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CBI's 4th Annual Bio/Pharmaceutical and Medical Device

Product Recalls Summit

Strategies and Guidelines for Compliant Recalls, Managing Your Supply Chain and Efficient Recall Execution

September 25-26, 2008 • Sheraton Premiere at Tysons Corner • Vienna, VA

Conference Chairman:

Chris Bosler, Vice President, Marketing and Business Development, **Stericycle, Inc.**

Three FDA Presentations:

"Update on Global Issues and Agency Trends in Product Recalls"

Melvin F. Szymanski, Senior Recall Coordinator ORA/OE/DCMO/Recalls, **U.S. Food & Drug Administration**

"Industry and Agency Expectations in the Recall Process"

Michael J. Verdi, Recall Coordinator, ORA/OE/DCMO, HFC-210, **U.S. Food & Drug Administration**

"Compliance Obligations and Liability Limits in Today's High Risk Device Recalls"

Casper E. Uldriks, J.D., MDiv, Associate Director, CDRH, **U.S. Food & Drug Administration**

Esteemed Faculty Includes:

Hal Baden, Principal QA Engineer, Recall Coordinator, **Cordis Corp., a Johnson & Johnson Company**

Mark Beeman, Quality Control Consultant, Consumer Products Quality Assurance, **Eli Lilly & Co**

Willie Bryant, Former FDA Senior Recall Coordinator; Consultant, **Stericycle, Inc**

Laurence (Larry) H. Burke, Sr., MS, Senior Consultant, **mdi Consultants, Inc**

Steve Edwards, Recall Product Manager, **Stericycle, Inc**

Ralph Hall, Counsel, **Baker & Daniels**

Bea Haupt, J.D., CPHQ, Recall and Safety Manager, **Inova Health System**

Tom Renkey, Director, Returns Solutions, **AmerisourceBergen**

Mike Rozembajgier, Director of Recalls, **Stericycle, Inc**

Jennifer Ruggles, Global Recall Coordinator, Global Quality Assurance, **Eli Lilly & Co**

Alan Schwartz, Executive Vice President, **mdi Consultants, Inc**

Connie Triller, Regulatory Associate, Communications, Global Regulatory Affairs, **Eli Lilly & Co**

Marta L. Villarraga, Ph.D., Principal Engineer, **Exponent, Inc.**

James Wood, Partner, **Reed Smith, LLC**

- Problem solve with the FDA to increase compliance
- Navigate industry trends and their impact on product recalls
- Learn where the FDA is heading on recall communications
- Understand the requirements for medical device risks and classification
- Clarify best practices for non-regulated activities
- Boost your CAPA systems to avoid FDA scrutiny and improve quality systems
- Manage your supply chain to detect and prevent counterfeiting

PLUS!

- Facilitated roundtable sessions to investigate recalls' biggest challenges and best practice solutions
- Special FDA interactive session on how to write a recall letter and the new standardized press release format
- A panel discussion on building communication procedures throughout the recall notification process

Choose from Two Pre-Conference Workshops – Thursday, September 25, 2008:

A: Risk Management — Tactics to Facilitate Compliance and Reduce Ambiguity in Recall Decision Making

B: Effective CAPA Management Systems to Maintain Compliance while Increasing Investigation Accuracy and Efficiency

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A

Risk Management — Tactics to Facilitate Compliance and Reduce Ambiguity in Recall Decision Making

An effective risk management strategy is a cornerstone for pharmaceutical and medical device companies. A proper system not only helps to identify risk, but also assists quality and regulatory decision makers in categorizing their risks to make quick decisions when an emergency situation arises. Although there are different models available for this process, there are certain guidelines and best practice approaches that should be followed when setting up a comprehensive system that meets regulatory standards and aids in decision making. This workshop illustrates how to set up an effective risk management program, gives best practice examples for managing risk and effective ways to apply them in your organization.

