Q&A Risk management ISO 14971

Question 1 - ISO 14971 applies to hazards affecting people/property/environment? Does it also apply to fault which does not result in harm to those categories?

Answer 1 – No. Such situations are not in the scope of the risk management process

Question 2 – I'm already performing an FMEA. Does FMEA equals risk management per ISO 14971?

Answer 2 – No. Often this creates confusion. However, FMEA is viewed as a tool to help identifying hazards; it cannot cover the risk management process since it is only partial.

Question 3 - Can I apply ISO 14971 if I´m part of the process of medical device manufacturing (contractor for instance) ?

Answer 3 – No. Risk management is a question of granularity. The whole overview of the activity is necessary to identify the impact on users. However as a contractor the inputs can be provided to the responsible entity for the complete risk management file. It could be possible to have a risk analysis of the process that is an input to the risk management file of the manufacturer. In the end there is only one

Question 6 - What is the expected content of an ISO 14971 risk management file (RMF)?
Answer 6 - See below:

1 - Reference to the qualification of people performing the risk management activities
2 - Risk management plan for the evaluated device
3 - Intended use (suggestion - verify IEC 62366) including answers to questions that can be used to identify medical device characteristics that could impact on safety
4 - Reasonable foreseeable misuse (suggestion - verify IEC 62366)
5 - Identification of essential performance (if for medical electrical equipment)
6 - Identification of hazards and hazardous situations, including all the relevant information for all identified hazards and hazardous situations; this includes foreseeable sequence or combination of events that can result in hazardous situations. This also includes P1 and P2 (see annex E)
7 - Data used and the sources (e.g. accident history, experience gained from risk reduction applied to similar medical devices, etc.)
8 - Any relevant assumption that have been made (e.g. users, environment, safety factors, means of protection)
9 -Tools for failure analysis and result of failure analysis (list of different tools used and explanation of

how they are been used)
10 - Explanation of the system used to categorize quantitatively or qualitatively the probability of occurrence and severity of the harm
11 - Estimation of the risk of each hazardous situation
12 - Risk evaluation
13 - Acceptability levels, if used
14 - Risk control information, including list of control measure, evaluation if controls are not of level 1 - inherit safe or 2 - protective measures, procedures to verify implementation and effectiveness of risk control measures
15 - The uncertainty associated with the data used and its impact on the risk evaluation
16 - Risk reduction (residual risk evaluation for control measures not derived from an international standard) + decisions regarding information on residual risk. Review of risks originating from risk control measures
17 - Overall risk control evaluation
18 - Overall risk acceptability evaluation (+ methods, risk/benefit analysis if needed, and information about overall residual risk)
19 - Risk management report
20 - Production and post-production information gatherer system

Question 7 - What if I am evolving in an US FDA context as a contractor? Am I still not responsible for risk management ?
Answer 7 – Yes. FDA may consider the contractor as responsible for his part. In such case performing a risk analysis which takes into consideration your knowledge of the impact on user/patient may be necessary.

Question 8 – Who is responsible for establishing the content of the risk management file (RMF)?

Answer 7 – An example of functional team below:

Clinical specialist, system engineering, engineers with various specialty (mechanical, software, hardware…), biomedical engineer, regulatory affairs, and risk managers

It's not so much a matter of function here but more of knowledge or skills.

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