaceutical, Inc.
Eli Lilly & Company
Genzyme Corporation
Johnson & Johnson
Purdue Pharma, L.P.

Hear Firsthand FDA Insights From:

Carla Cartwright
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
(Silver Spring, MD)

As scrutiny on the pharmaceutical industry continues to intensify, experts in pharmacovigilance and drug safety will teach you how to:

- SURVEY recent REMS decisions to identify factors that may signal that a REMS determination is likely
- DETERMINE when to bring safety/risk issues to the FDA
- DESIGN a cost effective risk minimization plan
- PREPARE for FDA review of a REMS
- CREATE inspection/audit procedures to ensure compliance with REMS obligations
- REVIEW incidence rates of all serious and non-serious adverse events within clinical programs

October 22, 2012

Pre-Conference Workshop

Fundamentals of FDA Regulatory Law

October, 24, 2012

Post-Conference Master Class

The "Win-Win" Pharmaceutical Manufacturing Outsourcing Agreement: Practical and Ethical Drafting and Negotiating Strategies for Pharmerging Markets

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Learn to comply with new regulations without compromising the commercial viability of products

ACI's Drug Safety, Pharmacovigilance and Risk Management Forum has been designed to provide you with a comprehensive understanding of safety regulations which will allow your company to successfully develop and implement a pharmacovigilance plan. Since the enactment of FDAAA, the FDA has identified over 100 products that require a REMS, and it is becoming almost inevitable that at some point a manufacturer will have to develop collateral safety material in order to obtain FDA approval. In light of this evolving regulatory landscape, it is increasingly important for drug and biologics manufacturers to understand the new safety obligations that can be mandated by the FDA.

Prepare your company for a drug safety assessment

While some safety mandates fall into the category of medication guides, others are more restrictive and impose burdensome obligations on manufacturers which have the potential to affect the profitability of a product. Beyond simply learning what the FDA expects of the manufacturers, this conference also focuses on the strategies manufacturers can employ to prevent a REMS or other safety requirement from negatively impacting a product in order to maximize profit.

Our faculty of in-house executives and outside counsel will provide you with the practical, real-world solutions you need to manage product risks in today's regulatory environment. Hearing from manufacturers who have already gone through this process or who are in the midst of the process themselves, will provide you with the examples you need to find solutions to your company's challenges.

Pre and Post-conference workshops enhance your conference learning

At the **Pre-Conference Fundamentals of FDA Regulatory Law**, participants can gain a primer on FDA regulatory matters that will provide a basic overview of FDA regulations and prepare you for the more in-depth discussions that will take place throughout the conference.

As manufacturing outsourcing becomes more of the norm for pharmaceutical companies, it is increasingly necessary to develop the skills to negotiate deals in foreign countries. At the **Post-Conference Master Class on Pharmaceutical Manufacturing Outsourcing Agreements**, workshop leaders will teach you how to minimize risk when conducting all or part of your manufacturing abroad.

Ensure your place in the conversation by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or registering online at **www.americanconference.com/drugsafety**.

A

PRE-CONFERENCE WORKSHOP | MONDAY, OCTOBER 22, 2012

1:00 p.m. – 4:00 p.m. *(registration begins at 12:15 p.m.)*

Fundamentals of FDA Regulatory Law

Paul Beninger
Vice President of Pharmacovigilance
Genzyme Corporation (Cambridge, MA)

Aimed at providing a primer to professionals who have limited experience working with FDA on regulatory matters, or who are new to the pharmacovigilance space, this workshop will provide you with a basic overview of FDA regulations and will prepare you for the more in-depth discussions that will take place throughout the conference. Topics addressed during this workshop will set the stage for the main conference by helping you thoroughly comprehend the structure of the FDA and walk you through the preapproval, approval, and post-approval process. Get the background you need to flow seamlessly into the conversations at the Drug Safety, Pharmacovigilance and Risk Management Forum.