7:30 *Workshop Registration and Continental Breakfast*

8:30 *Workshop Leaders' Welcome and Opening Remarks*

I. Develop a Robust Risk Management Process

- Analysis of available risk management methods
- Regulatory expectations for a compliant system
- Incorporate company policies and standards into your risk management system

II. Risk Assessment and Mitigation for Recall Decision Making

- Investigate the product complaint
- Create the risk management team
- Key considerations when assessing risk
- Means of measuring risk assessment

III. Analysis of ISO, ICH and Regulatory Requirements

- Drugs — Q9 and 21 CFR 211
- Devices — ISO 13485
- ISO 14971 and 21 CFR 211

IV. Apply Recall Case Examples

- Case examples for pharmaceutical recalls
- Case examples for device recalls



12:00 *Close of Workshop A*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

— About Your Workshop Leaders —

Alan Schwartz is the Executive Vice President for **mdi Consultants, Inc.** He has been providing strategic planning on FDA regulatory compliance issues since 1978. Prior to mdi, Mr. Schwartz was a Supervisor of field operations for the **U.S. Food and Drug Administration**. Mr. Schwartz has been an invited speaker on the FDA policy and issues both in the U.S. and internationally. He provides his expertise on the FDA to the medical device industry worldwide with clients in Japan, Korea, China, Taiwan, Germany, Italy, Argentina, Brazil and Canada.

He also has a widely read *Insight Report* on dealing with the FDA. His experience in dealing with FDA inspections, prior to, during and after the FDA Investigator has left, is extensive having personally participated in over 400 FDA inspections. His insight and understanding of the FDA strategy, preparing replies to the FDA 483 and Warning Letters and acting as a third party certification under FDA approval has provided companies with some very novel approaches to dealing with their regulatory problems. mdi Consultants, Inc. is the official consulting company to the Chinese Council for the Promotion of International Trade and the Chinese Council for International Standards to assist Chinese companies in dealing with the FDA. Mr. Schwartz also is an Internationally Certified Lead Assessor for ISO13485 and is on the editorial advisory board of the Institute of Validation Technology.

Laurence (Larry) H. Burke, Sr., MS is currently Senior Consultant with **mdi Consultants, Inc.** where his expertise includes hands on work with the drug and medical device industries, both in the U.S. and internationally. Prior to this, he held management positions in Regulatory Affairs, Quality Assurance, Quality Control and Materials Management departments within drug API, finished dosage form and medical device manufacturers. While working both as an employee and as a consultant, Mr. Burke has coordinated the creation of, and produced his own, CMC sections for INDs, DMFs, NDAs, ANDAs and 510(k)s for firms such as **Johnson-Matthey**, **Pathogenesis** (now a division of Chiron), **Kanika**, **Therakos**, **Sanofi** (France), **Watson Laboratories** and **Medeikon Corporation** (a medical device firm). Mr. Burke also served as a Field Investigator assigned to the Montgomeryville Resident Post of the **U.S. Food and Drug Administration, Philadelphia District Office**. He holds a BS in Pre-Medicine from Penn State University and a MS in Pharmaceutical Quality Assurance Control from Temple University, School of Pharmacy. Mr. Burke is an Associate Member of the Central States Association of the Association of Food and Drug Officials.

B

Effective CAPA Management Systems to Maintain Compliance while Increasing Investigation Accuracy and Efficiency

CAPA systems remain a highly scrutinized area by the FDA with more than fifty percent of Form 483 observations and warning letters citing CAPA deficiencies. The successful implementation of a CAPA system and the development of effective investigation techniques to determine root cause are paramount functions of the CAPA process. An insufficiency in a system quickly becomes apparent with a surge of quality issues resulting from the original problem. These deficits also subject your company to FDA scrutiny of your entire quality system. This workshop prepares you to conduct an effective failure investigation to root cause, take appropriate actions and maintain compliant quality systems with proven techniques and best practice examples. Also, evaluate the often overlooked, yet vital connection, between the effectiveness of CAPA systems to management's control and review responsibilities and processes.

