Documenting Medical Device Risk Management through the Risk Traceability Summary

Edwin Bills, Stan Mastrangelo, and Fubin Wu

About the Authors

Edwin Bills is principal consultant and vice president at Bilanx Consulting in Sumter, SC. E-mail: ed.bills@bilanxconsulting.com

Stan Mastrangelo is a consultant based in Roanoke, VA. E-mail: stan.mastrangelo@gmail.com

Fubin Wu is cofounder of GessNet risk management software in Sacramento, CA. E-mail: fubin.wu@gessnet.com

This article began as a discussion among the authors regarding the misuse of the failure mode and effects analysis (FMEA) methodology in medical device risk management. While analyzing the issue, it was noted that misuse of FMEA had been previously addressed by several authors.[1,2] This report will discuss why *only* using FMEA for the entire risk management process is not appropriate. The current work also will propose the use of the Risk Traceability Summary (RTS) in lieu of the FMEA method as the master reference document for risk management throughout the product life cycle. The goal of this article is to provide an improved approach for medical device manufacturers to fulfill their responsibilities for conducting product health and safety risk management.

Necessity for Comprehensive Risk Management

All medical device manufacturers should conduct and document product health and safety risk management. This should occur throughout the product life cycle in accordance with the requirements of the U.S. Food and Drug Administration (FDA) under 21 CFR 820, *Quality System Regulation*, and requirements contained in the following international quality system standards: ISO 13485:2003, subclause 7.1, and ISO 14971:2007, *Medical devices–Application of risk management to medical devices*.

Addressing product health and safety risk was first required by the European Union in the Medical Device Directive and was addressed in the development of the EN 1441, *Risk Analysis*, standard in 1994. Manufacturers began using FMEA to perform and document risk analysis. Later, as ISO developed a more comprehensive risk analysis standard (ISO 14971-1) in 1998 and a comprehensive risk management standard (ISO 14971) in 2000, manufacturers simply extended their use of FMEA to document more information as an attempt to meet all of the additional risk management requirements, including traceability requirements. Over time, manufacturers tried to extend FMEA beyond the original "failure modes" analytical tool to encompass most, if not all, of the required activities of the risk management process.

FMEA: Too Little, Too Late

Kim Trautman, one of FDA's leading experts on medical device quality management systems and a member of the technical committee that developed ISO 13485, publicly stated at the FDAnews 2011 Inspection Summit meeting, "I can't tell you how many manufacturers I have seen that have tried to present their risk management system by simply presenting a FMEA. That is *not* a risk management system. Do not make the mistake of presenting FMEAs as your whole risk management system." Trautman's statement was based on comment 83 in FDA's Preamble to the Quality System Regulation, 21 CFR 820: "When conducting a risk analysis, manufacturers are expected to identify possible hazards associated with the design in both normal and fault conditions."

Also of note is the requirement for traceability in subclause 3.5 of ISO 14971. Subclause 4.3 of the standard states, "The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions."

The standard FMEA process addresses only fault condition hazards and not normal condition hazards. Also, the standard FMEA process addresses only single-fault condition hazards. It is not the optimal tool for considering hazards caused by two or more failures. The standard FMEA process is not the best means for documenting risks that are not failure modes. It does not address qualitative or pass/fail data as well as other processes. Therefore, the singular use of FMEA does not meet the technical requirements for a complete risk analysis, evaluation, or assessment. However, based on public sources such as FDA Warning Letters, some manufacturers appeared to be unclear on how to manage and document the overall risk management process without using FMEAs.

Risk analysis is a required design input in ISO 13485, and safety requirements (identified in risk analysis) are a required design input in 21 CFR 820. Hazards are required to be inputs to risk analysis as defined in the risk management standard. Identifying these hazards then becomes a first step in risk analysis. Risk management tools (e.g., preliminary hazard analysis, fault tree analysis) are identified in Annex G of ISO 14971 to perform the risk analysis (or risk analyses) that can provide much of the necessary design input risk information. Figure 1 identifies a number of tools and techniques that can be used throughout the design process to perform the risk analyses. In addition, ISO 14971 requires maintaining (and updating) the Risk Management File throughout the product life cycle.

