Risk Management for Project Execution and MDR Compliance

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Speaker

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Agenda

- Product risk versus patient risk
- Thinking about Risk Management
- ISO/ MDR impacts
- Beyond compliance

Patient Risk

- Health Hazard Assessment (HHA) is all about the patient. Acceptable and desired to be disclosed.
- The Failure Modes and Effects Analysis (FMEA) is different than the HHA. It is looking at the design and production process.
- Format looks similar.
- FMEA is comprehensive and may include company sensitive information.

Risk Approach

- FDA is concerned about patient hazards and potential harm
- We want a comprehensive (yet manageable) system for risk management that supports the high level impacts on the patient
- The typical submission document is a hazard analysis
  - And now, the risk report
- The typical audit document is the FMEA

What is Risk?

- Anything with Uncertainty is a risk for execution
- We tend to only focus on Product or technical risks
- Cost and schedule risks also exist

Stages of Development Process

- Planning (did we allocate enough resources?)
- Requirements (which ones are difficult to achieve?)
- Concept (functional assessment)
- Design (detailed assessment)
- Manufacturing (processing depth in critical areas)
- Validation (confirmation)
- Clinical (feedback loop)
- Launch (living documents, further feedback)

Better Execution

- Project Plan includes resources for high risks
- Project Manager to keep eye on moderate risks as they do not have full resource levels
  - Most moderate risks will resolve themselves, with the early characterization work that is already being planned
- As things develop
  - Save resources on high risks that have been reduced
  - Shift resources to moderate risks that manifest into high risks

Early – But How?

- **Harms can be uncovered or anticipated during clinical work**
  - During requirement discovery, we need to collect these ideas to include in hazard list
- **Instead of doing bill of materials (component level), consider concept level FMEA (functional)**
- **Consider business risks**
  - Not within ISO 14971, but can be part of our process.
- **Our decisions depend on cost and schedule impacts, thus our above technical risks need to be translated into these other areas**

Core Risk Requirements – ISO/ MDR

- **Plan**
- **Process**
  - Hazards, analysis, evaluation, verification of controls
- **Report (and Review)**
  - Residual Risk
  - Benefit-risk
- **Production and post-production activities**
  - Complaint handling

Beyond Intended Use

- **Incorrect use and misuse**
  - This has been in the court system for years
- **Reasonably foreseeable**
  - This wording has been used in risk standards more recently
- **Think**

Risk: As Far As Possible

- **Vs. As far as reasonable**
  - MDR but not ISO
- **How will this be considered? Hard to know in detail**
  - Does not further reduce risk level
- **Consider benefit/ risk ratio. This is the context for defining our view of the situation**

Residual Risks

- **Residual risks and acceptance criteria**
  - Based on Benefit/ risk evaluation
  - Comparing with State of the Art (also called Standard of Care)
- **Verification of risk control activities**

Benefit/ Risk

- **This learning starts during clinical work**
  - A great time to have this discussion
- **This can be discussed with hazard analysis document**
- **What is the alternative to our treatment or diagnostic?**

Closing the Loop – Clinical Studies

- **This can gain clarity on impacts of failure modes (consequences)**
- **It can get a clear picture of probabilities**
  - What about other patient populations?
- **It can also refine our risk/ benefit understanding**

Closing the Loop – Field Experience

- **The challenge – are comments reflective of the true likelihood**
  - Similar with product returns.
- **Detectability – how many customers can see it, or see it properly?**
- **What about failure modes that are misread**
- **This experience can also impact our sample size thinking**
  - Does a recall mean our validation sample size was not appropriate?

Post Market Indicators

- **What are parameters that indicate performance, or lack of performance?**
  - These can be discovered during clinical work
- **This does not require identical data as was collected during the clinical study**
  - Consider a simple subset
- **These could be considered as simplifications of clinical data.**
  - Surveys
  - Surrogate measures

Risk Areas

https://resources.sei.cmu.edu/library/asset-view.cfm?assetid=11847

- **Requirements**
  - Stability, complete, clear, valid, feasible, precedence, scale
- **Design**
  - Function, difficulty, interfaces, performance, testability, constraints, non-developed items
- **Integration and test**
  - Environment, product, system
- **Engineering specialties**
  - Maintainable, reliable, safety, security, human factors, specs

Risk Areas (cont.)

- **Development process**
  - Formality, suitability, process control, familiarity, product control
- **Development system**
  - Capacity, suitability, usable, familiar, reliable, support, deliverable
- **Management**
  - Planning, project organization, experience, program interfaces
- **Management methods**
  - Monitoring, personnel management, quality assurance, configuration management

Risk Areas (cont.)

- **Work environment**
  - Quality attitude, cooperation, communication, morale
- **Resources**
  - Schedule, staff, budget facilities
  - Type of contract, restrictions, dependencies
- **Program interfaces**
  - Customer, other suppliers, vendors, politics

Risk Related References

- Valuable Risk Management – https://bit.ly/17q0y7g
- FMEA - https://bit.ly/2y0F6XS
- Requirements - https://bit.ly/1ciEAGP
- DOE – https://bit.ly/14HgKSz
- DOE White Paper - https://bit.ly/18rGYZD

Thank you!

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QUESTIONS?