

Advamed Medtech 2008  
Pre-Conference Workshop Sunday September 21<sup>st</sup> 2-6pm  
**Quality throughout the Product Value Chain –  
Key Trends in Operations**

Changes in regulations, complexity of products, globalization, and economy all have impact on today's medical device manufacturer costs, product quality and overall business operations. Join Advamed and Pilgrim Software in this free pre-conference workshop to learn about the hottest topics and challenges in engineering, manufacturing, and quality and benefit from the lessons learned and best practices from key industry experts that have increased their operational excellence and quality throughout the product lifecycle.

The pre-conference workshop is designed into three (3) sessions:

**Session One:**

**Going Global - addressing design control in an economic environment where R&D and manufacturing operations span the globe**

**Session Description**

Globalization demands new methods to efficiently address design control for R&D and manufacturing operations. Perhaps your company has grown globally by acquisition; additionally, you may have invested in global expansion by establishing new operational units around the world to leverage lower cost labor and/or specialized knowledge and technology. Whatever the case may be, if you're a global company, you have added complexity in your design control systems that were not present when you operated on a more local basis.

In this session, a panel of medical device industry experts including from some companies such as Siemens Medical, Zimmer, St. Jude Medical and others, will characterize their company's overall approach to maintaining and assuring globalized design control, as well as addressing specific global issues, including: communication and collaboration mechanisms, multi-language and literacy concerns, and opportunities for increasing efficiency.

**Speakers**

The panel will be hosted by Jim Thompson, Ph.D. – Director Healthcare Industry Solutions from Siemens PLM with case studies from several executives from major Medical Device organizations.

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**Session Two:**

**Meeting the challenge of the new quality paradigm – From supplier to customer —  
Driving quality throughout the entire supply chain**

**Session Description**

From toys to medical devices to food supplements, from “made in the USA” to “made in China” quality management is at the forefront of every manufacturer driven by global consumers wanting nothing but 100 percent safe products. For medical device companies there is no 99.9% it is either 100% or off the hospital or retail shelf or off the product list.

However, managing quality has become more difficult as we expand the number of global suppliers, manufacturing sites and external contractors needed to drive the right product at the right price at the right cost to the right place and at **the maximum quality**.

This panel of key leading industry knowledge experts will provide a view of the key issues and best practices on how to manage quality in your global upstream and downstream supply chain components. From supplier management to manufacturing trace and track to warehouse life cycle control management learn how the pieces fit together to drive the perfect lean quality supply chain.

**Speakers**

The panel will be hosted by Phil Friedman – Vice President Consumer and Life Sciences and Ms. Riya Cao from QAD with case studies from several executives from major Medical Device organizations.

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**Session Three:**

**Pre-Event Strategy for Product Recalls – Avoid the nightmare, reduce risk, and protect people through pre-event planning and strategy for recall execution**

**Session Description**

It's clear that all companies – particularly those whose products have the potential of being recalled – should be prepared for the worst. Getting a simple plan in place and taking measures to ensure its effectiveness are necessary in diverting crisis long before an event arises. Despite the fact that regulations and FDA guidance strongly recommend comprehensive recall planning, many companies have major challenges in determining what information is needed for a recall, as well as gathering that information and distributing it to the appropriate people. In the event of a recall, preparation may lend much more than a hand; it may save your company's reputation.

In this session, a panel of industry experts, including Cardinal Health and Stericycle, will discuss the important aspects of pre-event preparation, mock recall and assessments, and recall action team leadership and responsibilities. Learn valuable lessons on how to ensure public safety, be certain that all recall operations are effective and the public is protected.

**Speakers**

The panel will be hosted by Ken Edwards – Vice President of Recalls from Stericycle with case studies from Cardinal Health and other executives from major Medical Device organizations.