An interactive Workshop Featuring
20 Exercises Over 2 Days

Don't let FMEA be your downfall! If you're relying on FMEA as your risk management strategy, you need to attend this intensive two-day workshop.

July 14-15, 2015 • Wyndham Boston Beacon Hill • Boston, MA

Nov. 10-11, 2015 • Chicago Marriott Oak Brook • Oak Brook, IL

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

Medical Device Risk Management

From Understanding to Applications

Attend this invaluable workshop to learn:

- How a Risk Management System integrates into a Quality Management System
- The regulatory requirements from FDA QSR and ISO 13485:2003
- How to use ISO 14971:2007 for medical device risk management
- Risk/benefit analysis using the FDA-CDRH guidance document
- The limitations on risk management activities from the EU product directives (MDD, IVDD, and AIMD) documented in EN ISO 14971:2012
- How to employ IEC 62366:2007 Usability Engineering in a Risk Management System
- Specific applications for electrical medical equipment (IEC 60601-1) and software (IEC 62304)

YOUR EXPERT INSTRUCTOR

DAN O'LEARY has more than 30 years experience in quality, operations and program management in regulated industries, including aviation, defense, medical devices and clinical labs. Mr. O'Leary is the president of Ombu Enterprises, a consultancy focused on operational excellence and regulatory compliance serving small manufacturing companies.

The FDA's QSR expert, Kim Trautman, on risk management:

"Are FMEA or FMECA… good tools? Yes. They are very good tools that can be utilized. Are they in and of themselves a risk management system? Absolutely not. I can't tell you how many manufacturers I have seen that have tried to present their risk management system by simply presenting a FMEA — that is not a risk management system. Do not make the mistake of presenting FMEAs as your whole risk management system."

Visit www.DeviceRiskManagement.com or call (888) 838-5578

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WORKSHOP AGENDA

DAY ONE

8:00 A.M. – 9:00 A.M.
REGISTRATION AND CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.
The Concepts of Risk Management

- Introduction
- The fundamentals of risk management
  - The Consequence Diagram and the Decision Tree
- The components of risk and potential problems to consider
  - The EtO explosion case
  - **Exercise** – Analyzing the EtO Explosion case
    - The participants watch a video about an explosion in an EtO sterilization facility. The exercise asks participants to analyze the events and outcomes using the risk management model
- Definitions from ISO 14971:2007
  - Distinguishing between a hazard and a harm
  - Defining risk – a combination of probability and severity
- Assessing risk using its formal definition
- Why FMEA is not sufficient for risk management
- **Exercise** – The importance of risk management
  - This exercise is a discussion among participants as to why risk is important. They will discuss the various approaches their firms take to recognize risk by developing bullet points that describe the approach.

10:15 A.M. – 10:30 A.M.
BREAK

10:30 a.m. – 12:00 p.m.
The Regulatory Framework

- ISO 14971:2007 as the international standard
- National and regional variations
  - AAMI / ANSI / ISO 14971:2007/(R)2010
  - CSA-ISO 14971-07
  - EN ISO 14971:2012
- The Risk Management requirements in FDA's QSR
  - Risk Management as design validation
  - Essential design outputs as risk management inputs
  - Complaints and the risk management file
  - Risk reduction as design inputs
- ISO 13485:2003
  - EN ISO 13485:2012
  - Risk management outputs as design inputs
- Global Harmonization Task Force guidance
  - Integrating quality management and risk management
- FDA Warning Letters – Learning from others

ISO 14971:2007 Overview

- The structure of ISO 14971:2007
- Understanding the clauses and their requirements
  - An introduction to the nine clauses in ISO 14971:2007
- Introduction to risk management tools
  - The tools in Annex G
  - Applications of the tools to the risk management process
  - **Exercise** – Analyzing Risk Priority Numbers (RPN)
    - RPNs are a common tool in FMEA and are often applied to risk management. This exercise helps participant explore some of the issues associated with using RPNs.