Risk Traceability Summary Requirement

In Figure 2, we have depicted a documentation and management process that may serve to meet the risk traceability requirements of both CFR 820 and ISO 14971. The process uses a

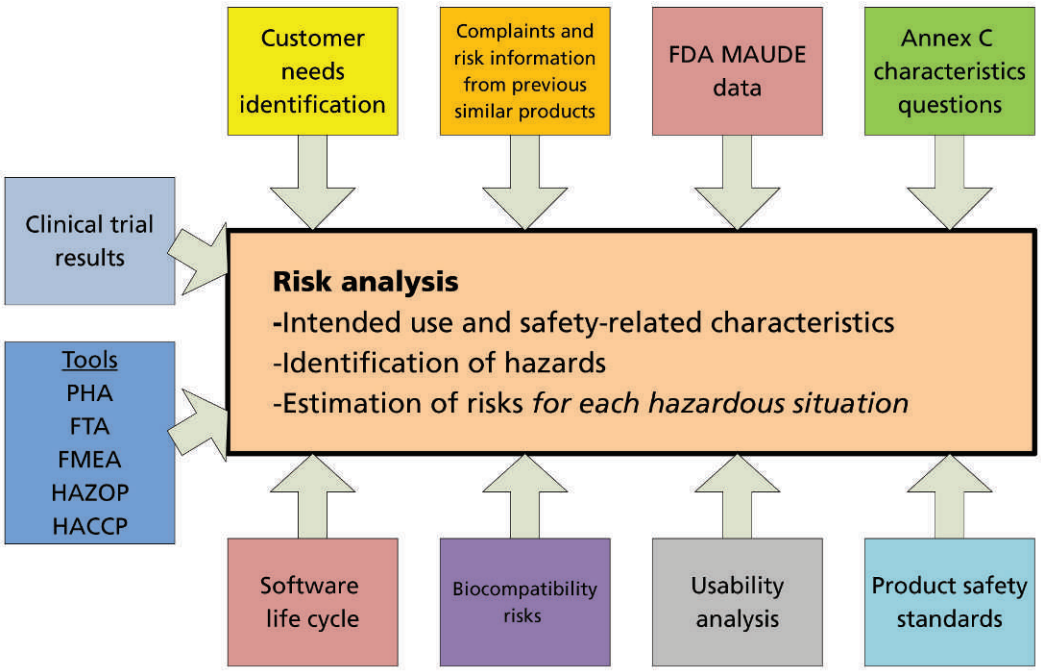

Figure 1. Inputs to the risk analysis process. Abbreviations used: FDA, U.S. Food and Drug Administration; FMEA, failure mode and effects analysis; FTA, fault tree analysis; HACCP, hazard analysis and critical control points; HAZOP, hazard and operability analysis; MAUDE, Manufacturer and User Facility Device Experience; PHA, preliminary hazard analysis.

