Managing Risks Associated with In Vitro Diagnostic Devices

Edutrack 3303

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2:45 pm – 5:00 pm
Managing Risks Associated with In Vitro Diagnostic Devices

Sponsored by the AACC Industry Division
Eduttrak Faculty

- Donald M. Powers, PhD (Moderator)
- Robert C Menson, PhD
- Steven Gutman, MD, MBA
Risk Management

- Historical Context
- Regulatory Requirements
- ISO 14971 Risk Management Process
- Risk Assessment Tools
- IVD Hazards / Indirect Harm
- Risk Controls
- Health Hazard Evaluation
Historical Perspective

- 1990 – SMDA ‘90 authorizes design controls
- 1995 – EU Medical Devices Directive
- 1997 – US Quality System Regulation
- 1997 – EN 1441, Medical Devices-Risk Analysis
- 2000 – EU IVD Directive
Historical Perspective

- 2000 – IOM, To Err is Human: Building a Safer Health System
- 2000 – ISO 14971, Medical devices - Application of risk management to medical devices
- 200x – ISO TC212 - Risk management guidelines for clinical laboratories?
Regulatory Requirements

EU IVD Directive

Devices must not compromise, directly or indirectly:
- clinical condition or safety of patients
- safety or health of users
- other persons, where applicable
- safety of property

*Essential Requirement, Annex 1.A.1*
Regulatory Requirements

EU IVD Directive

Any risks must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety

*Essential Requirement, Annex 1.A.1*
Regulatory Requirements

EU IVD Directive

In the following order,

1. eliminate or reduce risks as far as possible (inherently safe design and construction)
2. take adequate protection measures
3. inform users of residual risks

*Essential Requirement, Annex 1.A.2*
Regulatory Requirements

US Quality System Regulation

- Design validation shall include software validation and risk analysis, where appropriate.

21 CFR 820(g)
Regulatory Requirements

US Quality System Regulation

Risk analysis must be conducted for the majority of devices subject to design controls and is considered to be an essential requirement for medical devices under this regulation.

QSR Preamble (1996)