Product Risk Evaluation: Documentation and Best Practices

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Edwards

Topics


Importance of evaluation of risks impacting devices that have left the manufacturer's control


Timely escalation of safety and compliance issues is good for business but more importantly, good for patients


How risk evaluation interacts with the CAPA process


Best practices to document decision-making when assessing product risk – and what to avoid


Practical approaches for successful execution and comprehensive documentation


Potential Pitfalls

Why Is It Important?

Early Containment

Early containment and identification lead to actions that can avoid negative outcomes

Fast-track Issues

Expedite the identification and escalation of issues that may cause patient injuries, escape the Quality System, or involve violative products

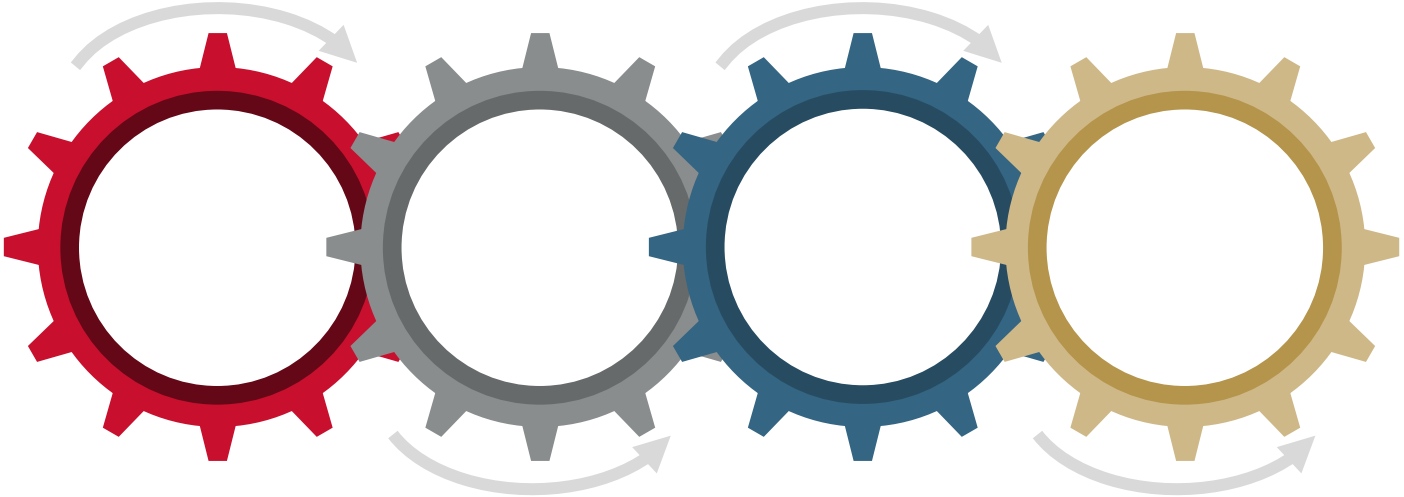
Compliance and Safety

When issues arise with distributed products in the field, whether commercial or clinical units, it can lead to patient safety concerns and regulatory compliance problems

Product Risk Evaluation - Not a bad thing!

It is a mechanism to escalate risk assessment of escapes

Facilitates the visibility of critical issues and enables informed decision-making for effective risk management



Demonstrates commitment to patients and compliance with regulations

Contributes to a strong post market surveillance program

Obstacles to Timely Escalation

Don’t wait to uncover every bit of information before initiating the risk evaluation– no need for CAPA investigation yet

Contact subject matter experts to clarify any questions or uncertainties regarding the issues or processes involved

Do not downplay issues related to products and processes

Focus on the escape, not the corrective action!

Product Risk Evaluation vs CAPA

PRE

- Complete explanation of the problem
- Focuses on the initiating or “assignable” cause not the root cause
- Comprehensive evaluation of the patient, user and compliance risk for product decision

Vs

CAPA

- Complete investigation of the problem
- Focuses on root cause(s) to correct and prevent the future escapes
- Comprehensive assessment to ensure effectiveness of actions

