



**Co-Sponsor:**

ASQ Biomedical Consortium

**About the instructor:**

Dawn Luehrs, has more than 13 years experience as a process and quality engineer. This experience includes process development and improvement, process validation, risk management, sterilization, and post market surveillance. Experience in both operations and quality provides the ability to address the topic of validation through different experiences.

**Who Should Attend:**

- Regulatory Affairs
- Quality
- Engineering
- Operations

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

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# Process Validation- A Risk Based Approach

## *Process Validation Methods for Medical Devices that Promote Continuous Improvement*

Process validation and continuous improvement are an important part of a successful Medical Device Operation. Completing a process change or product improvement can prove to be a long and costly process, requiring multiple process validations. This course provides insight and tools for the risk based approach to process validation, which promotes continuous improvement throughout the product life cycle. This approach provides the method to develop and justify the validation requirements, level of validation, and sample size that can be utilized on new and existing processes. The approach bases its method on process and product understanding and associated risk.

**What Will Be Covered?**

This interactive course provides participants the knowledge and tools to develop a risk based process validation and continuous improvement program. Material will be presented through experiences and examples. Participants are asked to bring examples of their process and continuous improvement projects.

- ◆ Structure and implementation of a risk based validation program
- ◆ Inputs into the validation planning process
- ◆ Challenges of continuous improvement and validated processes
- ◆ When is revalidation/requalification required?

**Thursday November 19, 2009 8:00 a.m. – 12:00 p.m.**

**Fee:** Members \$199 per person Non-members \$299 per person

**Location:** Coloplast  
1601 W. River Road Suite 101  
Minneapolis, MN 55411

**Reservations:** For instant confirmation, reserve on-line at [www.mfrall.com](http://www.mfrall.com), click on **Medical Device Alliance** then **Medical Seminars** by Tuesday, November 17, 2009. *Your satisfaction is guaranteed.*

**Cancellation Policy:** **No refunds** for cancellations after 5:00 p.m. Tuesday, November 17, 2009, or for no-shows at workshop. *(Substitutions accepted)*

**Pre-registration required!**