Implement an Efficient and Effective Recall Execution Strategy

- Develop a Recall Roadmap that Ensures Regulatory Compliance
- Conduct an Internal Risk Assessment — Perform a Health Hazard Evaluation
- Understand Key Components, Timelines and Stakeholders Involved
- Terminating and Evaluating a Recall — Performing Timely CAPAs and Root Cause Analysis
- Adhere to U.S. FDA Reporting Requirements from Start to Finish
- Discover New Technology that Improves the Process

Benchmark Against Industry Leading Case Studies:

- Be Prepared — Conduct a Mock Recall CareFusion
- Implement a Global Product Recall Execution Strategy Apotex Inc.

Learn from Three Interactive Industry Panel Discussions

- How to Work Effectively with Key Stakeholders During a Recall
- Maintain Brand Image — Prepare to Face the PR Battle
- Ensure Compliance to Minimize Legal Risk

PLUS! TWO FDA KEYNOTE PRESENTATIONS

FDA Regulatory Requirements, Expectations and Trends Related to Drug Recalls — A CDER Perspective
Israel Santiago, Chief, Recalls and Shortages Branch, CDER, U.S. Food and Drug Administration

The Impact and Requirements of 21 CFR Part 806 — A Year in Review
Ron Brown, Chief, Recall Branch, CDRH, OC, DRMO, RB, U.S. Food and Drug Administration

AND DON’T MISS OUR FAMOUS FDA REGULATORY TOWN HALL!
Work with the FDA Before, During and After a Recall

REGISTER AT WWW.CBINET.COM/RECALLSEAST • 800-817-8601
7:30  Conference Registration and Continental Breakfast

8:15  Chairman’s Welcome and Opening Remarks
Steve Edwards, Senior Solutions Manager, Stericycle ExpertSOLUTIONS

8:30  The Recall Lifecycle and Reach — An Overview of Key Components, Timelines and Stakeholders Involved in a Product Recall
With product recalls at an all-time high in the FDA-regulated industry, it is imperative that a firm has an efficient and effective recall process. This session outlines FDA expectations, Standard Operating Procedures (SOPs) and timelines to ensure proper execution. This session also teaches the audience how to handle key aspects of a product recall from start to finish.
• Recall lifecycle to include:
  * preparation
  * consignee identification
  * notification and response
  * product processing
  * remedy management
  * close out
• Understand FDA guidelines and expectations — Elements needed in a recall submission
• Evaluate, classify, monitor and audit
• Establish methods and timelines
• Define roles and responsibilities
• Ensure effective training for personnel
• Learn how to evaluate a recall
Steve Edwards, Senior Solutions Manager, Stericycle ExpertSOLUTIONS

9:15  Set SOPs for Adhering to U.S. Reporting Requirements from Start to Finish
Interaction with the FDA and foreign regulators at every step is crucial to ensuring successful recall, and that all regulatory requirements are met. This session provides a foundation that allows your company to meet all U.S. reporting requirements without distracting from the recall execution, with focus on U.S. reporting. Topics covered in the session include:
• When is it necessary to report?
• Communications with regulatory bodies prior to sending official documentation
• The contents of the “806” packet and timing of submission
• Periodic updates, including CAPA reporting
• Communications relative to product destruction and foreign product
• Termination request
Hal Baden, Principal Quality Engineer, Recall Coordinator, Cordis, part of the Johnson & Johnson family of companies

10:00  Networking and Refreshment Break

10:30  Conduct an Internal Risk Assessment — Perform a Health Hazard Evaluation
Implementation of the Health Hazard Evaluation (HHE) impacts multiple phases of a voluntary recall, including the decision to conduct a recall, communications with the FDA and execution. Yet, although it is a critical aspect of recall decision-making, it is an area where there may be major disconnects with the FDA’s internal HHE analyses and ultimate classification of your company’s recall. This session focuses on practical and actionable steps to enhance your company’s HHE process.
• Understand the impact of HHE on all phases of a recall
• Ways to better anticipate FDA’s expectations for analysis of risk to health
  * “reasonable probability” — the elephant in the room
• how to avoid major disconnects with FDA
  * avoid “back door” recalls
• Align public communications, including press releases, information to consignees and communications with healthcare providers
• Navigate internal corporate communication
Beverly Lorell, MD, Senior Medical & Policy Advisor, FDA Life Sciences Group, King & Spalding LLP

