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FDANEWS PRESENTS THE

MEDICAL DEVICE RISK MANAGEMENT

BATTEN DOWN THE HATCHES – ROUGH SEAS AHEAD

JUNE 27-28, 2017
SEPT. 13-14, 2017
AMA Executive Conference Center
Arlington, VA (Washington, DC)

AN INTERACTIVE WORKSHOP PRESENTED BY OMBU ENTERPRISES AND FDANEWS

AGENDA

Day 1

8:00 a.m. – 9:00 a.m. Registration and Continental Breakfast

9:00 a.m. – 10:15 a.m. Part A – 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 among a hazard, a hazardous situation, and a harm
  - Defining risk – a combination of probability and severity
- Assessing risk using its formal definition
- Why FMEA is not risk management

10:15 a.m. – 10:30 a.m. Break

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

- ISO 14971:2007 as the international standard
- National and regional variations (US, Canada, EU)

- Risk Management and 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
- Risk Management and ISO 13485:2003
  - EN ISO 13485:2012
  - Risk management outputs as design inputs
- Risk Management and ISO 13485:2016
- CMDCAS and MDSAP
- EU Standards

- Global Harmonization Task Force guidance
- FDA Warning Letters – Learning from others

Part C – ISO 14971:2007 Overview

- Structure of the standard
- The process flow in ISO 14971:2007

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:30 p.m. Part D – Implementing EN ISO 14971:2012 (Part 1)

- The process flow in EN ISO 14971:2012
- The Risk Management File
- Risk Management Plan
    - **Exercise** – Evaluating Personnel Qualification
        - During the introductions, participants identify the risk management roles they perform. In this exercise they identify the qualifications for those roles and the objective evidence that an auditor or inspector would expect.
- Using Product Safety Standards
- Risk Analysis
    - **Exercise** – FDA's 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.

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:30 p.m. Part D – Implementing EN ISO 14971:2012 (Part 1 cont'd)

- Risk Evaluation
- Risk Control
    - **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.
- Information for Safety v. Disclosure of Residual Risk
    - **Exercise** – Classification of Statements
        - Participants analyze statements and classify them as either information for safety or disclosure of residual risk.
- Disclosing residual risk
- Risk benefit analysis

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

Day 2

8:00 a.m. – 8:30 a.m. Continental Breakfast

8:30 a.m. – 10:00 a.m. Part D – Implementing EN ISO 14971:2012 (Part 2)

- Overall Residual Risk Evaluation
  - 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
- Production & Post-production Information
  - 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.

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. Part E – The EU Regulations

- The Medical Device Regulation (MDR)
- The In Vitro Diagnostic Medical Device Regulation (IVDR)

12:00 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:30 p.m. Part F – The Draft Guidance Documents for 510(k) Changes

  - Risk Management Considerations

Part G – Medical Electrical Equipment

- IEC 60601-1 Linkage to ISO 14971:2007

Part H – Usability Engineering

- IEC 62366-1:2015 Linkage to ISO 14971:2007
- FDA-CDRH Guidance Document Linkage to ISO 14971:2007

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:00 p.m. Part I – Software

- IEC 62304:2006+AMD1:2015 Medical Device Software – Software Life Cycle Processes
- IEC TR 80002-1:2009 Medical Device Software – Part 1: Guidance on the Application of ISO 14971 to Medical Device Software

Part J – Cybersecurity

- FDA-CDRH Premarket Cybersecurity Guidance
- FDA-CDRH Postmarket Cybersecurity Guidance

Part K – Biocompatibility

- ISO 10993-1:2009/Cor 1:2010 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO/TR 15499:2012 Biological Evaluation of Medical Devices – Guidance on the Conduct of Biological Evaluation Within a Risk Management Process
- FDA-CDRH Guidance Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process"

4:00 p.m. Adjourn Workshop