MEDICAL DEVICE RISK MANAGEMENT

UNDERSTANDING THE REGULATORY LANDSCAPE

AN INTERACTIVE WORKSHOP FROM FDANEWS AND OMBU ENTERPRISES

Agenda

<u>Day 1</u>	
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

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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

<u>Day 2</u>

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

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- 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