

**From:** "Nan Matthews" <rmras@themattgrp.com>  
**Subject:** **SUPPLIER CONTROLS AUDIOCONFERENCE**  
**Date:** December 7, 2009 11:46:49 AM MST  
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**Please join the Rocky Mountain Regulatory Affairs Society at Regus Business Center in Westminster  
to take advantage of discounted fees for the following audioconference**

## **Control of Products and Services Obtained from Suppliers**

Tuesday, December 15, 2009  
12:00 - 1:30

**Location:**

Regus Business Center  
10955 Westmoor Drive, 4th Floor  
Westminster, CO 80021  
303-379-2100

**Overview:**

The US FDA has discovered that a reasonably large number of recalls and adverse events are related to supplied product. Medical device supplier activities is now a focus area for FDA inspections and also third party audits. This concern is now reflected internationally with the publication of a GHTF guidance document on supplier activities. This increased focus by regulators on supplier activities should cause medical device companies to review their processes against requirements to avoid audit and inspection findings.

**Areas Covered in the Session:**

- Supplier Controls reduce supplier problems
- Supplier evaluation techniques lead to selection of better suppliers
- Supplier selection processes must be effective in choosing the right suppliers
- Acceptable Supplier Listings are used to show what products suppliers can efficiently provide
- Removing suppliers from Acceptable Lists when there are issues
- Impact of Risk Management on Supplier processes
- How to develop a Supplier Management process that meets regulators expectations.

**Instructor:**

**Edwin L. Bills, Principal Consultant, Bilanx Consulting LLC**

During his 20 year career in medical devices, Mr. Bills has held a number of quality and regulatory affairs positions. Mr. Bills is ASQ Certified as Quality Engineer, Quality Auditor, and as Manager of Quality/ Organizational Improvement. He also holds a certificate as Regulatory Affairs Certified through the Regulatory Affairs Professionals Society, and a BS and Masters degree from the University of Cincinnati. Recently, Mr. Bills served as US Industry Co-chair of the Association for Advancement of Medical Instrumentation committee, QM/WG04, on application of risk management to medical devices.

The cost for the audioconference is \$125.00. We are set up to initially only accept 10 registrants. Once that number has been reached, we will take a wait list for an additional six.

To register, go to [www.regonline.com/supplier](http://www.regonline.com/supplier)

For questions, contact Nan Matthews, [rmras@themattgrp.com](mailto:rmras@themattgrp.com) or 303-843-6414