7:30 *Workshop Registration and Continental Breakfast*

8:30 *Workshop Leaders' Welcome and Opening Remarks*

I. Regulations and Requirements for CAPA Systems

- Conformity measurements and expectations
- Develop proficient internal audit methods
- Handle nonconformities and/or deviancies
- Classify corrections and corrective and preventative actions

II. Conduct a Proper Failure Investigation to Root Cause

- Elements of a failure investigation
- Put proactive planning in place
- Components of the team
- Cooperation with FDA

III. Trending Analysis Used to Anticipate Investigation

- Examples of prescription products that give hints to trends
- Components of an investigation
- Lessons learned from competitors

IV. Utilize Quality Management Control

- Management's responsibility in the quality control process
- Tactics for maximizing quality systems
- Meet QSR standards for compliance and efficiency

12:00 *Close of Workshop B*

There will be a 30-minute networking and refreshment break at 10:00 am

— About Your Workshop Leaders —

James Wood is Partner at **Reed Smith, LLC**. Mr. Wood's practice has focused on the representation of manufacturers of prescription medicines and medical devices for thirty years. His practice has involved representing and counseling manufacturers of prescription products involving a variety of issues. These have included recalls of prescription products,

marketing and promotion of these products, first amendment issues in marketing these products, off-label issues, preemption, product liability issues and the reuse of single use medical devices. Based upon this experience he has recently co-authored a book that details planning for and implementing the recall process for all regulated products, "*Prescription Product Recalls — A Proactive Primer*." Mr. Wood has served as regional counsel for an international medical device company in a product liability action and was the multi-district litigation liaison counsel in the Gammagard® MDL litigation. Mr. Wood's practice has given rise to a number of landmark decisions involving prescription products medicines, devices and vaccines. Mr. Wood holds a B.A. from St. Mary's College of California, 1970 and a J.D. from the University of San Francisco, 1973.

Ralph Hall is Counsel at **Baker & Daniels LLP**. Mr. Hall has extensive experience in the areas of FDA, healthcare law and corporate compliance, including the application of those regulatory systems to the medical device industry. He also serves as a Distinguished Visiting Practitioner and Professor at the **University of Minnesota Law School** where he teaches courses in FDA law, corporate compliance, negotiation and alternative dispute resolution. Mr. Hall has extensive experience in the design and implementation of regulatory compliance programs and with FDA enforcement actions. Mr. Hall also has experience in managing complex patent litigation and licensing matters and in general corporate counseling. Before joining Baker & Daniels, Mr. Hall was with **Guidant Corporation** where he served as Senior Vice President and Deputy General Counsel — Litigation and Compliance. He also served as Special Counsel to Guidant's Board of Director's Compliance Committee and to Guidant's Compliance Office. Earlier, Mr. Hall was General Counsel of Guidant's Cardiac Rhythm Management group. Prior to joining Guidant, Mr. Hall was with **Eli Lilly and Company** where he served in a number of legal roles, including Chief Environmental Counsel. Mr. Hall has spoken frequently at legal seminars on a variety of subjects.


background photo by: Photodisc / Getty Images

“The presentations covered all aspects of the recall process from many different perspectives. Anyone/everyone involved in this process would benefit.”

— 2007 Attendee, Terri Magee, Director QC, Medicis

MAIN CONFERENCE

Day One — Thursday, September 25, 2008

12:00 *Main Conference Registration and Luncheon Hosted by:* 

1:15 *Chairman's Opening Remarks*
Chris Bosler, Vice President, Marketing and Business Development, Stericycle, Inc.

Mr. Bosler is responsible for developing long-term strategic business plans along with 'go-to' market strategies and tactics for Stericycle's current services portfolio and managing the marketing and communications teams. He also has responsibility for Stericycle's Trade Returns Business Integration team. Mr. Bosler has more than twenty years of experience in the healthcare industry. Prior to joining Stericycle, Mr. Bosler was Director, U.S. Product Marketing for Roche. At Roche, Mr. Bosler led large teams that managed extensive product portfolios, launched many key, strategic new products and drove the development of the annual strategic and financial plans. Prior to Roche, Mr. Bosler worked in a variety of sales and marketing leadership positions at Abbott Laboratories, including Worldwide Marketing Manager, Immunoassays, National Accounts Director, District Sales Manager and U.S. Product Manager, Blood Screening. Mr. Bosler holds a bachelor's degree in business from Florida State University and has done post graduate work through the executive education programs at The University of Chicago School of Business, The University of Michigan School of Business and Northwestern University's Kellogg School.