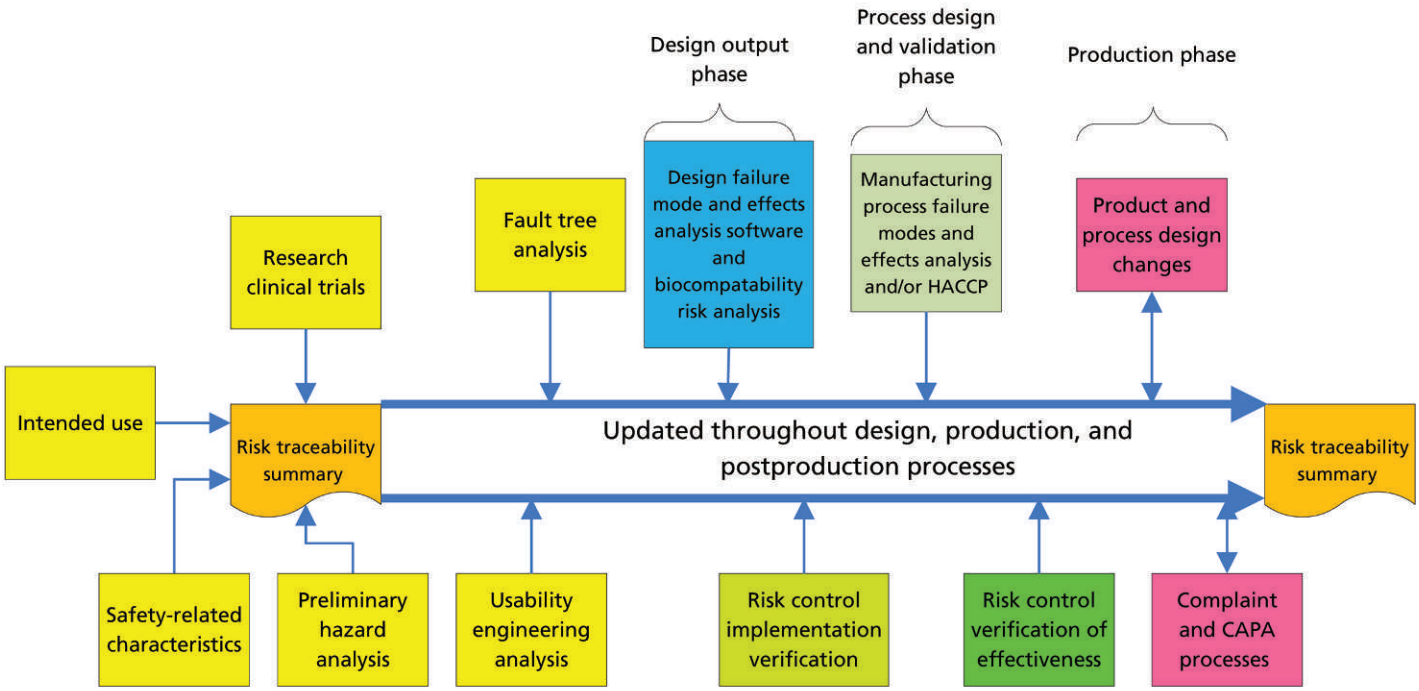

Figure 2. Use of risk management throughout the product life cycle. Abbreviations used: CAPA, corrective and preventive action; HACCP, hazard analysis and critical control points.

proven method for maintaining the required documentation (i.e., the Risk Traceability Summary [RTS]). The RTS captures the use of specific and appropriate risk analysis tools at various stages of the product life cycle, as required by the standard, in a form that can be efficiently and effectively used to maintain the Risk Management File. This document, and not the FMEA, becomes the master document of the overall risk management process.

Subclause 3.5 of ISO 14971 requires documenting traceability for each identified hazard in the Risk Management File. The RTS is a table used as the vehicle for maintaining the documentation connections to all of the various risk analysis tools actually utilized. The RTS was first documented in GHTF/SG3/N15:2005, *Implementation of risk management principles and activities within a Quality Management System* (in Appendix C). Although the GHTF document was not updated to reflect the 2007 revision of ISO 14971, it remains relevant and available today for reference through the International Medical Device Regulators Forum at www.imdrf.org.

RTS and Managing Risk Documentation During Design

In using this document over time, some modifications to the GHTF version have been developed and are recommended by the authors. These modifications have been used by several companies and have been accepted by European Notified Bodies. In Figure 3, columns were added to the original GHTF summary document to include the source document (and line item) for the hazard and causes of associated hazardous situation(s), which may include the FMEA or another tool, and to describe the hazardous situation that identifies the exposure to the hazard leading to harm. ISO 14971 indicates that just because a hazard exists, a harm possibly may not occur until there is exposure. The hazardous situation, through sequences of events, modifies the probability of occurrence that came from causes that may have been identified using tools such as FMEA. The resulting probability of occurrence of harm may in fact be a different value than the probability of an individual cause (i.e., failure mode) occurring (as documented in the FMEA).

The data residing in the RTS table provides a valuable link between the hazards and various risk tools. This will be of benefit later in the product life cycle, as it will allow information to be easily located during an audit or investigation of a potential design or process change, complaint, or corrective/preventive action.

The first page of the table shown in Figure 3 shows the documentation of the risk assessment phase (risk analysis + risk evaluation) of the risk management process. Additional rows are added as appropriate for the device in order to cover all of the hazard categories that may be applicable to a particular device. All of the hazards and causes from all risk tools, including the analysis of the software hazards, biocompatibility, sterility, process, and other hazards, reside within the single table, thus providing one location for identifying and referencing back-up information related to all hazard documentation. This may eliminate time-consuming searches through the many documents in the Risk Management File, in order to locate hazard information and provide links to the source documents.

All of the hazards and causes from all risk tools, including the analysis of the software hazards, biocompatibility, sterility, process, and other hazards, reside within the single table.

Figure 3 shows a few hazard category examples. Of note, a few example categories appear; many more categories will exist in a typical device. In a combination product, additional categories for drug or biological hazards, including manufacturing hazards, may be added to the summary. The result is a comprehensive list of all known and foreseeable hazards for the healthcare product.

