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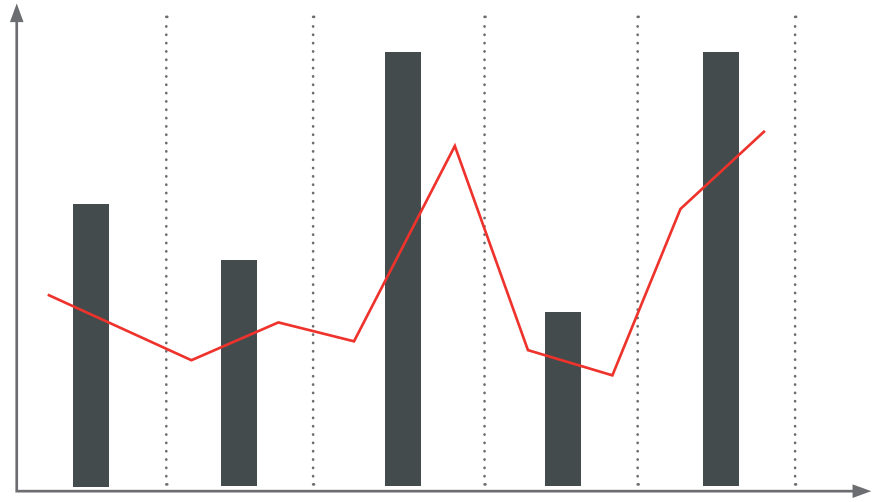


Risk Management from the trenches

The Frank Sinatra report

Executive summary

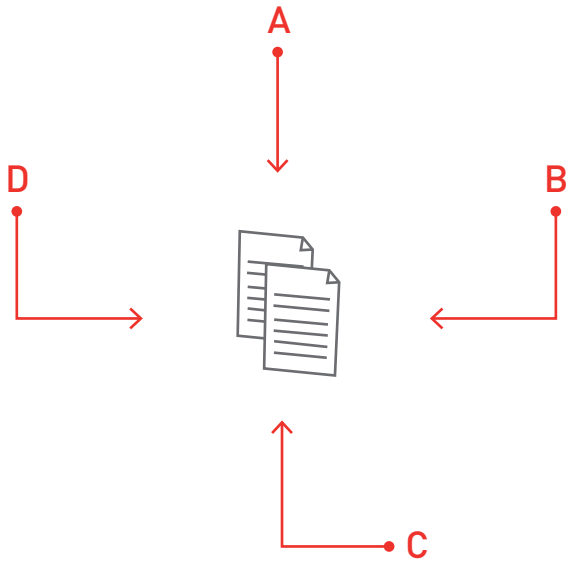
This survey explores how Medical Device Manufacturers practically implement risk assessments as required by ISO 14971. It highlights similarities and differences in the methods and approaches chosen to satisfy ISO 14971.

As ISO 14971 stipulates general outlines on how the risk assessment must be performed, the choice of risk assessment method and parameters are intentionally left open in order to accommodate for the best possible fit between the manufacturers situation and the method chosen.

As a result, there is a wide spread of risk assessment approaches and practices to be found among Medical Device Manufacturers, all being different and all making the claim of being conformant with ISO 14971.

In this survey, we explore the similarities and differences in the choice of practices. The survey clearly shows that, although all approaches are regulatory valid[1], there is a significant spread in the selection of risk assessment conventions. Thus many roads seem to lead to Rome.

[1)] Note that validity is always as interpreted by notified bodies/certification agencies and may differ from case to case.



The importance of conventions in risk management

The ISO 14971 "Medical Devices – Application of Risk Management to Medical Devices", is the established industry standard since 2000. It articulates the required steps needed to setup and fulfill a compliant Risk Management. However, it deliberately refrains from defining a particular risk assessment technique to be used.

By explicitly not stipulating hard requirements on the "how", the manufacturer is left to choose his own preferred method. Most risk assessment techniques are largely subjective and configurable.

Whereas most other DHF Design Control Categories such as verification and validation have an objective and scientific basis, it is often easy to forget that risk assessment techniques essentially are subjective and based on conventions selected by the manufacturer. From a regulatory point of view, one set of conventions does not necessarily deserves more merit than another, as long as the requirements of ISO 14971 are satisfied. In this survey we will assess the approaches and parameters manufacturers have used for:

- Identifying potential Hazards
- Number of severity and probability levels
- The use of a qualitative or quantitative probability
- The method of estimating probabilities
- The calculation formula of Risk priority numbers

About the Survey

Aligned AG conducted the survey in Q3 of 2013. We gathered input from four medical device manufacturer, all using FMEA as risk assessment approach. The respondents are representatives from either the R&D or the Quality/ Regulatory Departments.