Topics of discussion will include:

- FDA Mission
- FDA Organization
- History of FDA Laws
- Acronyms and Terminology
- Clinical Trials Process
- Types of New Drug Applications
- The Review Process
- The Hatch Waxman Act
- Legal Barriers to Approval
- Biological Products
- The Basics of Device classification and approval
- Post-marketing issues and enforcement, including recalls

DAY 1 – TUESDAY | OCTOBER 23, 2012

7:30 Registration and Continental Breakfast

8:30 **Co-Chairs' Opening Remarks**

8:45 **Analyzing Post-Marketing Drug Safety Regulations and Manufacturers' Obligations under FDAAA**

Marc J. Scheineson
Partner
Alston & Bird LLP (Washington, DC)

- Examining Title IX of the FDA Amendments Act of 2007
  - when can the FDA require a REMS?
  - REMS for products no longer on the market
  - what types of obligations can the FDA impose on manufacturers?
- Defining Post-Marketing Requirement (PMR) and Post-Market Commitment (PMC) and making the distinction between the two
  - understanding the purpose of a PMR and when the FDA can require one
  - recognizing the manufacturer's obligations under a PMR and a PMC
- What is the precedential value of RiskMAPS if any?
- Identifying the different types of REMS and the elements/components of each
  - timelines for assessing effectiveness
  - communications to patients and physicians
  - restrictions on distribution
- Requiring postmarket studies of drug safety concerns and drug labeling changes when new drug safety information is identified
- Ensuring that the benefits of a drug or biological product outweigh its risks
- Understanding the FDA's Sentinel safety surveillance network that will impact labeling
- Minimizing the potential for monetary penalties for violating REMS requirements

9:45 **Assuaging Agency Concerns About Safety: Developing a REMS Strategy and Successfully Negotiating with the FDA**

Carla Cartwright
Associate Chief Counsel, Office of the Chief Counsel
U.S. Food and Drug Administration
(Silver Spring, MD)

Hildy M. Sastre
Partner
Shook Hardy & Bacon LLP (Miami, FL)

- Preparing for a REMS or PMR at any stage in a product's life cycle
- Determining when to bring safety/risk information to the attention of the FDA
  - weighing the pros and cons of early discussions of potential safety issues
- Initiating REMS conversations with the FDA and taking a proactive role in guiding the negotiation process
- Framing the issues so the company can provide the best risk minimization information and plan for a REMS assessment
- Ensuring that the submission is developed in compliance with FDA requirements
- Drafting the language of a REMS and medication guides
- Training and certifying health care providers and pharmacies

11:00 Morning Coffee Break

11:15 **Understanding Evolving Pharmacovigilance and Benefit-Risk Assessment Requirements**

James Nickas, PharmD
Senior Director, Global Head Pharmacovigilance
BioMarin Pharmaceutical, Inc. (Novato, CA)

- Leveraging pre- and post-marketing safety patterns and insights for clinical trial design and safety analysis to balance the risk-to-benefit ratio of new products
- Developing novel products while mitigating the concerns about the unknown
- Reviewing safety profiles, potential risks, and missing information on the issue
- Designing a cost effective risk minimization plan
- Monitoring incoming cases and aggregate data, perform signal detection and highlight potential safety issues
- Incorporating more pharmacovigilance activities into biopharmaceutical product development

12:15 Networking Lunch

1:30 **Examining the FDA's Final Rule on IND Safety Reporting**

Heide Cunning
Director Drug Safety Operations
Johnson & Johnson (Titusville, NJ)

Natasha Leskovsek
Partner
Cooley LLP (Washington, DC)

- Evaluating FDA's new expectations for pharmaceutical manufacturers
- Reporting expeditiously a medically significant suspected adverse reaction that is listed in the investigator brochure
- Understanding how these regulations will affect the drug development process and the gathering, monitoring, evaluating and reporting of safety data from the investigational programs
- What are the practical implications for a global company?
- Assuring the safety and rights of subjects in all phases of research
- Selecting qualified investigators, ensuring protocol compliance, documenting, reporting, and monitoring
- Reviewing incidence rates of all serious and nonserious adverse events within clinical programs
- Incorporating regulatory strategy into the drug development plan

