



Agenda

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

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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.

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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
 - O And now, the risk report
- The typical audit document is the FMEA

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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

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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)

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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
 - o Save resources on high risks that have been reduced
 - Shift resources to moderate risks that manifest into high risks

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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
 - o 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

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Core Risk Requirements – ISO/ MDR



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

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Beyond Intended Use



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

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Risk: As Far As Possible



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

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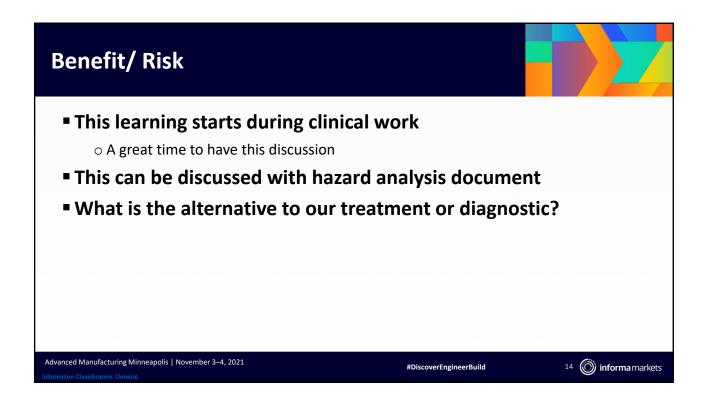
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Residual risks and acceptance criteria Based on Benefit/ risk evaluation Comparing with State of the Art (also called Standard of Care) Verification of risk control activities

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Closing the Loop – Clinical Studies



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

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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
 - o Does a recall mean our validation sample size was not appropriate?

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Post Market Indicators



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

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Risk Areas



Requirements

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

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Risk Areas (cont.)



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

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Risk Areas (cont.)



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

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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

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