

Recall Management for Medical Devices

Agenda

10:00 a.m. – 10:15 a.m. Welcome and Introduction

10:15 a.m. – 11:15 a.m. Are you Ready to Handle a Global Recall?

It can be a nightmare scenario: Your product is being recalled and your distribution network traverses the globe. It's a big problem, and you've got to get it right. The future of your company might be at stake. But are you prepared to handle the unique, scary challenges of a recall extending to both domestic and international markets? Learn the secrets of a leading industry insider to get your recall done right the first time.

Attendees will learn:

- Proven ways to communicate critical information before, during and after the recall
- How to update authorities/governing bodies in a proactive way to best protect patients and your company
- How to address key logistical issues and recall strategies to fix the situation right and fix it fast
- The tools and tactics to quickly and accurately determine the true scope of the recall, including affected products and consignee lists in the US and OUS
- The latest strategies and tools to track and reconcile recall actions

Mary Swift, Senior Manager, Regulatory Affairs, Terumo Cardiovascular Systems (invited)

11:15 a.m. – 11:30 a.m. Break

11:30 a.m. – 12:30 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 do you measure and document the financial and other costs of a recall?
- Can you purchase insurance coverage for recall-related losses and liabilities and recover from insurance when a recall happens?
- What lessons do prior recalls teach about financial risk management and cost-capture planning, before a recall happens?

Marialuisa (“ML”) Gallozzi, Partner, Covington & Burling
Suzan Charlton, Special Counsel, Covington & Burling

12:30 p.m. – 1:30 p.m.

Lunch

1:30 p.m. – 2:30 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 avoid potential product liability and other complex legal issues implicated by a recall

Todd Halpern, Assistant General Counsel, Regulatory Law, Pfizer

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 3:45 p.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 prepared is important. Understanding the process lifecycle is critical in developing your SOPs. Joe Falvo will demonstrate how to integrate best practices throughout the recall process. He will also highlight industry experiences on regulatory guidance, SOP development, recall classifications and execution techniques.

Attendees will learn:

- Strategies for effective SOPs for recalls
- Techniques to identify correction, removal and withdrawal
- The steps of notification and acknowledgement audits
- Strategies for an effective execution

Joe Falvo, Senior Manager: Post Market Risk Management, Ortho Clinical Diagnostics

3:45 p.m. – 4:00 p.m.

Closing Comments and Adjournment