2:30 **Utilizing Surveys to Evaluate the Effectiveness of REMS Plans**

Paul Coplan
Executive Director, Risk Management and Epidemiology
Purdue Pharma L.P. (Stamford, CT)

Daniel Jacob
Director, Risk Management
Baxter Healthcare Corporation (Deerfield, IL)

- Identifying what should be measured in preparation for FDA reviews
  - focusing on the impact of REMS implementation
  - ensuring that what is measured is directly related to what the REMS is intended to mitigate
- Conducting patient, physician, pharmacist and safety communications reviews
- Assessing the extent to which patients and health care providers understand the risks associated with the drug
- Submitting proposed survey methodologies to FDA for comment
- Identifying the key risk messages that should be understood by the group of interest

3:45 Afternoon Refreshment Break

4:00 **Adhering to the cGMP Regulations to Assure Strength, Quality and Purity of Drug Products**

Michael A. Swit
Special Counsel, FDA Law Practice
Duane Morris LLP (San Diego, CA)

- Acting in response to the FDA's request for a voluntary recall
- Preparing for an FDA site inspection
  - interacting with the FDA inspector – the DO's and DON'T's
- Incorporating FDA's suggestions into the manufacturers GMPs
- Obtaining a certificate of compliance for cGMPs
- Showing replicable results for what you are doing and your obligations to establish this
- Taking into account innovation and the progression of improvement
- Deciding individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures
- Responding to FDA Warning Letters relating to GCP noncompliance

5:00 **Conference Adjourns to Day 2**

DAY 2 – WEDNESDAY, OCTOBER 24, 2012

8:00 Registration and Continental Breakfast

8:30 **Co-Chairs' Opening Remarks**

8:45 **Risk Management Tools and Processes That Can Provide a Competitive Advantage in Drug Development and Commercialization**

Ken Hornbuckle
Senior Epidemiology Advisor
Office of Risk Management and Pharmacoepidemiology Global Patient Safety
Eli Lilly and Company (Indianapolis, IN)

Vernessa Pollard
Partner
Arnold & Porter LLP (Washington, DC)

- Up-stream opportunities to better characterize product risk issues early in drug development
- Simple tools and processes that better position risk management planning and discussions with regulators prior to and during NDA submission
- Key success factors to monitor
- REMS learnings to date and an integrated model for proactive product risk management
- Bringing to market important specialty products with challenging safety profiles
  - focusing on the specialist market from the outset and constructing regulatory and commercial infrastructures accordingly
- Using REMS when bringing orphan drugs to market
- REMS as a basis to facilitate and legitimize stronger communications with patients and prescribers
- Recognizing the role of REMS in obtaining financing and/or venture capital investments
- Maximizing pricing advantages
- Understanding lifecycle management issues and strategies
- Measuring the impact these programs have on key external stakeholders
- Designing and implementing feasible interventions with clearly measurable outcomes

10:00 **Harmonizing U.S. and Non-U.S. Regulatory Obligations – Developing a Comprehensive Drug Safety Program That Can Satisfy Multiple and Varied Regulatory Obligations**

Steven Du, M.D., Ph.D
Senior Director, Pharmacovigilance & Pharmacoepidemiology
AMAG Pharmaceuticals, Inc. (Lexington, MA)

- Understanding the key differences between pharmacovigilance expectations between the US and Europe
- Determining the best way to work across organizational and geographical boundaries to develop and implement effective strategies to manage global risk
- Anticipating global regulatory developments
- Ensuring adequate oversight, monitoring and auditing of third party manufacturers
- Creating inspection/audit procedures to ensure that REMS commitments are carried out
- Dealing with a finding that there has been less than 100% compliance

- Mitigating the risks of outsourcing to emerging markets
  - China
  - India
- Following the three-step EU Risk Management Plan
  - safety specification
  - pharmacovigilance plan
  - risk minimization plan
- Integrating pharmacovigilance requirements within the marketing authorization approval process
- Collaborating with non-EU regulatory agencies to create a surveillance system capable of rapid response to emerging safety issues