FDA ADDRESS

1:30 **Update on Global Issues and Agency Trends in Product Recalls**

There are many aspects a company must look at when developing or auditing their recall strategy, the priority being new or updated regulations. However, it is also important to fully understand current regulations and to be aware of trends in related markets and events overseas. This address provides the FDA's perspective on current policies, procedures and the foreseen effects of domestic and foreign events on product recalls. This insight is coupled with extended Q&A.

- Effects of FDA versus foreign investigation on recalls
- Changes stemming from recent recalls in human food, animal food and the potential future expectations in drug and device recalls relating to FDAAA 1003
- How FDA determines effectiveness checks and their class expectations

Melvin F. Szymanski, Senior Recall Coordinator ORA/OE/DCMO/Recalls, U.S. Food and Drug Administration

Mr. Szymanski serves as the Agency's Senior expert on recalls undertaken voluntarily by our regulated industry. He is responsible for keeping the Office of Directors apprised of all recalls including Class I Recalls advising also when Press has been issued. He works with the firms, districts, centers and Commissioner's Office of Press to make sure accurate, understandable

and timely Press is issued by the firm or FDA to the Associated Press so our consumers can learn of dangerous products not to be used. He is also responsible for the automated computer system of tracking recalls known as the Recall Enterprise System. Prior to this position, Mr. Szymanski served as a Senior Litigation Specialist in CDER, Office of Compliance from 1996 to 2004. He was responsible for applying scientific and legal expertise to civil and criminal Federal Court cases involving violations of the new drug and misbranding drug provisions of Food, Drug and Cosmetic Act. From 1991 to 1996, Mr. Szymanski was a Senior Litigation Specialist in the Office of Criminal Investigations, Metro Washington Field Office, Special Prosecution Staff where he was responsible for all Center cases including drugs, medical devices, biologics, cosmetics, foods and radiological health products. Mr. Szymanski began his career with the FDA in 1977 at the Office of Regional Operations, Florida (Orlando) and Baltimore District Offices as journey level CSO and later Senior CSO covering inspections and investigations of every type of industry FDA regulates. Mr. Szymanski holds a Bachelor of Science, Biology, St. Mary's College of Maryland, 1976 and attended the University of Maryland, Graduate School of Science.

FDA ADDRESS

2:15 **Compliance Obligations and Liability Limits in Today's High Risk Device Recalls**

Consumers and industry face new limits for product liability claims as the Supreme Court's decision in Riegel v. Medtronic, Inc., sets a landmark boundary for FDA's federal preemption authority over state law. The related premarket and postmarket compliance obligations should be an industry focus because CAPA investigations will continue to be a top FDA priority. This session discusses how the preemption authority applies to devices, the affects of deficiencies in CAPA programs and using communication to balance FDA requirements, company goals and consumer needs.

- FDA premarket review and federal preemption authority
- The cascading affect of compliance issues from CAPA deficiencies
- Benefits and roadblocks in recall communications

Casper E. Uldriks, J.D., MDiv, Associate Director for Regulatory Guidance and Government Affairs, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Mr. Uldriks is recognized as FDA's expert on several statutory provisions and regulatory programs for devices. He served for ten years as the senior special assistant to the Director of the Office of Compliance in CDRH, for five years as the Congressional Liaison in FDA's Office of Legislative Affairs for FDA's medical device program and served as a Public Health Advisor in the U.S. House of Representative's Small Business Subcommittee on Regulation, Business Opportunity and Technology under the LEGIS Fellows Program. He began his FDA career in 1978 as an investigator in Boston, Massachusetts. He earned his J.D. in 1986 from Suffolk University and his Master of Divinity from Boston University in 1976. He is a member of the bar in the Commonwealth of Massachusetts.

