COCKPIT® ENTERPRISE

RISK MODULE

Flexibility and Support for ISO 14971 Implementation in Medical Device Product Development

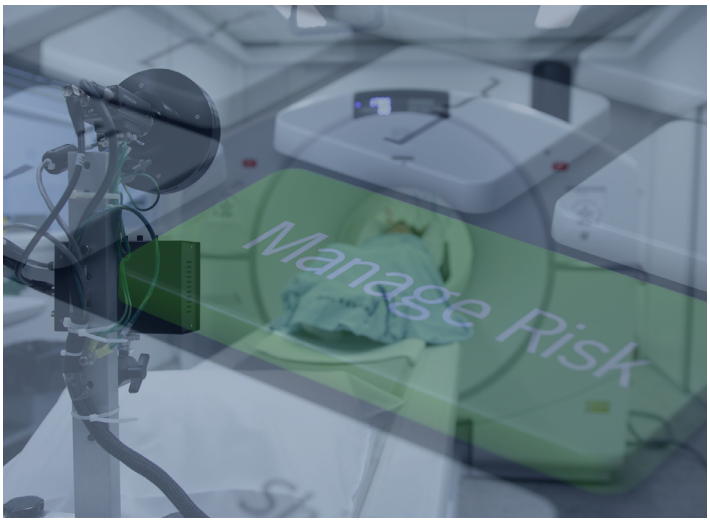
SITUATION

Medical device development is a complex process, with a critical element focusing on risk management. The consequences of not managing risk properly can be catastrophic. For many countries, ISO 14971 “Application of risk management to medical devices” is a consensus standard for complying with the regulation for medical device design, development, manufacture, and distribution. This standard helps companies provide evidence of risk management and is a required activity for medical device creation. The European Union recognizes this standard as a method to comply with the requirements to assess risk and has gone a step farther with the implementation of the EU MDR (Medical Device Regulation) which governs, by law, the production and manufacturing of medical devices in Europe.

Currently, risk management (and overall product) data is often managed in Excel and/or Word, which can quickly become overwhelming with the sheer amount and complexity of data. Not only do medical device manufacturers have to manage this data, they also need to ensure they are meeting applicable standards and laws. How can medical device manufacturers better align to applicable standards and regulations in their risk management process?

SOLUTION

At Cognition, we have developed a new risk module for our Cockpit Enterprise solution to support ISO 14971 implementation with the flexibility to align with existing processes at individual medical device companies, making it easier to address risk and deliver products to market.



The Risk Module extends the base-risk functionality included in Cockpit Enterprise, specifically to provide enhanced support for the array of ISO 14971:2019 risk management processes. It is designed to “plug in” to existing Cockpit Enterprise implementations, delivering new risk functionality without affecting existing requirement/test data. This gives users the control to specify data sources and object filters where required in order to connect the risk data to existing project data.

The Risk Module is an optional subscription add-on delivering new, supported functionality and UI elements for implementing risk/reliability analysis tools using the Safety Risk and FMEA Row classes, allowing users to start utilizing the risk functionality with minimal configuration needs.

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FEATURES

Risk Management Plan

- Easy access to change acceptability criteria
- Define at project level

Product Risk Analysis

- Analyzes risks associated with the device as a result of side effects, failures, or use errors

1.0 Risk Analysis

Description here...