Product Risk Evaluation Lifecycle

1

Identify the Problem
- Product/Use Problem
- Compliance Problem

2

Scope
- Distributed product Impact
- Contain the product

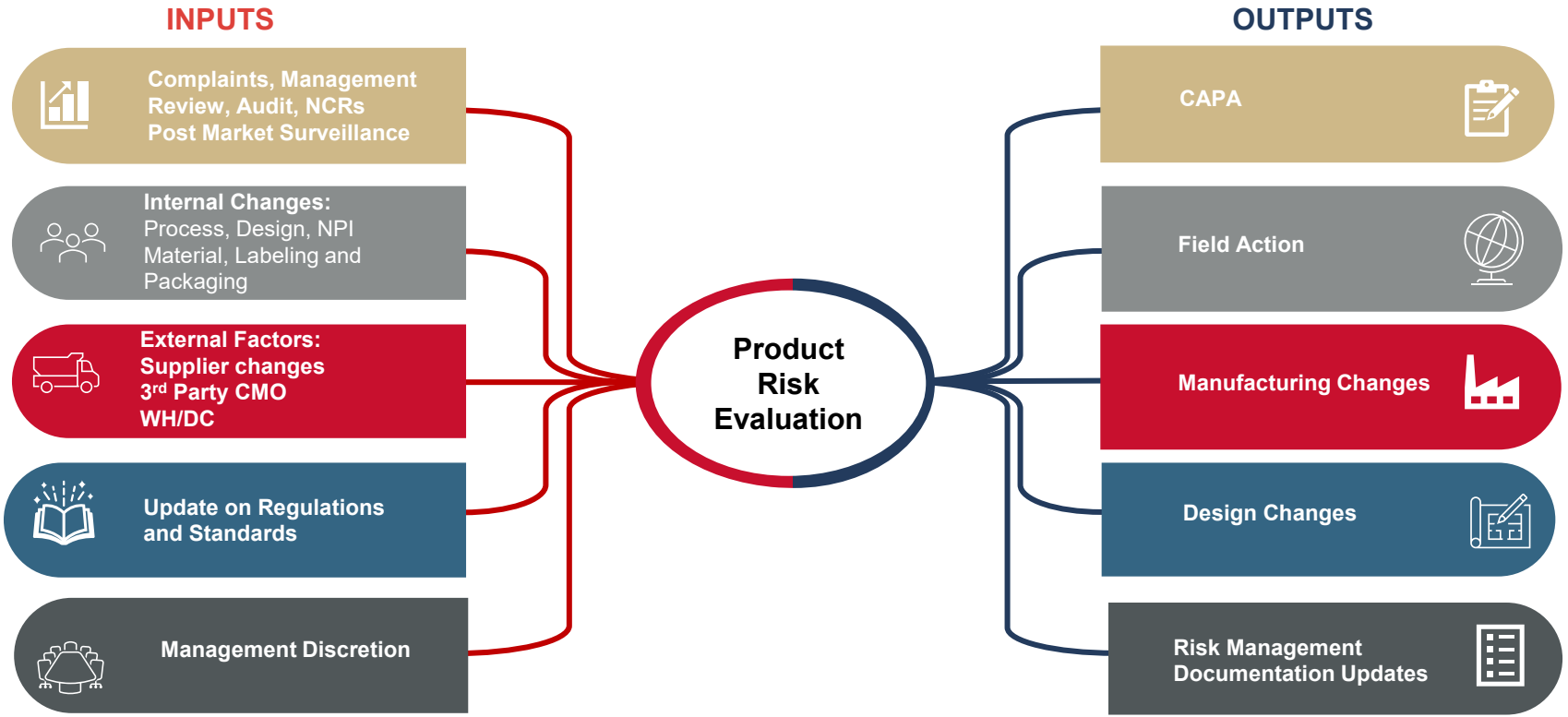
3

Evaluate and Escalate
- Health Risk Evaluation
- Compliance Risk Evaluation
- Escalate if needed