3:00 *Networking and Refreshment Break*

3:30

Recall Tracking and Removal — Bridging the Recall Communications Gap

Patients and consumers depend on their healthcare providers and government to remove any unsafe drugs or devices from the market and protect their wellbeing. An extra week, day or hour in this process has the potential to put more patients at unnecessary risk and further exhaust company resources. Given that there is no exact science of how recall information should be communicated down to the end user, it is up to the industry to develop an effective process that satisfies the needs of all stakeholders. Significant strides have been made in this area over the past few years, but gaps in the process remain a concern from manufacturers down to end users. This panel discussion aims to build on the communication processes that have been established in recent years and to continue to clarify lines of recall communications for the best interests of all involved.

- Effects of increased recall public awareness
- Timely and accurate vehicles for disseminating information to the public
- Responsibilities of the manufacturer through to the end user
- Methods for building your communications procedures
- Recall effectiveness beyond communications through product retrieval



Photo by: Jacobs Stock Photography / Getty Images

Moderator: Mike Rozembajgier, Director of Recalls, **Stericycle, Inc.**

Panelists: Michael Verdi, Consumer Safety Officer,

U.S. Food and Drug Administration

Bea Haupt, J.D. CPHQ, Recall & Safety Manager, **Inova Health System**

Tom Renkey, Director, Returns Solutions, **AmerisourceBergen**

Hal Baden, Principal QA Engineer, Recall Coordinator,

Cordis Corp., a Johnson & Johnson Company

FACILITATED ROUNDTABLES

4:15 Problem Solving Roundtables — Solutions for Your Biggest Recall Challenges

Multiple roundtables are available for discussion surrounding challenges facing industry professionals and best practice recall procedures. Group leaders are on hand to initiate dialogue, provide subject matter expertise and moderate the discussion. Come prepared with your specific challenges to get personalized guidance and practical solutions.

Group A Managing Recall Communications Expectations

As a follow up on the Recall Tracking and Removal panel, this roundtable discusses the necessary requirements of comprehensive recall communication procedures, what is acceptable by the FDA's standards and how to work together to expedite the recall process. Share best practices in the recall supply chain for advancements in how recall communications are managed.

- Understand the FDA's expectations for recall communications
- Collaborate with your supply chain partners for recall efficiency
- Best practices for building recall communication procedures

Moderator: Melvin F. Szymanski, Senior Recall Coordinator ORA/OE/DCMO/Recalls, **U.S. Food and Drug Administration**

Group B Medical Device Recall Reportability, Liability and Classification

With the recent developments in medical device recalls raising many industry concerns, device manufacturers are up against new challenges and potential regulation variances. This roundtable discusses the challenges specific to medical device recalls, related liability concerns and provides the FDA's guidance on device classification and reportability.

- FDA guidance on risk and recall classification
- MDR reporting requirements for all classes of medical devices
- Liability concerns and expectations for consumers and manufacturers

Moderator: Casper E. Uldriks, J.D., MDiv, Associate Director for Regulatory Guidance and Government Affairs Office of the Center Director, CDRH, **U.S. Food and Drug Administration**

Group C International Policies in Global Recalls

With today's increasing global business environment, coupled with heightened regulatory compliance requirements, international companies must have a process for monitoring and implementing global recall regulations. Share best practices and discuss processes for ensuring compliance with international drug and device recall requirements.

- Differences in major regulatory agency recall requirements
- Harmonization of recall requirements
- Development of comprehensive recall standards

Moderator: Jennifer Ruggles, Global Recall Coordinator, Global Quality Assurance, **Eli Lilly & Co**

5:15 *Close of Day One*



5:15-6:15 **Networking, Cocktail Reception**

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Day Two — Friday, September 26, 2008

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*

Chris Bosler, Vice President, Marketing and Business Development, **Stericycle, Inc.**

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8:15 **Combating Counterfeits — Partnering with Suppliers, Distributors and Retailers to Fight a Growing Threat**

Illegal and unsafe, counterfeit products are an increasing concern for industry. It is currently estimated that ten percent of all drugs sold in the U.S. are counterfeit and these numbers are expected to grow. To fight this widespread issue and protect brand integrity, organizations must have an anti-counterfeiting strategy that involves their suppliers, distributors and retailers to detect and prevent counterfeits before they enter the market. This session explains the potential affect of counterfeit products on your organization, common sources and entry points to be aware of, what anti-counterfeiting resources are available and how to involve your supply chain in your anti-counterfeiting strategy.

