FDANEWS

Drug and Device Recalls Boot Camp

Agenda

PRE-CONFERENCE WORKSHOP – Tuesday, April 29, 2014

8:30 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 12:00 p.m. **Harness the Power of Text Mining — Using the FDA's Recall Data to Identify and Isolate Root Causes of Nonconformances**

Nonconformance reports are written by different people in different areas of your business. That's why they often use different words or ideas to report the same problem. The solution? By developing a word matrix that scours FDA data and ranks pre-determined words based on importance and frequency, drug and device companies can now translate various nonconformance reports into a "word cloud" that very often shows what the true root problem is for a nonconformance. One medical device company conducted this exercise and found the words "ventilator," "infusion" and "simulator," which led them to quickly determine what their true root problems were in relation to nonconformance.

During this workshop, the instructor will teach attendees, using live FDA data, how text mining can help them analyze FDA data and determine how their products and other products in their class are being reported and if there are trends that show potential problems they may not anticipate.

Attendees will learn:

- How a medical device company was able to analyze its various nonconformance reports and narrow its root causes down to three words: infusion, ventilator and simulator.
- How to develop and populate a tracking matrix to collect the raw data needed for text mining.
- Proven tools and tactics to perform text analytics to decipher that data.

Heath Rushing, Principal Consultant Adsurgo, LLC

Plenary DAY ONE – Tuesday, April 29, 2014

12:00 p.m. – 1:00 p.m. **Registration and Lunch**

1:00 p.m. – 1:15 p.m. **Opening Comments by Chairperson**

David Elder, Vice President of Strategic Compliance Services, PAREXEL Consulting; former Director of the Office of Enforcement, ORA, FDA

1:15 p.m. – 2:15 p.m. **FDA's Recall Root Cause Research Project**

Lessons from the past can protect against the disaster of tomorrow. Data and information collected by the FDA's Recall Root Cause Research project is being analyzed to illuminate the root causes of recalls within the bio/pharmaceutical industry. By learning from these examples, pharma companies can minimize defects and failures leading to recalls and thus improve patient safety. This session reviews the goals and objectives of the project and gives an update on key findings to this point.

Attendees will learn:

- The most common and simple mistakes FDA observes in recall programs.
- Five simple tips to make a quick assessment of your own program.
- What specific kinds of information you can supply FDA to make your recall run more smoothly.
- The key differences between effective drug and device recall programs.

2:15 p.m. – 3:00 p.m. **How to Recover the Costs of a Recall**

Drug and device companies correctly put patient and consumer safety first when dealing with product recalls. In this presentation, the speakers will delve into how companies can recapture the financial and reputational cost of a recall. Insurance can provide coverage for many of the costs of a recall, potentially including direct losses of product and indirect losses from business interruption, loss of market share and sometimes even brand rehabilitation. Plus, various unique insurance policies help with product liability, directors' and officers' liability, and errors and omissions.

Attendees will learn:

- How and why to measure and document the financial and other costs of a recall.
- How to purchase insurance coverage for recall-related losses and liabilities and recover from insurance when a recall happens.
- What lessons prior recalls teach about financial risk management and cost-capture planning, before a recall happens.

3:00 p.m. – 3:15 p.m. **Refreshment Break**

3:15 p.m. – 4:45 p.m. **Panel Discussion: How to Master International Recalls**

As supply and demand requirements become more and more international, it has never been more important to drug and device firms to understand the unique requirements of a global recall. Regulatory requirements and attitudes can vary from country to country just as much as their cultures can vary from national to nation, region to region, and even among individual regulatory officials. It's not easy to understand all of those nuances; unfortunately, learning them isn't optional for any company operating outside the United States. This panel will probe these and other considerations when developing and executing a global recall.

Attendees will:

- Understand the different regulatory expectations in dozens of foreign markets.
- Build processes that address both domestic and global recalls.
- Understand best practices for working to strengthen the global supply chain.

4:45 p.m. – 6:00 p.m. **Networking Reception**

Tracks and Plenary Closing Session - DAY TWO – Wednesday, April 30, 2014

8:00 a.m. – 8:45 a.m. **Continental Breakfast**

8:45 a.m. – 3:00 p.m. **Two Concurrent Breakout Tracks**
Track 1 — Drugs and Biologics
Track 2 — Medical Devices and Diagnostics

Drugs and Biologics Track

8:45 a.m. – 9:00 a.m. **Track Chairperson Comments**

9:00 a.m. – 10:00 a.m. **Pharmaceutical and Biologics Recall 2014 Update**

The number of drug recalls shot up 17 percent in 2013 compared to 2012, buoyed by a spate of generic injectable drug recalls. There were 341 pharmaceutical recall events in 2013, up from 291 in 2012. In 2013, the FDA published 21 recall notices due to a lack of sterility assurance, far above the seven in 2012. Foreign particles in drug products were another key quality problem of concern last year, accounting for 19 recall notices, compared with 12 in 2012. In this session, you'll get a look at how the FDA classified recalls in 2014 and what triggering events were keys in high profile recalls.

