

**From:** "Nan Matthews" <rmas@themattgrp.com>  
**Subject:** **Quality System Audits audioconference**  
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**AUDIOCONFERENCE SPONSORED BY RMRAS**

**Quality System Audits: What You Must Do to Prove Compliance**  
**Tuesday, November 17, 2009**  
**11:00 am – 12:30 pm**

**Location:**

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

*"Failure to adequately establish and maintain procedures for conducting quality audits...according to your Operations Support management, your firm's last documented internal quality audit was conducted in 2002."*

*"Your firm did not use certain audit forms required by your Internal Audit Procedure SOP-03, Revision B"*

26 warning letters were issued in the last 12 months for failures in the audit and documentation of quality system (QS)----more than a third of all the QS warning letters issued. Now, with the FDA stepping up enforcement, and turning 483s into warning letters faster than ever, you must be sure your audit procedures and documentation will pass inspector scrutiny.

But how do you prove compliance, and capture necessary information in a fashion from a diverse workforce of busy individuals with technical and non-technical backgrounds?

In this 90 minute audio conference, QS expert **Kim Kurschner** will provide the processes to effectively expedite and document investigations for their organization.

**You Will Benefit From:**

**Guidance to evaluate your audit before it happens:**

- \* Do you have enough time and resources to find what you are looking for? Are your goals realistic?
- \* Are your audit SOPs up to date? Have you been following them? Do they reflect the best practices your company uses?
- \* Do you have buy-in from management and stakeholders along the audit chain? Are the specific goals shared by all?

**Plans for documenting your audit as you go:**

- \* Does your team understand the documentation standards? Are you monitoring adherence to documentation conventions throughout the audit?
- \* How are you editing and compiling results? Who is responsible for audit documentation QC?

**Strategies for audit close-out and follow-up**

- \* 8 dos and don'ts for evaluation of results-what does it all mean?
- \* How to prioritize resolution and executing the management review
- \* The role of CAPA and looping back to future planning

**Kim Kurschner**

Kim Kurschner of Pathwide brings more than a decade of knowledge and insight to client companies in the areas of the quality system, external and internal audit performance, onsite investigations coaching, process redesign and revalidation, lead manufacturing, corrective and preventive action, and process development.

Kim previously was a [Senior Global Regulatory Compliance Auditor](#) with Boston Scientific, where he was responsible for conducting compliance quality system audits, writing audit reports, and following the audit findings to closure of the corrective actions across 27 sites around the world. He has been certified by and worked with companies including Tyco Healthcare, Miracle Ear, Boeing Aircraft, Honeywell and King Radio. He also served as a trainer and instructor within the U.S. Army Signal

School as part of his active duty assignment.

**The cost for this audio-conference is \$50. To register, go to [www.regonline.com/audits](http://www.regonline.com/audits) Your credit card will not be charged until we reach the required number of attendees. For questions, contact Nan Matthews, 303-843-6414, [rmas@themattgrp.com](mailto:rmas@themattgrp.com)**