ComplianceOnline
The Largest GRC Advisory Network

2-day In-person Seminar:

Medical Device Risk Management A to Z - Best Practices for Effectiveness and Efficiency

By: **Stan Mastrangelo**, Consultant

Location 1: May 5-6, 2016 | Boston, MA

Location 2: September 8-9, 2016 | Chicago, IL

SPEAKER

Stan Mastrangelo, Consultant

Stan Mastrangelo has over 30 years of professional work experience in Quality Assurance of medical devices, pharmaceuticals, and foods. Stan has held positions such as Senior Quality Engineer, Corporate Quality Assurance Auditor, Plant QA Manager, QA Director, and Consultant. Stan was a member of the ANSI Executive Standards Board. Stan has had extensive involvement in the development of International Risk Management Standards. Stan was a member of the ISO Joint Working Group for Risk Management of Medical Devices (that developed ISO/IEC14971).

Stan was a committee liaison to the ISO Technical Management Board Joint Working Group on Risk Management that developed ISO 31000 which is the Risk Management Standard for all sectors. Stan was on the US PhRMA (Pharmaceutical Research and Manufacturers Association) Team that supported the development of ICH (International Conference for Harmonization) Standard Q9 titled Quality Risk Management for Pharmaceuticals. Stan also served on various IEC Standards Teams related to IEC 60601, IEC 80001 and Risk Management in the Software Lifecycle. Stan is an Adjunct Professor at Virginia Tech and was a co-developer of a Masters Degree Program in Medical Product Risk Management. Stan is on the Risk Management Committee for the IECEE.

LEARNING OBJECTIVES

Upon completion of the course, the participants will have learned how to implement good risk management principles into medical products manufacturing operations such as medical devices, combination products, and pharmaceuticals:

- Understand what are the current issues and recommended solutions
- How to implement the ISO 14971 framework
- Use a Traceability Report for improved risk management operations
- How to Use Standards to Facilitate Product-to-Market Achievements
- How to Use Risk Management to Identify the Critical Success Factors
- Key implementation issues related to Risk Management
- Using Risk Management to identify key opportunities for the organization
- Risk Integration Issues, especially related to the Quality System and Design Controls
- Use of appropriate risk management tools beyond FMEA

COURSE DESCRIPTION

The course is designed for Medical Products Manufacturers. The course will be taught for Medical Devices and Combination Products, but will also be of benefit to Pharmaceutical Manufacturers.

AGENDA

DAY ONE (8.30AM – 4.30PM)

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

1. Introduction to Risk Science
   - What Is So Special About Medical Products?
   - Complexity Theory, Chaos Theory, and Decision-making
2. Introduction to ISO 14971
   - What it is
   - What it isn't
3. What Is New?
   - New European Requirements
   - Risk Management in IEC 60601
   - Human Factors
4. Frameworks for Successful Risk Management
   - Review of ISO 31000
   - Combination Products and ICH Q9
5. Planning for Effective Risk Management
   - Integrating Risk Management into Design Controls
   - Risk Concepts in Project Planning
6. The Master Document – The Traceability Report
   - Key role of this document
   - Leverage this report to meet new EN requirements
7. ISO 14971 - By The Numbers
   - Management Responsibility
   - Risk Policy
   - Establishing Risk Acceptability Criteria
8. Risk Analysis
   - The Importance of Preliminary Hazard Analysis
   - Risk Estimation – Effective Use of Qualitative Analysis
   - Using More Tools Than Just FMEA

DAY TWO: (8:30 AM – 4:30 PM)

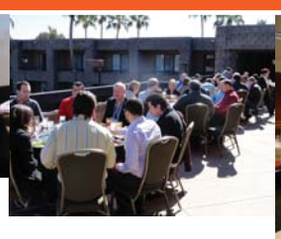
9. Risk Assessments
   - Using a Modular Strategy for Complex Products
   - How to Assess Overall Risk and Risk-Benefit
10. Risk Control Techniques
    - Verification of Implementation
    - Using Validation for Effectiveness
11. Production & Post – Production
    - Is Production Being Monitored and Documented in the Risk File?
    - Documenting Field Performance in the Risk File
    - Making Recall Decisions
    - Communicating Risk to Stakeholders
12. Risk Management in R&D
    - Risk Science in the Research Phase
    - Risk Management in Design Phase Reviews
13. Risk Management in IEC 60601, Third Edition
    - Using Risk Science to Address Unique Product Characteristics
    - The Test Lab and the Risk Management File
14. Risk Management in the Supply Chain
    - Assessing Supply Chain Risk
    - Controlling Supply Chain Risk
15. Organization of the Risk Management File
    - Product Families
    - Products and Accessories in Medical Systems
16. Conclusion
    - Confirmation of Learning Objectives
    - Key Topics to Watch

WHO WILL BENEFIT

The course is designed for manufacturing professional employees that must interface with or implement product risk management activities in a medical product manufacturing operation.

- Product Risk Managers
- Quality Assurance
- Regulatory Affairs
- Research & Development
- Project Managers
- Operations Managers
- Manufacturing Managers
- Engineers

TESTIMONIALS



"Well-chosen topics, experienced presenter and excellent support material. In all, a good training experience."

- Manager, Instrument Risk, Abbott Molecular, Inc.

"Very useful support material and a good presenter. The course was well structured."

- Senior Project Manager, Risk Management, Abbott Molecular, Inc.

"The presenter offered a fresh perspective of the subject."

- Regulatory Affairs Supervisor, Hu-Friedy

"The seminar content and presentation were both good."

- Quality Engineer, Hu-Friedy

"The course covered everything I thought it would. Overall well presented."

- Lead Compliance Agent, ForeverGreen International

"The topics covered were really helpful and the presenter had a wealth of information to share. The support material provided during the course was useful too."

- Senior Quality Engineer, Harvard Apparatus Regenerative Technology

"The presentation was designed well and the presenter was conversant. I found the sessions interactive and well-planned."

- QA Program Engineer II, Abbott Medical Optics Inc.

"The topics covered were sound. The group interaction and discussions were helpful."

- Program Engineer III, Abbott Medical Optics Inc.

"I found the presenter to be very knowledgeable and he spent time covering all the topics effectively. The support material he shared with us was quite useful too. The topics covered and the overall presentation were both sound."

- Regulatory Affairs / Compliance Manager, LSI SOLUTIONS®

Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
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Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Medical Device Risk Management A to Z - Best Practices for Effectiveness and Efficiency

Date & Location: .....

Attendee Details:

Register for 3 and 4th person gets a free pass.

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

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State ..... Zip.....

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