RISK MANAGEMENT: WHAT HAVE WE LEARNED?

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CDRH MISSION

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products.

FDA RESPONSIBILITIES

- Risk Management
  - First human use (IDE)
  - Safe experimental use (product development)
  - Widespread use (market approval)
  - Adverse Experience Evaluation (complaints)

Definitions

- Risk is a combination of the probability of occurrence of harm and the severity of that harm.
- Harm is physical injury or damage to the health of people, or damage to property, or the environment.
- Hazard is a potential source of harm.

Definitions

- Risk management is the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.

Risk Management:

- Is a continuous and developing process which runs throughout an organization's strategic planning, decision making and implementation activities
- Provides a framework that enables future activity to take place in a consistent and controlled manner
- Contributes to move efficient use and allocation of resources
- Integrated into the culture of an organization with an effective policy and program led by senior management

RISK MANAGEMENT & THE QUALITY SYSTEM REGULATION

- Part 820.1(a)(1) …The requirements in this part are intended to ensure that finished devices will be safe and effective…
- Part 820.30(g) …Design validation shall include software validation and risk analysis…

- YOU CANNOT ENSURE THAT A DEVICE IS SAFE WITHOUT RISK MANAGEMENT IN PLACE

Premarket Approval

- Base degree of control on risk (Class of device)
- Weigh potential benefits vs. risk to determine safety and effectiveness
- Science based evidence
- Control risk – prevent, eliminate, or reduce to an acceptable level
- Least burdensome approach

POSTMARKET SURVEILLANCE

- MDR, MEDWATCH, and MedSun
- Recalls
- Inspections (Complaints, CAPAs)

TOTAL PRODUCT LIFE CYCLE

- Risks should be managed throughout the entire product life cycle.
  - Design through Disposal.
  - Risk management activities change over time.

RISK MANAGEMENT

- SHOULD BEGIN EARLY IN THE RESEARCH AND DEVELOPMENT STAGE
  - Is the device safe?
  - Product – Design Phase
  - Process – Additional hazards may be introduced
  - Use – Clinical, OTC, home health
  - Distribution
  - Disposal

TYPES OF RISK

- Business Risk
- Actual Risk
- Potential Risk
- Perceived Risk

Risk Management should be:

- Product Specific
  - Probability of occurrence
  - Consequence of loss (severity)
  - Perception of the loss
- Process Specific
- Facility Specific

RISK MAMAGEMENT TOOLS

- QSR - DOES NOT REFERENCE TOOLS
- ISO 14971 - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
  - Preliminary Hazard Analysis (PHA)
  - Fault Tree Analysis (FTA)
  - Failure Mode and Effects Analysis (FMEA)
  - Failure Mode, Effects and Criticality Analysis (FMECA)

RISK MAMAGEMENT TOOLS

- ISO 14971 - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES cont.
  - Hazard and Operability Study (HAZOP)
  - Hazard Analysis and Critical Control Point (HACCP)

Risk Based Inspections

- Class of Device (III, II, I)
- Critical Process Environments (Clean Rooms)
- Facility Type
  - Manufacturer
  - Re-packer
  - Assembler
  - Sterilization

INSPECTIONAL FINDINGS FOR 2008

- 3234 Observations

  P & PC – 984 - Risks

  CAPA – 943 - Risks

  MGMT – 563

  DES – 421 - Risks

  DOC - 323

IMPROVEMENT IS NEEDED

- Risk Management is often driven by failures:
  - Recalls
  - Complaints
  - Field Reports
  - MDRs, MEDWATCH, MedSun

THESE DATA MUST BE EVALUATED FOR AN EFFECTIVE RISK MANAGEMENT SYSTEM!

DEVICE FAILURES:

- Not complete for many devices. (Preventive)
- Not understood by users.
- Begins after product development.
- Risks are not identified or known.
- Risk communication is not adequate.
  - Risk analysis
  - Residual risk

POTENTIAL OUTCOMES OF A RISK MANAGEMENT PROGRAM

- Safer Devices
- Improved Public Health
- Higher Profit Margin

THANK YOU

- QUESTIONS

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