12:00 P.M. – 1:00 P.M.
LUNCH BREAK

1:00 p.m. – 2:30 p.m.
Understanding ISO 14971:2007 (Part 1)

- The Risk Management File
  - Understand the content of the risk management file and development of an internal quality audit checklist to help demonstrate compliance.
- Risk Management Plan
  - Learn the required content of the risk management plan and how it relates to the design and development plan and other QMS documentation.
  - **Exercise** – Evaluating Personnel Qualification
    - During the introductions, participants are asked to identify the risk management roles they perform. In this exercise, they are asked to identify the qualifications for those roles and the objective evidence that an auditor or inspector would expect.
  - **Exercise** – The Risk Management Plan
    - The risk management plan has some specified elements. This exercise asks participants to develop bullet points for some of the elements in the plan.
- Risk Analysis
  - Risk analysis start with hazards and follows them to estimate risk. This section develops the methods and helps participants understand the issues.
  - **Exercise** – Device Characteristics
    - Participants analyze device characteristics for an example medical device using the criteria in Annex C of ISO 14971:2007 and GHTF/SG1/N41R9:2005
    - Essential Principles of Safety and Performance of Medical Devices
  - **Exercise** – Essential Design Outputs
    - Participants develop design outputs for an example medical device and identify the essential design outputs required by 21 CFR §820.30(d).
  - **Exercise** – TPLC Database as a source of hazards
    - This exercise has participants analyze information about an example medical device using the FDA's Total Product Life Cycle (TPLC) database to identify hazards.
- Risk Evaluation
  - Risk analysis estimates the risk. The risk management plan defines the acceptability criteria. Risk evaluation combines them to help determine the need for risk control.
- Risk Control
  - Risk control is the method to bring risk to an acceptable level using the techniques of option analysis. It also includes the cases where risk might be unacceptable, but is outweighed by the device benefits.
  - **Exercise** – Oral B Toothbrush
    - Participants analyze the recall of a powered toothbrush to help identify the components of risk management and their analysis.
  - **Exercise** – Spinbrush Toothbrush
    - Participants analyze the risk reduction activities of a powered toothbrush recall to understand classification and effectiveness.

2:30 P.M. – 2:45 P.M.
BREAK

2:45 p.m. – 4:30 p.m.
Understanding ISO 14971:2007 (Part 2)

- Overall Residual Risk Evaluation
  - Overall residual risk covers the device in contrast with the residual risk associated with individual hazards and hazard situations.
  - **Exercise** – Overall Residual Risk Acceptability
    - The Risk Management Plan must contain criteria for the acceptability of overall residual risk. The project must apply these criteria to the device. Participants develop risk acceptability criteria and apply them to an example medical device.
  - **Exercise** – Communicating Risk
    - The manufacturer must communicate risk information as either information for safety or disclosure of residual risks. In either case, understanding the information is important. This exercise gives participants an opportunity to evaluate readability using the Flesch-Kincaid grade reading level (built into MS Word) and to reduce the grade reading level for an example.
- Risk Management Report
  - The risk management report documents

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a review of the risk management process required prior to release for commercial distribution of the medical device.
- **Exercise** – Risk Management Report
  - The exercise gives participants an opportunity to understand the role of the Risk Management Report by creating sections based on the project for a sample medical device.

- Production & Post-production Information
  - Production information collection reviews information collected while producing the device and evaluates its impact on risk management.
  - Post-production information collection reviews information after the product releases for distribution. This includes complaints and MDRs, including MDRs filed by other manufacturers.
  - The impact of the Unique Device Identification (UDI) rule on complaints and MDRs.
  - **Exercise** – Evaluating a Rework Disposition
    - A rework disposition requires a determination of any adverse effect on the device. This exercise evaluates the relationship between risk management and an adverse effect.
  - **Exercise** – Pareto Analysis of the TPLC Database
    - This exercise has participants utilize a common quality tool, Pareto Analysis, to analyze information from the TPLC database. This helps determine if there is new information that might require reevaluation of a hazard.
  - **Exercise** – Complaint Signals
    - This exercise has participants analyze complaints to determine if the frequency of complaints changed after the initial frequency determination in the hazard analysis.

