Agenda

Day 1

8:00 a.m. – 8:30 a.m. **Registration and Continental Breakfast**

8:30 a.m. – 10:00 a.m. **Part A – Concepts of Risk Management**

- Introduction
- Fundamentals of Risk Management
- Components of Risk and Problems to Consider
- Analyzing an EtO Explosion
- Definitions from ISO 14971:2019
- Using the Definitions to Assess Risk

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m. **Part B – The Regulatory Framework**

- ISO 14971:20019 as the International Standard
- National and Regional Variations (US, Canada, EU)
- Risk Management in FDA QSR
- Risk Management in ISO 13485:2016
- MDSAP
- EU Standards
- FDA Warning Letters – Learning from Others

12:00 p.m. – 1:00 p.m. **Lunch Break**

1:00 p.m. – 2:30 p.m. **Part C – The PFMEA Relationship**

- FMEA is NOT Risk Management
- Hazard Analysis, not FMEA, as the Primary Tool
- Hazard Analysis and Communication with the PFMEA
- Detectability, RPNs, and related issues

Part D – ISO 14971:2019

- Description of Changes
- The Process Flow in ISO 14971:2019
- The Risk Management File
- The Risk Management Plan
- Evaluating Personnel Qualification
- Using Product Safety Standards
- Risk Analysis
- Risk Evaluation
- Risk Control
- Application Examples – Powered Toothbrushes
- Disclosing Residual Risk
- Benefit/Risk Analysis
- Overall Residual Risk Evaluation
- Risk Management Report
- Production & Post-production Information

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:30 p.m. **Part E – ISO/TR 24971:2020**

- Description of Changes
- Relocation of Annexes
- Content of the Annexes

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 F – The EU Regulations**

- The Medical Device Regulation (MDR)
- The Role of CEN/TR 17223:2018
- The Z Annexes in EN ISO 14971:2019
- Benefit/risk in the EU-MDR
- Side-effects in the EU-MDR
- Post-market plans and reports in the EU-MDR

Part G – The 510(k) Change Guidance Documents

- Risk Management as a Decision Factor

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m. **Part H – Medical Electrical Equipment**

- IEC 60601-1 Ver 3.1

Part I – Usability Engineering

- IEC 62366-1:2015
- IEC/TR 62366-2: 2016
- FDA-CDRH Guidance Document

12:00 p.m. – 1:00 p.m. **Lunch Break**

1:00 p.m. – 2:30 p.m. **Part J – Software**

- IEC 62304:2006+AMD1:2016 (Version 1.1) 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
- IEC/TR 80002-3:2014 Medical Device Software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

Part K – Cybersecurity

- FDA-CDRH Premarket Cybersecurity Guidance Document
- FDA-CDRH Draft Premarket Cybersecurity Guidance Document
- FDA-CDRH Postmarket Cybersecurity Guidance Document

- HHS IG Report on Postmarket Cybersecurity Guidance

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:00 p.m. **Part L – Biocompatibility**

- ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing 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"

Part M – Animal Tissues

- The ISO 22442-X Family as Applied Risk Management

4:00 p.m. **Adjourn Workshop**