

From: "Nan Matthews" <rmras@themattgrp.com>
Subject: **Auditing Suppliers and Contractors - audioconference**
Date: February 7, 2010 8:11:33 PM 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. This is only available at Regus, not in your office.

Auditing Suppliers and Contractors: Be Ready for Increased FDA Scrutiny

A 90 Minute Interactive Audio Conference
Wednesday, February 24, 2010
9:00 am – 10:30 am

FDA regulations are clear----whether for drugs or devices, you are responsible for the quality of your product, regardless of what areas of your operation you outsource, or who actually made your product. And, with the New FDA focused on enforcement, you must ensure that your suppliers are manufacturing product to the same high standards you would.

In this 90-minute audio conference, former FDA credentialed inspector Dennis Moore will show how to ensure your outsourced suppliers will follow FDA regulations. You'll learn what the FDA is looking for, and how things may change with the many recent supply chain safety failures.

You Will Benefit From:

- 7 things you should know about supplier's business practices
- 8 items to evaluate on a supplier's quality systems
- What to ask a supplier about their records, procedures, validation, maintenance, calibration and traceability
- What do they do about non-conforming product?
- What to look for in CAPA, product release, training, and customer complaint handling
- 6 questions to ask to differentiate between adequate and gold standard suppliers
- Information sharing, contracts and more

Speaker

Dennis Moore, president and CEO of AUK Technical Services, is an expert in GxP auditing and training, risk-based quality systems, complaint management and failure investigation, Part 11, process validation and monitoring, OOS, documentation and change control programs, and other areas of FDA compliance.

Location:

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

The cost of this audioconference is \$70.00. To register, please go to www.regonline.com/auditing

PLEASE NOTE, IF YOU HAVE PREVIOUSLY REGISTERED FOR AN AUDIOCONFERENCE, THE SYSTEM MAY NOT TAKE YOUR INFORMATION.

If so, contact Nan Matthews, rmras@themattgrp.com or 303-843-6414, and she will take your registration over the phone. We must have at least 10 people register in order to host this meeting. Your credit card will not be charged until we reach that number.

For questions, please contact Nan Matthews, rmras@themattgrp.com or 303-843-6414.