After unacceptable risks have been identified, additional steps in the risk management process, including determining control measures, are required (Figure 4). The spreadsheet illustrated in Figure 4 is used to document risk controls and to verify implementation and

Risk assessment						
Risk analysis						Risk evaluation
Hazard list				Risk estimation		Risk acceptability
Hazard	Source document (e.g., FMEA, FTA, PFMEA)	Hazardous situation and document	Specific harm	Probability of harm	Severity of harm	Risk level
1.0 Energy and design hazards						
1.1 Electrical hazards						
1.1.1						
1.1.2						
1,1,3						
1.2 Thermal hazards						
1.2.1						
1.2.2						
1.2.3						
1.3 Mechanical hazards						
1.3.1						
1.3.2						
1.3.3						
2.0 Biological and chemical hazards						
2.1 Biological hazards						
2.1.1						
2.1.2						
2.1.3						
2.2 Chemical hazards						
2.2.1						
2.2.2						
2.2.3						
2.3 Sterility hazards						

Figure 3. Risk Traceability Summary: risk assessment phase. Abbreviations used: FMEA, failure mode and effects analysis; FTA, fault tree analysis; PFMEA, process failure mode and effects analysis. Note: A few example categories appear; this figure is not intended to represent an exhaustive list of categories.

Risk control										Additional information
Risk controls						Postcontrol risk				Comments
Risk control measures	Product requirement or characteristic ID	Verification of implementation protocol ID	Verification of implementation results report	Verification of effectiveness (validation) protocol ID	Verification of effectiveness results report	Probability of occurrence of harm	Severity of harm	Residual risk	Risk-benefit analysis source document	
1.1 Electrical hazards										
1.1.1										
1.1.2										
1.1.3										
1.2 Thermal hazards										
1.2.1										
1.2.2										
1.2.3										
1.3 Mechanical hazards										
1.3.1										
1.3.2										
1.3.3										
2.0 Biological and chemical hazards										
2.1 Biological hazards										
2.1.1										
2.1.2										
2.1.3										
2.2 Chemical hazards										
2.2.1										
2.2.2										
2.2.3										
2.3 Sterility hazards										

Figure 4. Risk Traceability Summary: risk control phase. Note: Page 2 of the risk summary table is shown. A few example categories appear; this figure is not intended to represent an exhaustive list of categories.

effectiveness. It also shows the final residual risk estimate for the identified hazard. A column is provided for reference to a risk-benefit analysis report for the hazard, if the risk control measures do not reduce the risk to acceptable levels. It also is important to understand that several harms may be possible for an individual hazard and that the result may be more than one row of the spreadsheet.

RTS Throughout the Product Life Cycle

While the RTS is an excellent tool for assessing products during the design phase, its use also is beneficial at any stage in the product life cycle, including retrospective summaries. The RTS is an optimal tool for referencing miscellaneous risk-related information, such as individual studies and other required reports. Another benefit of the RTS is that it will mature as the product matures. Due to its modular nature, it obviates the need for one single massive risk assessment. Therefore, it can foster the use of an appropriate risk tool for the specific risk analytical situation by the appropriate department(s). The RTS allows a manufacturer to accumulate and archive risk data in a convenient manner as information becomes available.

Using the RTS approach is preferable to performing massive retrospective or prospective risk management projects that are outside of the routine product information flow. Because this single document contains connections to all risk information, it can be used to meet the requirements of the standard (subclause 3.5) and to provide a tool for future research of risk information in cases such as complaints, corrective and preventive action, and potential recalls. Accumulating this information in one document provides some assurance that no documented hazards will be overlooked during these research activities.

The RTS also provides a complete index of all risk analyses and other studies and reports during the Overall Residual Risk Evaluation stage. It becomes a resource for exploring all information supporting the risk estimates identified during the various risk activities that occur during all stages of the life cycle of a medical device or combination product. The

Another benefit of the RTS is that it will mature as the product matures. Due to its modular nature, it obviates the need for one single massive risk assessment.