- Current trends in counterfeit products
- Manage supplier quality to prevent counterfeit ingredients
- Communicate with your distributors and retailers to increase counterfeit detection
- Effects of counterfeits on product recalls

Mark Beeman, *Quality Control Consultant, Consumer Products Quality Assurance, Eli Lilly & Co*



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Jacobs Stock Photography /
Getty Images

10:15 **Comprehensive Recall Planning and Notification Best Practices**

One of the most effective ways to assess your recall state of readiness, and develop a comprehensive plan, is to implement a mock recall. When executed properly, a mock recall can save you time, money and most importantly can help to protect your brand from the public and government ramifications of being unprepared for a recall. This session demonstrates the mock recall process in an interactive setting to understand the necessary steps and benefits of having a recall preparedness plan in place.

- Best practices for regulatory, supply chain, internal and consumer communications
- Experience and participation in a mock recall simulation
- Situational examples showing the consequences of being unprepared for a recall

Steve Edwards, *Recall Product Manager, Stericycle, Inc.*
Willie Bryant, *Former FDA Senior Recall Coordinator, Consultant, Stericycle, Inc.*

11:00 **Simulating a Global Product Withdrawal — Building Process Preparedness**

Developing a product withdrawal plan before a crisis situation occurs assists companies in decision-making, information dissemination and with the overall timeliness of withdrawal execution. The goal of this session is to understand how simulation can help define the steps of a withdrawal, identify the areas impacted by withdrawal and develop the communication channels and tools needed to ensure preparedness.

- Creation of an emergency team from key functional areas
- Withdrawal plan development
 - * communication
 - * product return
 - * simulation planning, training and execution

Jennifer Ruggles, *Global Recall Coordinator, Global Quality Assurance, Eli Lilly & Co*
Connie Triller, *Regulatory Associate, Communications, Global Regulatory Affairs, Eli Lilly & Co*



F D A A D D R E S S

9:00 **Industry and Agency Expectations in the Recall Process**

There are many responsibilities and expectations put on the FDA when recalling a product and vice versa for industry. Learn what procedures the FDA uses to overcome recall issues, their view on acceptable recall strategies, responsibilities of industry and the FDA and how to collaborate to create a more favorable public persona.

- FDA perspective for an adequate recall strategy
- Recommendations for recall documentation
- Recall and shortages
- Best practices for communicating with the FDA
- Collaboration tactics to build better public relations

Michael J. Verdi, *Recall Coordinator, ORA/OE/DCMO, HFC-210, U.S. Food and Drug Administration*

Mr. Verdi began his career with the Food and Drug Administration in September 1977, as a Field Investigator inspecting all categories of regulated products in Richmond, Virginia from 1977 until 1987. From 1987 until 1995 he specialized his work in sterile drug/device operations as the resident in charge of the Des Moines, Iowa FDA Office. In this time period he also performed inspections for the FDA in foreign pharmaceutical sites of both bulk and finished drugs. In 1995 he moved to the **Center for Drugs, Office of Compliance**, as a Compliance Officer, reviewing both domestic and foreign inspections, for regulatory action. In April of 1996, he transferred within the Center to take the position of Recall Coordinator/Drug Shortage Manager, which involves classification and trending of U.S. human drug recalls and establishing policy/procedures to avoid drug shortages in the United States. In February of 2006, Mr. Verdi transferred his expertise to the **Center for Devices and Radiological Health**, Division of Risk Management, as their Senior Recall Coordinator. In April of 2008, he carried his expertise on recalls to the Division of Enforcement, within the **Office of Regulatory Affairs**, to help coordinate all Centers and Field operations in the recall arena, as well as, develop Industry guidance. In his career with the Food and Drug Administration, he has received numerous awards including FDA's Commendable Service Award and the Award of Merit. Mr. Verdi holds a B.S. from Virginia Polytechnic and State University, School of Agriculture, Forestry and Wildlife/Fisheries Science, 1976.