11:15  Terminating and Evaluating a Recall — Performing Timely CAPAs and Root Cause Analysis
It is up to the designated recall team to ensure the investigation outcome, root cause analysis and resulting solutions (CAPAs) are completed in a timely, effective and compliant manner. The speed and rigor demonstrated by this group drives a culture that prevents unplanned deviations through a robust and proactive investigation process. This session provides an in-depth, practical look at the at conclusion of a recall and lessons learned in order to prepare for next situation. Participants attending this session gain an understanding on how to collaborate with an investigation team to determine timely CAPA.
• Communication strategy so all stakeholders have appropriate information
• Investigation strategy including a clear and actionable problem statement
• Solution selection
• CAPA action plan and effectiveness checks
• Utilize the appropriate and approved investigation tools necessary to drive the team to root cause
• Collaborates with functional leaders to prioritize team member workload to aid in timely decisions and completion of investigation
• Effectively remove obstacles as required
• Work within and across functions, sites, and regions as necessary to assure connectivity of investigations between functional areas and sites
Sonali P. Gunawardhana, Of Counsel, FDA Practice Group, Wiley Rein LLP; Former Regulatory Counsel, Office of Compliance, U.S. Food and Drug Administration
1:15 FDA Regulatory Requirements, Expectations and Trends Related to Drug Recalls — A CDER Perspective
The FDA continues to monitor and oversee all recalls to ensure the public is protected and that all industry professionals are working with the utmost quality concerns in our global environment. This address speaks to the current state of drug recalls and outlines FDA expectations from a CDER perspective.

- Gain Insights on FDA's compliance and enforcement strategy
- Global recall trends and outlook
- Working with the FDA before, during and after a product recall
- FDA's expectations on a firm’s responsibilities
- Corrective action in response to FDA enforcement

Israel Santiago, Chief, Recalls and Shortages Branch, CDER, U.S. Food and Drug Administration

1:45 The Impact and Requirements of 21 CFR Part 806 — A CDRH Year in Review
This session overviews key decision making considerations and how companies can prepare for steps necessary to take with FDA, key stakeholders and the public. This presentation also reviews CFR Part 806 and clarifies when a manufacturer needs to notify the FDA of a correction or removal of a device. Gray areas are reviewed and discussed.

- Recall trends — A CDRH perspective
- An update of 21 CFR Part 806
- Key considerations for all recall decisions
- Root cause, health risks, severity and timelines
- Communicate strategically with recall stakeholders

Ron Brown, Chief, Recall Branch, CDRH, OC, ORMO, RB, U.S. Food and Drug Administration

2:15 FDA REGULATORY TOWN HALL
Work with the FDA Before, During and After a Recall
What are your most challenging issues when dealing with product recalls? Take a moment to write them down and bring them with you to this FDA-led town meeting. Representatives from the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) are on hand to help you understand the FDA’s policy regarding product recalls and directly answer your most pressing questions.

Ron Brown, Chief, Recall Branch, CDRH, U.S. Food and Drug Administration

Israel Santiago, Chief, Recalls and Shortages Branch, CDER, U.S. Food and Drug Administration

Cecilia Wolyniak, Recall Team Leader, Office of Regulatory Affairs, U.S. Food and Drug Administration

3:00 Networking Lunch

3:30 Explore a Cross-Industry Global Perspective on Recall Execution
Global recall execution takes precision and expertise no matter what industry you are in. During this interactive session, gain a clear understanding of the nuances and differences with recall execution across multiple industries and the agencies that regulate those recalls including CPSC, NHTSA and FDA. Hear firsthand case studies that highlight opportunities and best practices between automotive/consumer products and pharmaceutical/medical device industries.

- Explore recalls across industries and compare their execution requirements and strategies
- Discover a new perspective through case study examples of cross-industry recalls

Chris Harvey, Recall Strategist, Stericycle ExpertSOLUTIONS

4:15 LEGAL PERSPECTIVE
Ensure Compliance to Minimize Legal Risk
Removing a product from the market requires extreme precision and navigation through many legal components. How prepared is your company to handle this complicated process? During this interactive panel discussion, expert legal counsels discuss the risks associated with correction and removal.

- Explore the legal implications of the recall process
- Learn how to best position your firm for compliance
- Mitigate the most challenging legal risks
- Work with legal counsel before, during and after a recall

Moderator: Anthony Schiavone, Counsel, Philips Healthcare
Panelists: James N. Czaban, Partner, Wiley Rein LLP
Todd Halpern, Assistant General Counsel, Regulatory Law, Pfizer
David Bloch, Principal Legal Counsel, Medtronic

5:15 Using Technology to Assess and Mitigate Recalls
Technology has advanced significantly for Medical Devices over the years from products whose technology was used almost exclusively to operate the device to products that internally captured data that can be used to assess device performance, etc. to electronically connected devices that can transmit data to diagnose and even predict device performance. This session analyzes how data capture and transmission technology was used almost exclusively to operate the device to products that internally captured data and directly answer your most pressing questions.

- Understand the risks of identified failure modes and how to use failure patterns to minimize the scope and severity of a potential recall
- Gain insights on optimizing data capture and transmission technology

Joe Falvo, Senior Manager Post-Market Risk Management, Ortho-Clinical Diagnostics
6:00  Close of Day One  

Networking, Wine and Cheese Reception  
Immediately following the final session on day one

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**DAY TWO**  
**TUESDAY, OCTOBER 28, 2014**

7:30  Continental Breakfast

7:30  **Eye Opener Breakfast Discussion**  
Discover a Web-based Technology that Streamlines and Improves the Recall Process  
- Learn an effective management system  
- Document all actions  
- Integrate multiple departments  
  Rachel Eckles, B.S., CPhT Coordinator of Pharmacy Purchasing,  
  Children's Mercy Hospital of Kansas City, Missouri