4:30 p.m.
Session Wrap-up, End of Day One

DAY TWO

8:30 A.M. – 9:00 A.M.
CONTINENTAL BREAKFAST

9:00 a.m. – 10:15 a.m.
Using ISO/TR 24971:2013
- Scope
- The role of international product safety and process standards in risk management
- Developing the policy for determining the criteria for risk acceptability
- Production and post-production feedback loop
- Differentiation of information for safety and disclosure of residual risk
- Evaluation of overall residual risk

Usability Engineering
- Linking IEC 62366-1:2015 to ISO 14971:2007
- The FDA-CDRH Current Guidance
- The FDA-CDRH Draft Guidance
- Human Factors and Medical Devices; The CDRH program
  - **Exercise** – Information for Safety as a Risk Control Measure
    - This exercise provides participants an opportunity to explore Usability Engineering when using information for safety from ISO 14971:2007 as a risk control option.

10:15 A.M. – 10:30 A.M.
BREAK

10:30 a.m. – 12:00 p.m.
Understanding EN ISO 14971:2012
- The Z annexes of EN ISO 14971:2012
- Current status of EN ISO 14971:2012
- Content Deviations
  1. Treatment of negligible risks
  2. Discretionary power of manufacturers as to the acceptability of risks
  3. Risk reduction "as far as possible" versus "as low as reasonably practicable"
  4. Discretion as to whether a risk-benefit analysis needs to take place
  5. Discretion as to the risk control options/ measures
  6. Deviation as to the first risk control option
  7. Information of the users influencing the residual risk
- Team-NB Recommendations

12:00 P.M. – 1:00 P.M.
LUNCH BREAK

1:00 p.m. – 2:30 p.m.
Medical Electrical Equipment
- Linking IEC 60601-1 to ISO 14971:2007
- Understanding the CB scheme
- Working with the Test Report Format
- Using IEC 60601-1 for acceptable residual risk
  - **Exercise** – An Application of Electrical Safety
    - This exercise provides participants an opportunity to explore electrical safety issues and the implications of the linkage between ISO 14971 and IEC 60601-1.

2:30 P.M. – 2:45 P.M.
BREAK

2:45 p.m. – 3:00 p.m.
Software
- IEC 62304:2006 Medical Device Software
- FDA-Guidance on Management of Cybersecurity in Medical Devices
  - **Exercise** – A Software Application
    - This exercise provides participants an opportunity to look at the application of software for an example medical device.

3:00 p.m. – 4:15 p.m.
Risk/Benefit
- FDA-CDRH Risk Benefit Guidance
  - **Exercise** – Developing a Risk/Benefit Case
    - Participants develop a risk/benefit case for an example device using the FDA-CDRH guidance document model

4:15 p.m. – 4:30 p.m.
Summary, Conclusions and Lessons Learned

4:30 p.m.
Adjourn Workshop

WHO SHOULD ATTEND

- Project managers involved in design and development
- Design engineers
- Quality engineers
- Manufacturing engineers
- Quality auditors
- Production managers
- Scientists involved in device research and development
- Medical staff evaluating risk, safety or effectiveness
- Quality or regulatory staff assigned to complaint, CAPA or MDR management
- Training personnel
- General/corporate counsel

COURSE BINDER MATERIALS

- Slides from PowerPoint presentations
- Case review worksheets
- Interactive exercise worksheets
- Reference docs:
  - Design Control Guidance for Medical Device Manufacturers
  - Medical Device Use — Safety: Incorporating Human Factors Engineering into Risk Management
  - Medical Device Quality Systems Manuals: A Small Entity Compliance Guide
  - Essential Principles of Safety and Performance of Medical Devices
  - Implementation of Risk Management Principles and Activities Within a Quality Management System

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews Workshop** to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

Lodging and Conference Venues:

July 14-15, 2015
Wyndham Boston Beacon Hill
5 Blossom St.
Boston, MA 02114
Toll Free: (800) 937-8461
+1 (617) 742-7630
www.wyndhambeaconhill.com
Room rate: $231.00 plus 14.45% tax
Reservation cut-off date: June 22, 2015

Nov. 10-11, 2015
Chicago Marriott Oak Brook
1401 West 22nd St.
Oak Brook, IL 60523
Toll Free: (800) 228-9290
+1 (630) 573-8555
www.MarriottOakBrook.com
Room rate: $169.00 plus 9% tax
Reservation cut-off: Oct. 19, 2015

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 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 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews 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.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call (888) 838-5578 for details.

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

FOUR EASY WAYS TO REGISTER

Online: www.DeviceRiskManagement.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Mail: FDAnews, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend **Medical Device Risk Management**.

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