We are well aware of that the risk assessment process is significantly larger than the scope evaluated in this study. The main point in this survey is to highlight the similarities and differences in selected practices for several manufacturers operating in the same field.

Identification of hazards and hazardous situations

Section 4.3 and 4.4 of ISO 14971 requires the manufacturer to document known and foreseeable hazards and to identify the hazard situations.

There are essentially two approaches used by the participants in this survey for hazard identification.

The first takes a list of potential hazards as starting point, trying to identify all situations where a given hazard can occur. This can be considered to top-down approach.

The second approach takes the complete list of requirements and/or specifications as starting point, trying to identify all hazards that can occur from a given specification or requirement. This can be considered as a bottom-up approach.

Both methods are systematic and strive to identify all potential hazards for the product. From a theoretical standpoint, the first approach ought to be more efficient in cases where the specifications are not yet established, i.e. early in the development process whereas the second approach is efficient when the specification scope is fully known, i.e. later in the development process.

	Method for identification	Approach
Company A.	Use list of Potential Hazards as basis	↓ Top-down approach
Company B.	Iterate through all Specifications and consider hazardous situations	↑ Bottom-up approach
Company C.	Iterate through all requirements and specifications, crosscheck against list of „standard risks“	↑ Bottom-up approach
Company D.	Use list of Potential Hazards	↓ Top-down approach

Severity levels

A risk consists (at least) of the two components probability and consequence. The degree of risk consequence is often termed "severity" and as part of the risk classification, the severity is often rated as level on a scale e.g. from 1 to 10 where 10 indicates the worst possible outcome, usually death of a patient or device user.

ISO 14971 does not explicitly specify how the Severity should be estimated and graded. All the respondents in this survey use an FMEA approach where a quantitative severity scale is an integral part. The number of levels varies among the respondents.

	Severity
Company A.	1 - 5
Company B.	1 - 10
Company C.	1 - 4
Company D.	1 - 10

Estimating probability

It is entirely up to the manufacturer to define how the probability component of the risk shall be parameterized. However, whereas severity often is perceived as a relatively straight-forward concept, there is more flexibility (and confusion) when it comes to probability.

The probability can be set up as a qualitative or (semi-) quantitative parameter and in the latter case, linear or non-linear.

ISO 14971 suggests a number of available techniques for estimating the probability of a risk including:

- published standards
- clinical evidence
- scientific technical data
- field data from similar devices
- usability tests

The survey participants converge on the usage of a technique called "expert opinion" which essentially relies on the risk assessors' judgement of estimating the probability without further evidence.

	Probability	Method to estimate probability
Company A.	1-5 Quantitative, Non linear	Expert Knowledge
Company B.	1-10 Qualitative	Expert Knowledge
Company C.	1-6 Quantitative, Non linear	Expert Knowledge
Company D.	1-10 Quantitative	Expert Knowledge

Risk priority numbers and unacceptable risk threshold

The FMEA approach usually prescribes that a risk priority number (RPN) is calculated from the severity and probability components. A high RPN denotes a grave risk. The formula for calculating the RPN is, like many other parameters in this survey, left to the manufacturers own devices. It is therefore interesting to observe that all respondents are using the same calculation formula. Furthermore the manufacturer must define a threshold criterion that defines if risk reduction for a particular risk is required. Among the survey participants we find a large variety in the definition of the threshold criterion. Again, there is nothing in the ISO 14971 that makes one criterion more valid than another.

It is highly interesting to observe the manufacturers' rational for selecting a particular criterion. There seems to be little consideration given to why a particular threshold is selected. This is startling conclusion since it introduces a significant portion of arbitrariness in judging weather a risk is unacceptable or not.

Since there is significant workload in finding, implementing and documenting risk reductions, this arbitrariness has a serious impact on the work scope of the project.

	Forumula	Threshold	Rational
Company A.	Severity x Probability x Visibility	Severity >3 or RPN >40	Don't know
Company B.	Severity x Probability x Visibility	RPN >100	Default by Risk Management tool
Company C.	Severity x Probability x Visibility	Defined combinations of severity and probability	Not given
Company D.	Severity x Probability x Visibility	RPN >100	Not given

Conclusion

Throughout the survey, we can conclude that there are both significant differences and similarities in selecting risk assessment conventions.

It is clear that the selection of conventions has an impact on the amount of work required to complete the risk assessment task. In short, different convention sets result in different workloads.

The study indicates that the regulatory focus on the convention selection significantly outweighs the consideration of the conventions impact on the documentation work.

Therefore we see room for significant productivity improvements in the risk assessment process by including the work aspect when selecting conventions. These include:

- use a systematic approach for identification of potential hazards
- apply fewer levels for severity and probability which leads to less time spent on classifying these parameters for each risk
- relying on expert knowledge for estimating probability is sufficient in many cases
- take an extra look on the rational for selecting the threshold for in-acceptable risks.

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