Pre Risk Control													Post Risk Control				
ID	Sequence of Events	Hazardous Situation	P1	Hazard	Harm	P2	Overall P	Severity	Risk	Risk Controls	Type	Implementation	Residual P1	Residual P2	Overall Residual P	Residual Severity	Residual Risk
RSK0003	(1) The sequence of a possible side effect... Intended Use	A Hazardous Situation that is a side effect of intended use	Remote	Library Hazard 3	Library Serious (S=3)	Remote	Remote	Serious	Broadly Acceptable	Risk Control 4	Information for Safety	DO0012: Design Output 4	Remote	Remote	Remote	Serious	Broadly Acceptable
RSK0001	(1) A sequence leading to Local Effect 1 Some additional information about this sequence... Causes: • Device Failure Mode 1 (Possible) - DEVFMEA0001, DEVFMEA0009	Local Effect 1	Occasional	Library Hazard 1	Library Minor (S=2)	Remote	Occasional	Minor	Broadly Acceptable	Risk Control 1	Inherent Safety by Design	DO0011: Design Output 3 DO0010: Design Output 2	Remote	Remote	Remote	Minor	Broadly Acceptable
RSK0004	(1) A sequence leading to Local Effect 1 Some additional information about this sequence... Causes: • Device Failure Mode 1 (Possible) - DEVFMEA0001, DEVFMEA0009	Local Effect 1	Occasional	Library Hazard 1	Library Negligible (S=1)	Probable	Probable	Negligible	Broadly Acceptable	Risk Control 1	Inherent Safety by Design	DO0011: Design Output 3 DO0010: Design Output 2	Remote	Probable	Probable	Negligible	Broadly Acceptable
RSK0005	(1) A sequence leading to Local Effect 1 Some additional information about this sequence... Causes: • Device Failure Mode 1 (Possible) - DEVFMEA0001, DEVFMEA0009	Local Effect 1	Occasional	Library Hazard 1	Library Serious (S=3)	Remote	Occasional	Serious	Investigate Further	Risk Control 1	Inherent Safety by Design	DO0011: Design Output 3 DO0010: Design Output 2	Remote	Remote	Remote	Serious	Broadly Acceptable
RSK0008	(1) A sequence leading to Local Effect 2 Causes: • Use Error 1 (Possible) - AFMEA0003 • Device Failure Mode 2 (Unlikely) - DEVFMEA0007 (2) Another possible sequence leading to Local Effect 2 Causes: • Device Failure Mode 1 (Possible) - DEVFMEA0001, DEVFMEA0009	Local Effect 2	Occasional	Library Hazard 2	Library Catastrophic (S=5)	Improbable	Occasional	Catastrophic	Requires Benefit - Risk Justification	Risk Control 3	Protective Measure	DO0009: Design Output 1	Remote	Improbable	Remote	Catastrophic	Requires Benefit - Risk Justification
										Risk Control 2	Inherent Safety by Design	DO0009: Design Output 1 DO0010: Design Output 2					

Figure 1: Example of Capabilities for Product Risk Analyis

Preliminary Hazard Analysis

- Ability to define questions similar to those from ISO 24971:2020 to assist in identifying Hazards
- Uncovers Situations, Justification for not applicable questions, Safety Characteristics, Initial Hazards, Side Effects

Design FMEA

- Analyzes failures associated with the device

1.0 Device FMEA

Description here...

ID	Requirement	Failure Mode	Failure Mode Type	Potential Local Effect	Severity of Local Effect	Potential to Lead to Harm	Associated Safety Risks	Potential Causes(s)/Mechanism(s) of Failure	Existing Detection and Prevention Methods	Likelihood of Occurrence	Detectability	RPN	Recommended Action(s)	Residual Severity	Residual Likelihood of Occurrence	Residual Detectability	Residual RPN
DEVFMEA0001	Design Input 1	Device Failure Mode 1	Partial Function	Local Effect 1	Serious	Yes	RSK0001 RSK0004 RSK0005	Device Cause 1	**Detection:** NONE **Prevention:** NONE	Possible	Not entirely obvious	Investigate Further	Action: Device Recommended Action 1 Type: Prevention Implementation: DO0009: Design Output 1	Serious	Very Unlikely	Not entirely obvious	Acceptable
DEVFMEA0006	Design Input 3	Device Failure Mode 3	Unintended Function	Local Effect 4	Critical	No	NONE IDENTIFIED	Device Cause 3	**Detection:** NONE **Prevention:** NONE	Unlikely	Not entirely obvious	Investigate Further	NONE	Critical	Unlikely	Not entirely obvious	Investigate Further
DEVFMEA0007	Design Input 2	Device Failure Mode 2	Intermittent Function	Local Effect 2	Serious	Yes	RSK0002 RSK0006 RSK0007 RSK0008 RSK0009	Use Error 2	**Detection:** NONE **Prevention:** NONE	Unlikely	Not too hard to find	Investigate Further	NONE	Catastrophic	Unlikely	Not too hard to find	Investigate Further
DEVFMEA0009	Design Output 4	Device Failure Mode 1	Partial Function	Local Effect 2	Serious	Yes	RSK0002 RSK0006 RSK0007 RSK0008 RSK0009	Device Cause 1	**Detection:** NONE **Prevention:** NONE	Possible	Really obscure	Need Corrective Action	NONE	Catastrophic	Possible	Really obscure	Need Corrective Action

