Workshop – Risk management

Introduction

Dr. Peter Linders, chair ISO/TC 210

Philips, Global Regulations & Standards
ISO/TC 210 and BSI - WORKSHOP Risk management, 08 October 2019
What is ISO/TC 210?

**ISO/TC 210**: Quality management and corresponding general aspects for medical devices

Standards and other documents for:

- Quality management systems
- Risk management
- Medical device software
- Symbols & labelling
- Usability engineering
- Essential Principles & related standards
- Information to be supplied by the mfr.
- Post-market surveillance
- Small-bore and other connectors
- Life-cycle aspects for medical devices
Why a workshop (and why on risk management)?

New concept in ISO/TC 210 meetings

Benefit from presence of international standards experts; see them ‘at work’

Discuss & chew on issues

2018: Seoul, QMS/ISO 13485

2019: London, Risk Mgt./ISO 14971
Workshop – Risk management

Background:
- Medical device regulations (such as EU MDR) require risk management
- Third edition of ISO 14971 is expected to be published in 2019
- Different standards and definitions exist for risk management
- Regulations and standards are expanding their scope to health products

Purpose and goals:
- Discuss different risk concepts and terminology with international experts
- Exchange knowledge and obtain insights from international experts
- Discuss future role of risk management for medical devices and health products
Workshop - homonyms

Homonyms:
Each of two or more words having the same spelling or pronunciation but different meanings and origins

Examples:

Atmosphere  Crane  Range
Ball  Pitcher  Rest
Chair  Plant  Workshop

And:
Risk
Workshop - Presentations

Risk management and the new ISO 14971 – Jos van Vroonhoven (Philips)
  o Summary of changes in the third edition of ISO 14971
  o Concepts and terminology for risk management for medical devices

Risk management terminology in other standards – Russel Price (BSI)
  o Risk terminology in ISO 31000 and ISO/IEC High-Level Structure
  o Application of risk management for organisations/businesses

Risk management and regulations – Melissa Torres (US FDA)
  o Risk concepts and terminology in medical device regulations
  o Regulatory requirements for risk management for medical devices
Workshop – Cases (to chew on)

**Work Case 1: Risk terminology**
- Different risk terminology in ISO 14971, ISO 31000 and HLS
- How to work with different risk definitions?

**Work Case 2: Risk and other standards**
- Relation between ISO 14971, other process standards and product standards
- How to consider their relationship?

**Work Case 3: Risk and health products**
- Health products without medical purpose do not provide (medical) benefits
- How to perform risk management and evaluate benefit-risk balance?
Thank you!