

**From:** "RMRAS Programs" <programs@rmras.org>  
**Subject:** **April 20 RMRAS Meeting**  
**Date:** April 5, 2011 11:30:56 AM MDT  
**To:** "RMRAS Programs" <programs@rmras.org>  
▶ 1 Attachment, 42.7 KB

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*Rocky Mountain Regulatory Affairs Society (RMRAS)  
presents*

## **Navigating the Electronic Maze Practical Advice for Companies Considering Electronic Document and Data Management**

Wednesday, April 20, 2011

3:30 pm – 5:00 pm

Front Range Community College

*[Please note that this announcement reflects a new way of designating the content level for our regular meetings. We are going to use Colorado ski area descriptions;*

*● green for beginner; ■ blue for intermediate and ◆ black diamond for expert.]*

### **This presentation is intended for the following audience:**

- Industries: All FDA-regulated industries
- ■ ◆ Experience level: Intermediate/advanced
- Expected knowledge/experience: Solid understanding of document control issues and some experience in document control and quality system implementation; Basic understanding of FDA 21CFR Part 11 regulations.

**If you ponder any of the following questions, this session will interest you:**

- What are the advantages of electronic document and data management?
- What are the pitfalls?
- What are some of the available packages and how can I evaluate them?
- How hard is it to implement an electronic system?
- What can I do to prepare for the switch from paper to electronic systems?

The program will include presentations from three organizations, followed by a question-driven panel discussion. Our expert panel includes David Hadfield of Integware, Tim and Lenisse Lippert of KickStart Professionals, and TK Train from Gambro.

Please RSVP to [programs@rmras.org](mailto:programs@rmras.org)

**Presenter Bios:**

**Dave Hadfield** joined Integware in 1997 and is the Director of the Client Transformation group. Dave has over 14 years of experience in helping companies automate Quality Management Systems with Product Lifecycle Management and helping Fortune 500 companies achieve their business goals. For the past 12 years, Dave has worked heavily in the medical device industry. His customer list is extensive and includes some of the biggest life science companies as well as a number of smaller organizations and divisions. With his partners at Integware, Dave often works on defining the QMS strategy with a common goal of ensuring compliance with part 11, part 820 regulations and conformance with the ISO 13485 standard while at the same time helping to accelerate innovation and customer value.

**Lenisse Lippert** has over 20 years of experience working in biotechnology and medical device industries. Recent experience includes managing a 1.5M Johnson and Johnson data conversion project; electronic Deviations/CAPA forms development for Agilent Technologies; Electronic Documentation Management System (EDMS) validation project for Allergan and validation script writing and execution for other biotech companies. Lenisse was also responsible for managing a \$150K EDMS project with a return on investment of \$500K over a three year period. This successful Part 11 compliant project included completion of a return on investment to get approval of the project, building a project plan, writing and running validation scripts, training personnel, and writing needed documents such as a validation master plan, user requirements, risk analysis, change control, problem reporting, workstation configuration, and disaster recovery.

**Tim Lippert** has over 30 years project management and business development experience. Tim developed much of his business knowledge and management skills while working for a major utility company. Tim co-founded KickStart Professionals in 2008. This enterprise offers

electronic solutions in regulatory, quality and the documentation arenas of the Life Sciences industry. In addition to leading marketing efforts Tim has also been involved in various projects for major biotechnology companies such as Allergan, Johnson and Johnson, and Agilent Technologies. Tim has a passion for going "green". Electronic Documentation Management is his way of contributing to a cleaner, greener world.

**TK Train** has 25 years experience in Records and Information Management Compliance and has served as a Subject Matter Expert for numerous corporations in both the private and public sectors. She has experience on the vendor and the end-user side of the business. She holds a BS in Business Information Systems and an MBA in Global Business Management. She is a Certified Records Manager and an Enterprise Content Management Practitioner through AIIM International. Her experience with regulatory agencies include SEC, FDA, FCC, EPA and DOD. TK's first experience with Document Management was when she implemented an optical imaging DM system in 1990 in So. California. She is currently working for Gambro.

### **Location**

Front Range Community College  
College Hill Library, L-211  
Westminster, Colorado 80031

#### **Directions from Denver**

Take I-25 to Hwy 36 toward Boulder  
Take Hwy 36 to Sheridan Blvd, exit north  
Stay on Sheridan to 112th Avenue, turn east  
Go ½ mile and Front Range Community College will be on your left  
Turn left into the first street into the parking lot and enter the building at the main entrance  
Take a left, go through the Library and Room L-211 is on your left  
[For further directions, call 303-404-5539]

#### **Directions from Boulder**

South on Highway 36 to 104th Avenue (Church Ranch Blvd) exit  
East on 104th Avenue one mile to Sheridan Blvd  
North on Sheridan Blvd to 112th Avenue  
East on 112th Avenue, go .5 mile – Front Range will be on your left  
Turn left into the first street into the parking lot and enter the building at the main entrance  
Take a left, go through the Library and Room L-211 is on your left.  
[For further directions, call 303-404-5539]