

From: "RMRAS Programs" <programs@rmmas.org>  
Subject: Complaint Handling Audioconference - Aug 24  
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To: "RMRAS Programs" <programs@rmmas.org>

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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 teleconference. (This discount is only available at Regus, not in your office. If you want to participate from your office, contact the Sponsor for full price rates.)**

**AUDIOCONFERENCE**  
**Complaint Handling: A Former FDA Official & Industry**  
**Experts Discuss Best Practices**  
**Thursday, August 24, 2011**  
**11 – 12:30**  
followed by an informal discussion

**[Your registration is needed by August 19 - If there are fewer than 10 participants, this event will be not be held.]**

For over a decade, complaint handling systems have been a top FDA-483 observation and are frequently cited in warning letters sent to device and pharmaceutical firms.

In 2010 alone, FDA cited complaint handling deficiencies over 300 times - 100 deficiencies were observed at drug firms; device firms accounted for over 200 more.

The trend is ongoing. In a typical example in early 2011, Steven D. Smith, Director of the Office of Compliance at CDRH, wrote to the president of AID United International Co. Limited, citing the firm for failing "to maintain adequate complaint files" and for failing "to establish and maintain adequate procedures for receiving, reviewing and evaluating complaints, as required by 21 CFR 820.198(a)."

**What You'll Learn:**

- Which areas are you most likely to find troublesome in complaint handling systems?
- How is an "adequate investigation" defined?
- If you are already investigating complaints within a CAPA, does your complaint handling system also have to be involved?
- What is considered "timely" for closing a complaint investigation?
- If you service your own products, is a service request a complaint?
- Should you do anything if you receive an MDR-reportable complaint for another company's products?
- How often should you contact a user facility to follow up on a complaint?
- Is documentation needed if you decide a complaint does not require investigation?
- Are there incentives quality can use to effectively motivate other departments to conduct thorough complaint investigations?
- Does FDA prefer a particular method for complaint trending?
- What data from complaint trending should be reviewed by management?
- How do you decide if a complaint can be closed?
- How long should it take to close a complaint? Should you set goals for this timing?

**Panel of Experts**

**Denise Dion** was FDA's medical device investigator liaison between the Office of Regulatory Affairs (ORA), CDRH and field staff and was one of the designers and trainers of QSIT. She was an integral part of FDA's Design Control Inspection Strategy Team, served as the editor of the Investigations Operations Manual for five years and participated in the FDA's basic medical device and process validation training. Denise was ORA's final reviewer for online basic investigator training courses and helped develop FDA's Risk Management and Computer System Validation online training courses. Denise is currently with EduQuest.

**Nancy Singer** has served as AdvaMed's Special Counsel for FDA compliance and enforcement matters. In that role,

**Paul A. Arrendell** is Vice President of Global Quality for Kinetic Concepts, Inc

**Jonathan Lee** His career encompasses experience as V.P. Regulatory, Quality & Clinical Services at Medtronic Surgical Technologies, dealing with ISO, EN, MDD & GMP standards and regulations. Jonathan now heads Medical Device Consulting Solutions International.

**Terry Callahan** is the Director of Global Customer Quality Assurance for Covidien Surgical Devices, where his group is responsible for handling customer complaints worldwide.

**Robie Aridi** has over two decades of industry experience, including a term as Vice President of Operations for Lansinoh Laboratories, which markets OTC drugs, devices, cosmetics and other consumer products.

**Sponsor:** For additional information about this audioconference, see FOI Services, [www.foiservices.com/tc](http://www.foiservices.com/tc).

**Cost:** The cost of this teleconference is \$75

**To register, please go to:** [https://www.paypal.com/cgi-bin/webscr?cmd=\\_s-xclick&hosted\\_button\\_id=PFE48DYB35VWU](https://www.paypal.com/cgi-bin/webscr?cmd=_s-xclick&hosted_button_id=PFE48DYB35VWU)

Note: Your credit card will be charged at registration, but you will be fully refunded if the event is cancelled.

**Location:**

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

Follow the signs for the Golf Course and after you see the clubhouse, look for the blue building with the gazebo (approximately 0.9 miles from entrance of complex. (Warning: the building numbers are hard to see.)

**Questions:** Questions can be addressed to: Neil Burriss at [neil@sssnpartners.com](mailto:neil@sssnpartners.com) or to [Webinars@RMRAS.org](mailto:Webinars@RMRAS.org)