8:30  **Chairman's Review of Day One**  
Steve Edwards, Senior Solutions Manager,  
Stericycle ExpertSOLUTIONS

8:45  **STAKEHOLDER PERSPECTIVE**  
Collaborate with Key Stakeholders to Optimize the Recall Process  
Effective stakeholder communication is of the utmost importance during recall. This panel discussion analyzes the internal recall processes from the pharmacy and hospital perspective to provide insights on key issues including what protocols they use during a recall and how they coordinate communications with the manufacturer and the end user.  
- Implement strategies for working with hospitals and pharmacies before, during and after a recall  
- Understand how hospitals and pharmacies communicate recalls to the end-user and develop partnerships that streamline effective resolution  
- Develop effective messaging to your key customers and discuss how to provide the best level of support  
- Utilize stakeholder collaboration to minimize the scale and severity of a recall  

  **Panel**  
  **Moderator:**  
  Alyce Nelson, President, FAS, Inc.
  **Hospital Perspective:**  
  Rachel Eckles, B.S., CPhT Coordinator of Pharmacy Purchasing,  
  Children's Mercy Hospital of Kansas City, Missouri  
  **Pharmacy Perspective:**  
  Gina Hastreiter, Manager of Pharmaceutical Returns, Walgreens

9:30  **INDUSTRY PANEL**  
Maintain Brand Image — Prepare to Face the PR Battle  
Are you effectively handling your product recall? Brand image and customer satisfaction are at stake. Product recalls impact thousands of companies every year — Affecting sales, testing customer relationships and disrupting supply chains. Without the appropriate plan, expertise and systems in place, a recall event can cause irreparable damage to a company’s brand. The session prepares you how an effective recall process and strategy can help maintain your brand and possible image.  
- Strategies for crisis management  
- Best practices to alert the public  
- Working with stakeholders and customers before, during and after the recall  
- What is the impact of social media and how can you leverage?  
- Restore customer confidence  

  **Panel**  
  **Moderator:**  
  Chris Harvey, Recall Strategist, Stericycle ExpertSOLUTIONS  
  **Panelists:**  
  Hal Baden, Principal Quality Engineer, Recall Coordinator,  
  Cordis, a part of the Johnson & Johnson family of companies  
  Anthony Schiavone, Counsel, Philips Healthcare  
  Fabrizis Suarez, M.D., Ph.D., Director Medical Safety and Surveillance, Abbott Laboratories  
  Richard Petruschke, PharmD, Head NA Consumer Relationship Center, Novartis Consumer Health, Inc.

10:15  Networking and Refreshment Break

10:45  **BREAKOUT THINK TANKS**  
**BENCHMARK AGAINST YOUR PEERS**  
In this 90-minute interactive session, bio/pharmaceutical and medical device companies discuss their most pressing challenges on their desk today, as well as best practices. The content for this session is driven by the participants who are surveyed ahead of time and the presentation is built and shared during and after the session.  

  **Bio/Pharmaceutical Moderator:**  
  Fabrizis Suarez, M.D., Ph.D., Director Medical Safety and Surveillance, Abbott Laboratories  
  **Medical Device Moderator:**  
  Mindy Faber, RN, BSN, Manager Specialty Disposables, CareFusion

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REGISTER AT WWW.CBINET.COM/RECALLSEAST • 800-817-8601
1:00    **Be Prepared — Conduct a Mock Recall**

Being prepared to execute a product recall is a critical element of the Quality Management System to assure compliance with 21CFR Part 806. If your firm discovers a product issue that represents a potential patient safety risk, you must be prepared to deploy the recall team to quickly and seamlessly execute the recall in a timely manner. The implementation of a regularly, executed Mock Recall will help to assure your firm’s readiness. Patient safety is your number one priority and a delay in recall notification could impact lives.

I. Understand the importance of a regular mock recall exercise
II. Structure a recall team to assure adequate recall support
III. Strategies for directing multi-functional recall team to address critical functions of a product recall
IV. Recall procedure and helpful templates for customer communication and regular monthly updates to the FDA
V. Review of critical timelines and tips for assuring accurate and timely communication with customers and the FDA
VI. Recall closure timelines and communication

Lindy Schenning, Clinical Risk Coordinator, Specialty Disposables, CareFusion
Mindy Faber, RN, BSN, Manager Specialty Disposables, CareFusion

1:45    **Implement a Global Product Recall Execution Strategy**

With the increased globalization trend in the pharmaceutical industry, companies are distributing products all over the globe. These global changes present an unique set of challenges to the firm and also to their global affiliates. This session provides insight into the quality systems improvements required to deal with these challenges.

- Developing enhanced communication strategy between head office and local subsidiaries
- Managing inbound and outbound information
- Establishing global policies on incident management and recalls
- Leveraging local affiliates to execute recalls

Rufina Ho, Consultant, Global Field and Market Action, Apotex Inc.

2:30    **Close of Conference**
Product Recalls Summit

REGISTRATION FEE:

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Or Fax To My Attention 781-939-2694
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