Figure 2: Example of Capabilities for Design FMEA

aFMEA / Use Risk Analysis

- Analyzes use errors associated with the use of the device

Data Libraries

- Harms (with severities) are only sourced from a library
- New Hazards (local to the project) can be created or Hazards can be sourced from a library

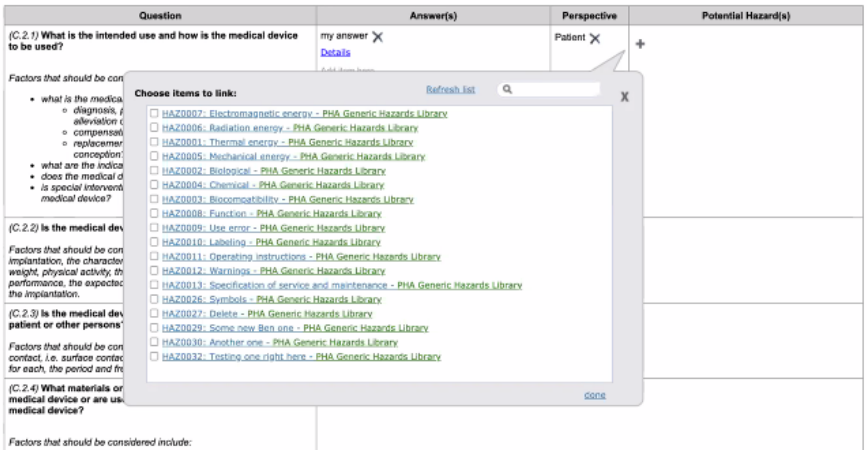

Figure 3: Example of Harms Library

BENEFITS

Configurability

- Offers document tables/section formats that can be used to create, manage, and report on risk data while working alongside existing requirements/test data
- Uses included tables as starting points and configure the layout. It allows configuration to be done at the engineering level rather than needing developers.
- User configurable document layouts
- Standard table definitions and library of reusable snippets

Process Independence

- Does not force data connections so in most cases processes can be updated without affecting the integrity of the overall data
- The module expects that the customers will configure their implementation to integrate and connect with existing requirement, test, and library data

Maintainability

- Increases use of off-the-shelf functionality, maintained/supported by Cognition; decreases customer-unique configurations, maintained by the customer

Faster Deployment

- Leverages a starting place for configurability; simplified configuration means that aligning the system to customer's processes is faster and less burdensome
- Configuration can be done quickly by Cognition application engineers and customer's users can start using the implementation within a few hours

Flexible Risk Environment

- Formalized Risk Acceptability criteria, reflects and enforces customer's QMS procedures
- Separate setups for Hazard Analysis and FMEA
- Wide range of options to support existing processes

Reusability

- Utilizes centrally managed libraries for Hazards and Harms
- On-the-fly libraries of reusable items created during analysis, such as Mitigations, Hazardous Situations etc.
- Items reusable between different analysis tools such as FMEAs, Use Error Analysis, and Hazard Analysis

Integrated Reporting and Analysis

- Built-in analysis tools look at different risk aspects such as use errors, design failures, etc.
- Easy custom report creation (including risk control implementation, sources of highest-risk items, risk control sources of new risks, etc.)
- Simple identification of critical elements, such single Design Input or Output controlling multiple risks

Workflow Availability

- Integrates with existing Cockpit Enterprise workflows, allowing for review and approval of outputs

NEXT STEPS

To learn more about our Risk Module for Cockpit Enterprise, request a demo.

ABOUT COGNITION

For more than 20 years, Cognition Corporation has designed its product development solutions specifically for the life sciences industry including medical device, pharmaceutical, laboratory equipment, and combination products. Cognition software uses a unique technology of generating structured data items, dynamic links between items, reusable templates, and structured documents and reports to support the generation of both internal technical reports and submission deliverables to global health authorities.

COGNITION®

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