11:00 Morning Coffee Break

11:15 **Assessing and Managing Product Risks in the Regulatory Environment**

Areta Kupchyk
Partner
Nixon Peabody LLP (Washington, DC)

- Developing an organizational structure that will support an effective risk management program
  - what departments should be involved in risk management and product safety issues?
  - getting departments that typically work separately to work together
- Surveying recent REMS decisions to create a checklist of factors that may signal that FDA involvement is likely
- Putting procedures in place to standardize the risk management process
- How are companies adjusting existing risk management policies and procedures to account for REMS regulations?
- Quantitative and qualitative methods for formally assessing benefit/risk
  - creating standardized methods for capturing potential and identified risks
  - various approaches to analyze safety data
  - interpreting adverse event data with regard to potential risks

12:15 **Main Conference Concludes**

12:15 Networking Luncheon for Master Class Attendees

B POST-CONFERENCE MASTER CLASS | WEDNESDAY, OCTOBER 24, 2012

1:30 p.m. – 4:30 p.m. *(registration begins at 1:00 p.m.)*

The "Win-Win" Pharmaceutical Manufacturing Outsourcing Agreement: Practical and Ethical Drafting and Negotiating Strategies for Pharmerging Markets

David G. Glazer
Partner
Morgan, Lewis & Bockius LLP (Princeton, NJ)

At a time when manufacturing outsourcing has become the norm for most pharmaceutical companies, it is increasingly necessary to develop negotiating skills that ensure the parties to the contract carry out the true intentions of the deal. You must take on a leadership role as the U.S. buyer in order to maintain control of the process – an often difficult task when you consider that priorities, laws, and regulations are completely different in countries like China and India. In order to facilitate this process you must develop innovative strategies for more efficient negotiation of agreements, which means moving away from timely, contentious negotiations and moving towards a more global, real world approach. Targeted due diligence is crucial to determine who the other party's decision-makers are and in most cases, it will help you learn about their contractual history with other companies. Through this three-hour comprehensive session, workshop leaders will teach you how to minimize risk when conducting all or part of your manufacturing abroad. Plus, this master class will address the specific ethical concerns that arise during these negotiations. Specific highlights include:

- Engaging in preliminary due diligence to uncover necessary information about the other party's manufacturing contract history
  - determining who the real decision-makers are and the history of who you will be negotiating with
  - obtaining and reviewing copies of agreements from public sources
- Setting ground rules for the negotiation in advance
- Implementing techniques and strategies for more efficient deal negotiation
- Maintaining control of the drafting
- Determining whose form to use
- Effectively putting an end to "log-jams" to keep momentum going
- Avoiding ethical compromises and the potential ethics issues that can arise at the negotiation and execution phases

Who You Will Meet

- From pharmaceutical manufacturers:
  - Vice Presidents, Directors, and Managers for
    - Regulatory affairs
    - Regulatory policy & strategy
    - Drug safety
    - Pharmacovigilance
    - Epidemiology
    - Risk management
    - Post-market operations
    - Clinical affairs and operations
    - Sales and marketing
  - Internal audit
  - Counsel
  - Compliance Officers
  - Medical Affairs Officers
- Law firm attorneys with practice areas in:
  - FDA regulatory
  - pharmaceutical, food and drug, and healthcare law
  - product liability
  - healthcare fraud and abuse

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You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

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Unparalleled Learning and Networking

ACI understands that gaining perspectives from – and building relationships with – your fellow delegates during the breaks can be just as valuable as the structured conference sessions. **ACI** strives to make both the formal and informal aspects of your conference as productive as possible.

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Managing product risks and complying with FDAAA safety regulations

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Enhance your conference experience by attending a pre or post-conference workshop:

A Fundamentals of FDA Regulatory Law

B The "Win-Win" Pharmaceutical Manufacturing Outsourcing Agreement: Practical and Ethical Drafting and Negotiating Strategies for Pharmerging Market

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The fee includes the conference, all program materials, continental breakfasts, lunches and refreshments.

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