



Corrective and Preventive Action

CAPA Best Practices for Medical Devices

About the instructor:

Ken Link, Alquest, Inc., has more than 18 years experience with process validations (IQ/OQ/PQ), supplier auditing/approval, new product development support, development and implementation of quality systems, including CAPA programs, at both large and small organizations. Mr. Link has a B.S. in Biomedical Engineering and currently is a member of the American Society for Quality (ASQ) as a Certified Quality Auditor, Engineer, and Manager

Who Should Attend:

- Regulatory Affairs
- Quality
- Engineering
- MDR/Complaint support
- CAPA Management

Certificates of attendance offered at all seminars and programs may be used towards Contact hours and CEUs.

Visit www.mfrall.com

for details on:

Upcoming Seminars & Events. Click on the "Medical Device Alliance" tab.

Learn which concerns top the FDA's list, how to establish your system requirements, set objective criteria for assignment to CAPA, and ways to close the loop on CAPA actions in a timely manner. Whether you are with a large established firm or a start-up, our instructor can provide you with guidelines to improve your CAPA system. This hands-on class will ensure you know how to build and maintain a strong and effective CAPA program.

What Will Be Covered:

- ◆ Data Analysis/Managing input sources to CAPA
- ◆ Root Cause Analysis
- ◆ Verification of CAPA Effectivity
- ◆ Internal Audits and CAPA

Thursday, April 29, 2010 8:00 a.m. – 12:00 p.m.

- Fee:** Members \$199 per person Non-members \$299 per person
(Fee includes materials and continental breakfast)
- Location:** **Alquest, Inc.** Free Parking
4050 Olson Memorial Highway, Minneapolis
(For directions and map go to www.mfrall.com)
- Reservations:** For instant confirmation, reserve on-line at **www.mfrall.com**, click on **Medical Device Alliance** then **Medical Seminars** by Tuesday, April 27, 2010.
Your satisfaction is guaranteed.
- Cancellation Policy:** **No refunds** for cancellations after 5:00 p.m. Tuesday, April 27, 2010, or for no-shows at workshop. *(Substitutions accepted)*

Pre-registration required!