10:00 a.m. – 10:45 a.m. **Lessons Learned in the Aftermath of Notable OTC Recalls: Understanding the Consequences and Corrective Actions**

Drawing on the best practices — and biggest mistakes — that have come out of several illustrative recalls, this session offers attendees a front-row seat in the dissection of an effective Corrective and Preventative Action program. What worked? What didn't? Which are the models to emulate — and what are the disasters you need to learn from and avoid? This session will deliver the invaluable perspective of the former Associate Chief Counsel in the FDA's Office of Chief Counsel.

Attendees will learn about:

- Examining recall activity relating to OTC products from 2009 to present.
- Evaluating the risks and benefits of cooperating with the FDA in the course of a recall.
- The FDA's recall and oversight authority with respect to OTC and other drug products.
- The FDA's recall expectations for prescription drugs vs. OTC products.
- Recall requirements under the Consumer Product Safety Act.
- The implications of voluntary recalls versus mandatory recalls.
- Best practices for managing market withdrawals and stock recoveries.
- The consequences of not instituting a recall.
- The FDA's latest posture on using its seizure and injunction powers.
- Tips for assuring building procedures to link your recall strategy to corrective and preventive action strategy.
- Proven strategies for introducing a product back to market.
- Examples of recent successful product reintroductions.

10:45 a.m. – 11:00 a.m. **Refreshment Break**

11:00 a.m. – 11:45 a.m. **The Role of Regulatory Affairs in Recall Management and Drug Shortage Notification**

Regulatory affairs has both an important internal and external role. When a recall hits, regulatory affairs should be an early responder working with the FDA and internal departments. In October 2013, the FDA announced its Strategic Plan for Preventing and Mitigating Drug Shortages. The plan's goals include early and open dialogue between the FDA and manufacturers regarding recalls and other manufacturing related shortages. Walk step-by-step alongside a drug industry regulatory affairs expert to learn to how recalls can require prompt communication with the FDA as required by the Strategic Plan for Preventing and Mitigating Drug Shortages.

Attendees will learn:

- How regulatory affairs best function both internally and externally from the outset of a possible recall.
- Manufacturer's responsibilities regarding notification under the FDA's Strategic Plan for Preventing and Mitigating Drug Shortages.
- Best practices for getting and keeping regulatory affairs and quality affairs on the same page during recalls.

11:45 a.m. – 12:30 p.m. **Improving Your Recall Execution Process**

It all comes down to proper planning and your recall process. Understanding the distribution process and the specifics of how a product gets to market will help with a more effective collaboration and communication in a recall situation. Each stakeholder should have a comprehensive understanding of the interworkings of the process and how they can best work together to accomplish the desired results.

Attendees will learn:

- How to identify the key stakeholders within your supply chain; wholesalers, distributors, hospitals, pharmacies.
- What unique role each plays in a recall situation — and what your responsibilities to each are.
- Best practices for communicating to stakeholder group to

accomplish a successful recall.

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 3:00 p.m. **Panel Discussion: Impact Analysis of Recalls — Keys to a Positive Outcome**

It is important to focus on the standard of compliance during a recall situation. But that shouldn't be your only focus. Many companies lose sight of the end impact a recall can have on a company. This session will discuss processes and techniques that can be implemented in your company to help achieve a positive outcome.

Attendees will learn:

- Ways to improve the economic impact of recall
- Techniques for a positive result from a recall situation

Medical Devices and Diagnostics Track

8:45 a.m. – 9:00 a.m. **Track Chairperson Comments**

9:00 a.m. – 10:00 a.m. **Medical Device Recall 2014 Update**

In this session, you'll get an inside look at how the FDA classifies recalls and what triggering events suggest a potential recall. Learn how field service corrections can become recalls and how using prior information can facilitate earlier vigilance, outreach and action.

10:00 a.m. – 10:45 a.m. **Recall Process Lifecycle — SOPs, Preparation and Effective Execution**

If you do not experience many recalls, or have not experienced any in the past couple years, keeping your process up-to-date can suffer. Understanding and constantly maintaining recall readiness vigilance is imperative as you now know when a recall might be necessary. This session will demonstrate how to integrate best practices throughout your organization that will maintain your recall readiness.