4

Decision Outcome
- Product Disposition
- CAPA
- Field Notification/Action

Product Risk Evaluation Process

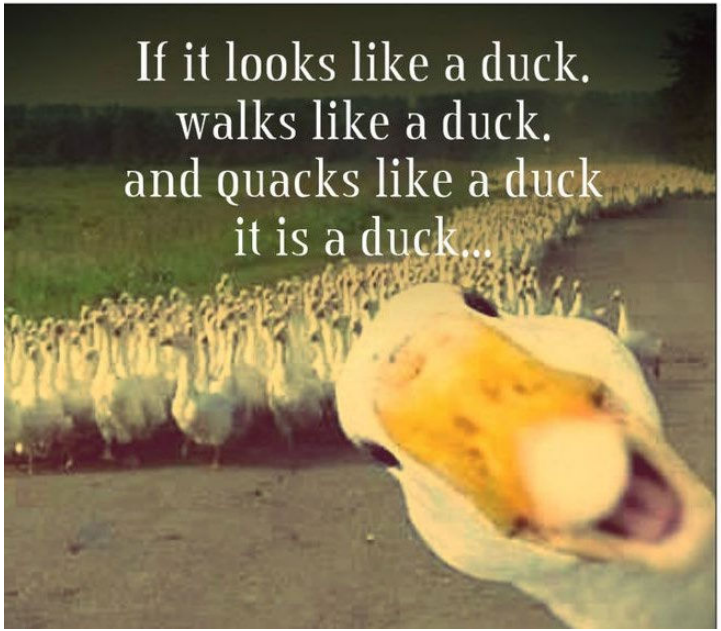


Best Practices: Documenting the Problem

- Clearly defines the scope of the problem being escalated
- Explains how the problem affects the patient, the user, or the device performance
- May begin with a complaint but complaints are not the entire description
- Explains how similar complaints are connected
- Facilitates informed and timely decision-making when evaluating risk
- Needs to stand alone without requiring specialized knowledge to follow the story

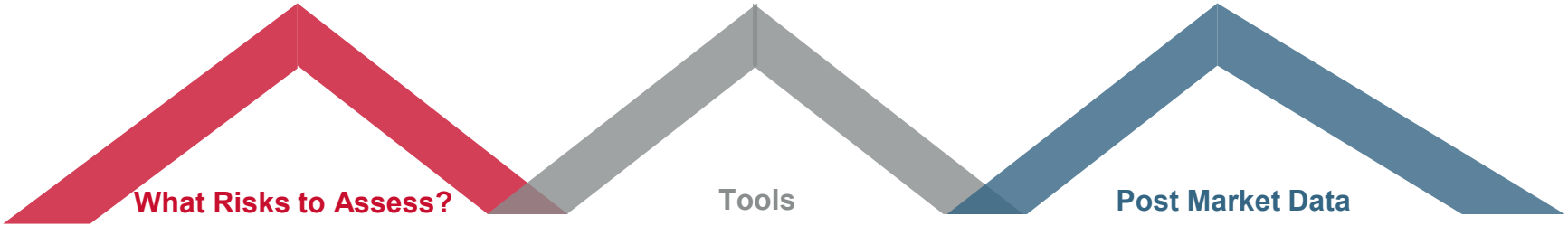
Best Practices: Scope Identification

- Determine if the problem affects other
  - Models, lots, part numbers
  - Components across product families
  - Manufacturing sites
- Similar complaints without product return should be evaluated for confirmation based upon the specificity of the complaint report
- Do NOT rely on having no complaints, or low complaint rate to justify not evaluating the risk



Wenn es wie eine Ente aussieht, läuft und quakt, dann ist es wahrscheinlich eine Ente

Best Practices: Risk Evaluation



What Risks to Assess?

- Patient Risks
- User Risks
- Compliance Risks

Tools

- Health Hazard Evaluation
- Benefit Risk Assessment
- Risk Acceptance Matrix
- Risk Management Documentation

Post Market Data

- Incident driven – immediate attention
- Review driven – data analysis

Tools may help decide what actions to take BUT be careful NOT to use them justify NOT doing an action!

Best Practices: Escalation

- Have the right audience to review the information and the data
  - Compliance
  - Medical
  - Legal
  - Regulatory
  - Engineering/Technical
- The higher the safety risk, the more important it is to move swiftly to address the issues IN THE FIELD
- The sooner the escalation the sooner a decision on affected product can be documented
- Waiting may create the impression the company is allowing violative product to remain with customers until it is consumed

Potential Pitfalls

1. Avoid all references to financial implications of taking corrective action
2. Metrics that push to limit risk escalations are bad.
3. Continuing to ship potentially violative product
4. Failing to document the good and the bad
5. Over-reliance on Risk Benefit Assessment
6. Lack of feedback loop between risk evaluation outcome and regulatory reporting decision
7. Failing to obtain medical input on safety issues
8. Avoid lengthy delays in taking action
9. Using different set of facts for specific regional outcomes.
10. Do not do silent Field Action!

Characteristics of a well executed Product Risk Evaluation

Timely

1. Provides enough information to ensure timely evaluation/escalation of patient, user and compliance risk

Patient-centric

2. Prioritizes patient safety while addressing user and compliance issues.

Comprehensive

3. Identifies the issue scope, including known and potential aspects, without relying on past decisions

Risk-focused

4. Focuses on the escape and its cause, not the root cause

Actionable

5. Highlights critical issues to support informed decisions for product in the field