11:45 **Luncheon Hosted by:**



1:00 **Use Historical Class I Medical Device Recall Information to Enhance Internal Quality Practices — A Four Year Overview**

Public awareness of medical device recalls has increased as a result of increasing media focus. A review of Class I medical device recalls from fiscal years 2004 to 2007 is presented to synthesize the voluminous publicly available information. This information is put into a series of “snapshots” that are useful to medical device manufacturers for understanding historical recalls in the context of regulatory, manufacturing, engineering, clinical and human factors standpoints and how both pharmaceutical and medical device companies can apply this information going forward. Discussion includes suggestions for how to use this information to enhance your quality practices. Recall issues to be discussed include:

- Trends in the number of recalls and number of total units recalled in the last four years
- Predominant reasons for medical device recalls
- Breakdown of recalls by device category
- Analysis of recalls in the context of current public health issues
- Relevance for quality practices

Marta L. Villarraga, *Ph.D., Principal Engineer, Exponent, Inc.*

9:45 **Networking and Refreshment Break**

1:30 **Best Practices for Composing Recall Letters and Press Releases — Including the New Standardized Press Release Template**

Every member of the recall supply chain feels that the information communicated about a product recall is lacking in some way. The primary way that this information is structured is in a recall letter and/or press release. Unfortunately, many overlook these communications and their importance, and the FDA is continuing to receive letters that are incomplete, improperly structured and require many edits. This leads to lost time in expediting your recall, more time your product is on the market and more attention on your regulatory procedures from the FDA. This interactive session teaches you the basics of writing a recall letter that satisfies the FDA and public needs, when a press release is necessary and the new FDA press release format anticipated to be approved in the summer of 2008.

- Convey the appropriate message in a recall letter that satisfies both the FDA and the public
- Understand the criteria of when a recall press release is necessary
- Analyze the new FDA press release guidance and the necessary items for the FDA and the public

Michael J. Verdi, Recall Coordinator, ORA/OE/DCMO, HFC-210, Food and Drug Administration



2:15 **Apply What You Have Learned — Navigating a Case Study to Test Your Recall Ability**

There are many decisions and procedures that need to take place to get a company from the original product complaint or failure notice to closing of the recall. Over the past two days, these processes have been discussed in-depth to properly prepare you for these events, and now is your opportunity to pull it all together. This interactive session provides a hypothetical recall situation, based on an actual prescription product recall case example, which serves as a catalyst for discussion on proper quality, regulatory and planning procedures involved in a product recall.

- What types of adverse reactions trigger consideration of a recall and when?
- Where the best planned recalls can go wrong
- Who should be on the recall team and why (and who should not)?
- Why the patient always comes first

James Wood, Partner, Reed Smith, LLC



3:00 *Close of Conference*

WHO SHOULD ATTEND:

This conference will benefit VPs, Directors and Supervisors at biotech, pharmaceutical and medical device companies with responsibilities in the following areas:

- Recalls
- Risk Management
- GMP
- Public Relations
- Quality Assurance
- Compliance
- Logistics/Distribution
- Legal
- Quality Control
- Customer Service
- Technical
- Supply Chain
- Regulatory Affairs
- Product Safety
- Communications

This conference will also benefit recall and distribution outsourcing companies; drug and device consultants; compliance service providers; risk, liability and recall lawyers; PR firms; freight, warehousing and product disposal providers; and other firms providing services to the above audience.

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ABOUT OUR PLATINUM SPONSOR:



Stericycle's unmatched suite of solutions and industry leading experts enable us to provide some of the most comprehensive and intelligent solutions available in reverse logistics and telephony. Stericycle takes a highly customized approach in providing compliant, risk mitigating recall management for every client. From initiation to termination, we have successfully executed critical recall programs for hundreds of major clients, including some of the world's largest pharmaceutical, medical device and consumer product manufacturers. No matter how large or how complex the requirements, our technical resources and industry experts provide validated technologies, robust support and years of experience to ensure that every aspect of your event is covered. As we continue to expand our capabilities and meet the needs of our clients in the future, we're committed to maintaining our role as the industry's most complete resource in data driven technologies.

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