Attendees will learn:

- How to assure staff understands recall SOPs so they are prepared for the day a recall occurs.
- How mock recall audits help staff to know their roles and be prepared.

- Best practices for putting SOPs into action once a recall is initiated.

10:45 a.m. – 11:00 a.m. **Refreshment Break**

11:00 a.m. – 11:45 a.m. **Secrets of Successful Recall Termination Procedures**

Once all reasonable efforts have been made to remove or correct the product, now the termination process can begin. The final step is just as important as the first. It is necessary to maintain a functional supply chain and continue to foster the relationships with the key stakeholders.

Attendees will learn:

- Crucial timing for the recall termination.
- Importance of keeping in communication with the District Office.
- How to execute a formal recall closeout.

11:45 a.m. – 12:30 p.m. **Risk Evaluation and Techniques that Meet FDA Standards**

Recent trends in recalls suggest the FDA is more demanding of a company's analysis of potential health risk associated with the recalled product. The FDA is looking closely at the classification of recalls based on health risk. Companies must be confident that their health risk analysis dovetails with the FDA's use of risk tools such as Health Hazard Evaluation (HHE). It is crucial that companies understands the FDA's health risk analysis, including its recall classification and potential direct public outreach to physicians, patients and consumers.

Attendees will learn:

- How to align your internal health risk assessment with the FDA's HHE process.
- Common misalignments between industry and FDA health risk analyses.
- The reporting obligations related to health risk.
- How to prepare your company for the agency's potential public communications about your product.

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 3:00 p.m. **Panel Discussion: Field Corrections vs. Silent Recalls vs. Enhancements**

Many firms are issuing field corrections and product removal announcements without ever notifying the FDA. CDRH's Office of Compliance has said the agency is on the lookout for these "silent recalls," noting that something as simple as sending out a patch to fix a software glitch can rise to the level of a reportable event. Where you draw the line between a routine servicing issue and a malfunction repair can be complicated. Firms that understand the reporting requirements can avoid taking an already expensive problem and turning it into a regulatory mess. A February 22 FDA guidance suggests that device modifications that enhance the quality, safety or effectiveness of a product — such as improvements in design — won't necessarily trigger a recall of supplies in the field. Understanding the nuances of terms such as correction and enhancement and how you manage them is paramount for devicemakers.

Attendees will learn:

- What types of events must be reported, what are the deadlines and how to document your actions.
- Understanding what constitutes an enhancement and how to apply the Feb. 22 guidance.

3:00 p.m. – 3:15 p.m. **Refreshment Break**

PLENARY SESSION PANEL DISCUSSION

3:15 p.m. – 4:00 p.m. **Lessons from the Front Lines: Understanding How to Build Effective Internal Recall Committees**

Walk through the step-by-step process for developing and implementing stress-tested Internal Recall Committees with a leading industry expert and long-time professional.

Attendees will learn:

- How to design an efficient process and cross-functional team.
- Best practices for communicating with regulators, healthcare professionals and other key stakeholders.
- How to handle potential product liability and other complex

legal issues implicated by a recall.

4:00 p.m. – 5:00 p.m. **Panel Discussion: Recall Trends — Finding the Root Cause**

The number of drug recalls shot up 17 percent in 2013 compared to 2012, buoyed by a spate of generic injectable drug recalls. There were 341 pharmaceutical recall events in 2013, up from 291 in 2012. In 2013, the FDA published 21 recall notices due to a lack of sterility assurance, far above the seven in 2012. Foreign particles in drug products were another key quality problem of concern last year, accounting for 19 recall notices, compared with 12 in 2012. Device recalls also have been on the rise, the report shows. In 2007, the number of CDRH recalls was 1,279, and that figure climbed to 3,211 in 2011. Of those, 16 percent were due to process controls, 14 percent to design flaws and 12 percent to software design concerns. This panel discussion will examine multiple recalls and discuss how the root cause was determined and how the company and the FDA determined that effective CAPAs were put in place to allow for continued production.

Attendees will learn:

- What recall examples of recent years teach us about how to conduct better root cause investigations.
- How arriving at comprehensive root cause determinations can positively impact future manufacturing improvements.
- What the FDA wants to see in CAPAs related to recalled products so products can safely be put back on the market.

5:00 p.m. – 5:15 p.m. **Closing Comments by Chairperson**

5:15 p.m. **Conference Concludes**