Claims		Context and assumption	Strategy and argument	Evidence and reference
Top claim	ABC medical device is safe for its intended use	Refer to intended use. "Safe" and "mitigated" mean residual risk is acceptable per 21 CFR 860.7(d)(1).	Argue that all applicable hazards are identified and mitigated. Confidence argument on why hazards are identified correctly, completely, and appropriately.	Intended use, risk acceptance policy, other evidence as needed.
Top subclaims	Sources of **harm** (top hazards) are mitigated	Explain the potential harm and its severity. Describe context and assumption as applicable.	Argue that hazardous situations are identified and mitigated. Confidence argument on why hazardous situations are identified correctly, completely, and appropriately.	Evidence to support strategy or argument, as applicable.
Subclaims	Risk of **hazardous situations** is mitigated	Explain the hazardous situations. Describe context and assumption as applicable.	Argue that causes are identified and mitigated. Confidence argument on why causes are identified correctly, completely, and appropriately.	Evidence to support strategy or argument, as applicable.
Subclaims	Risks of **causes** are mitigated	Causes include faults, conditions, interactions, and contributing factors. Describe context and assumption, if any.	Argue that subcauses are identified and mitigated. Confidence argument on why subcauses are identified correctly, completely, and appropriately.	Evidence to support strategy or argument, as applicable.
Subclaims	Risks of **subcauses** are mitigated	Describe context and assumption information, as applicable.	Argue that controls are established. Confidence argument on why controls are collectively sufficient to reduce the risk (severity or probability) to be at acceptable level.	Evidence to support strategy or argument, as applicable.
Subclaims	**Risk control** is established	Describe context and assumption information, as applicable.	Argument on why control implementation is correct, complete ,and appropriate.	Requirements, design, testing, labeling, standard operating procedures, etc.

Figure 5. Safety assurance case for medical devices: tabular report template

team having responsibility for the Overall Residual Risk Evaluation then will have an index to all information necessary to complete its specific task.

The RTS also provides a good foundation for new risk management requirements, such as safety assurance cases and overall risk-benefit determinations, particularly for highly critical or complex medical devices.

Medical Device Safety Assurance Cases and RTS

The RTS also provides a good foundation for new risk management requirements, such as safety assurance cases and overall risk-benefit determinations, particularly for highly critical or complex medical devices. For example, in 2014, FDA issued the final guidance for infusion pumps.[3] The guidance requires infusion pump manufacturers to submit safety assurance cases as part of premarket submissions. Safety assurance cases routinely are used in other business sectors such as the aerospace industry. An assurance case is a formal method for demonstrating the validity of a claim by providing a convincing scientific argument together with supporting evidence. An assurance case addressing safety is called a safety case. A tabular format medical device safety case template is illustrated in Figure 5.

RTS: Easing Transition to Safety Assurance Cases

When a manufacturer has already established the practice to generate and maintain the RTS as illustrated in Figure 3, the effort to develop and maintain a safety assurance case is simplified considerably. Most of the information captured in the RTS can be automatically converted into the safety case. The key information primarily needing to be added includes the rationales, which can serve as the argument for the safety case. For a manufacturer who uses FMEAs solely as the tool for risk management, developing a safety case can be very challenging. First, the arguments in a safety case typically are organized in a logical and hierarchical fashion with multiple layers of subclaims, each supported by appropriate evidence (as illustrated by Figure 5). Second, those who use FMEAs as the only risk analysis technique could face difficulty in convincing safety case reviewers that all applicable risks are adequately identified and controlled.[4]

Medical device manufacturers must have risk management in place for their organization in order to meet the FDA 820 requirements, the product realization planning requirements of ISO 13485:2003, and the specific requirements of ISO 14971. Effective risk management is a regulatory requirement, a good business practice, and a competitive advantage. The RTS

discussed in this article provides an improved conceptual approach for manufacturers to achieve these objectives efficiently throughout the life cycle of the device and thereby foster an optimal product health and safety risk management process. ■

Acknowledgment: To Dr. Alfred Dolan (University of Toronto and convener of ISO TC 210 JWG 1) for valuable assistance in reviewing and commenting on the article.

References

1. **Schmidt MW.** The Use and Misuse of FMEA in Risk Analysis. Available at: www.mddionline.com/article/use-and-misuse-fmea-risk-analysis. Accessed January 22, 2015.
2. **Hartford J.** Use, Misuse, and Abuse of the Device Failure Modes Effects Analysis. Medical Software. Available at: www.mddionline.com/article/use-misuse-and-abuse-device-failure-modes-effects-analysis. Accessed January 22, 2015.
3. **U.S. Food and Drug Administration.** Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff. Available at: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209337.pdf. Accessed December 5, 2014.
4. **Eagles S, Wu F.** Reducing Risks and Recalls: Safety Assurance Cases for Medical Devices. *Biomed Instrum Technol.* 2014;48(1):24–32.