Risk Management: Lessons Learned

Perry K. Parendo (Perry's Solutions, LLC)

Speaker

Perry K. Parendo

President, Perry's Solutions, LLC

Perry@PerrysSolutions.com | PerrysSolutions.com | @PerrysSolutions

651-230-3861

Background

- Risk discussion at MDM last year
- Have been applying risk management in aerospace, automotive, defense and medical device industries
- After recently working with several organizations, we acquired some points of emphasis

Topics

- Risk Plan
- Management Review/ Report
- Suppliers
- Existing Products
- P1/ P2 Approach

Risk Plan - Expectations

- **Risk activities by life cycle phases for all new products**
  - Prefer to begin at concept level and when process is first laid out
  - Can use functions or components
  - Ratings tend to be more qualitative early, until we are able to test
- **Responsibilities for each activity**
- **Requirements for risk review, expected data and information sources, and roles**
- **Criteria for risk acceptability**

Risk Plan - Process

- **Method to evaluate overall residual risk and acceptable level**
- **Method to verify risk control measures effective – validation? Data review. Inspection plans**
- **Collection and review of production and post-production information**
  - Manufacturing data, field/ return data, plus clinical
- **Approvers of Risk Management Report**

Risk Report - Team

- **Residual risk review**
- **Benefit-risk analysis compared to state of the art**
  - No longer just your own product
- **All risks have been considered and actions completed**
  - How does this link to activity tracking. Yes – a protocol and report will be generated, but not always for characterization testing

Risk Report - Management

- **Risk plan has been implemented**
- **Overall residual risk is acceptable (and reviewed by management)**
  - A blending of all data, reports, information
- **Methods are in place to collect and review production and post-production data**

Suppliers – Customer Considerations

- **Flow expectations through Supplier Quality Agreement**
  - How does this impact future activities? Ongoing risk reviews
    - Low volume situations
- **Be flexible with format**
- **Be prepared to be involved**
- **Expectations should depend on the risk level**

Suppliers – Key Activities

- Methods to ensure compliance
- Practical process to execute this activity
- Method for maintaining the accuracy of process FMEAs over time – including state of the art
- Need a hazard analysis for vendor changes? Yes

Existing Products

- **When to update to new format**
- **Impact of different scoring methods**
- **Impact on suppliers**
- **Solutions to risk questions – depends on where you were and what new system has been put in place**
  - Standard answers do not exist
- **There are as many templates, as companies I have worked with**
  - And no “good” software exists

P1 / P2 Approach

- **The concept is logical**
- **Execution is complex**
- **Prior approach of occurrence and detectability is blurred together**
- **Performing risk assessment early in a project, the details required will not be available**
  - Nice to allow flexibility so value can be obtained as project matures
- **Using qualitative and quantitative together is hard**
  - Yet if we are to do it early, we do not have good data to estimate percentages

Related References

- Risk Management (MDM 2021 Presentation) - https://bit.ly/3tD6avd
- Risk Management (MDDI Article) – https://bit.ly/3vtD0h8
- 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

Thank you!

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QUESTIONS?