Risk Management in Process Development

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Agenda

- **Development Process**
- **Early Integration of Risk Management**
- **Variety of FMEA tools**
- **Risk Areas/ Triggers**
- **Validation Strategy**

Risk

- **Anything with Uncertainty is a risk for execution**
  - **Things that have not happened yet**
  - **Unless we have done the exact same thing before, uncertainty exists**
- **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)**
  - **Design of Experiments (DOE) can be a big help**
- **Manufacturing (processing depth in critical areas)**
- **Validation (confirmation)**
- **Clinical (feedback loop)**
- **Launch (living documents, further feedback)**

APQP - Phases

- Plan and Define the program
- Product Design and Development
- Process Design and Development
- Product and Process Validation
- Feedback, Assessment and Improvement Action

Better Execution

- Project Plan includes resources for high risks
- Project Manager to keep eye on moderate risks
- 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

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

Types of FMEA

- Design FMEA
  - Prevention of failure modes due to inadequate design.
- Process FMEA
  - Prevention of failure modes due to inadequacies in the production process.

Types of FMEA (cont.)

- **Service FMEA**
  - **Prevention of failure modes due to inadequate installation.**
- **Machine FMEA**
  - **Potential failure modes of equipment**
  - **Review of sub-systems within equipment**
- **Business Process FMEA**
  - **Using the established procedures**
  - **As a way to evaluate a change to a process, form, etc.**

Profitability

- **End date for profits from a new product is "fixed" but the sooner we start to make money, the longer we have to profit**
  - **This is controlled by not going thru design loops**
  - **Delaying launch is a major financial impact**
  - **It also reduces the opportunity for patients to benefit from our product.**
- **Cost – with proper knowledge of cost risk, we can manage the project to best use resources**
- **These actions accelerate the pay back period**

Risk Areas

- **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**

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

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**

Impact on Validation Strategy

- **Validation plans depend on levels of risk**
- **Low risk areas can be evaluated at a higher level**
  - **A sanity check**
- **High risk areas deserve deeper level of testing to confirm robust performance**
  - **More attention to the development effort is expected**
  - **Validation simultaneously confirms our technical understanding**
- **Resolve the areas of uncertainty**
  - **What questions do we need to answer**

Related Videos

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

Conclusion

- **Risk management should provide resources and confidence for you**
- **Risk management should not be a burden**
- **Following a risk process early in development provides the most benefit**
- **Risk triggers can help you expose the unknowns**

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