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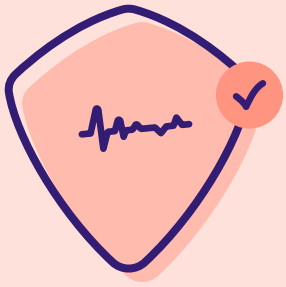

Introduction to medical device risk management

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Risk management terminology

The first step to making progress towards understanding risk is to dissect the slight variations in the terminology. Some of these can be very nuanced, so it's important to get a good grasp on the differences before proceeding.

Risk Analysis: Risk Analysis is the process of looking at a design or system and actually coming up with possible hazards that could possibly cause harm to people, property, or even the environment. Think of risk analysis as sitting around a table with your team and coming up with any possible, often seemingly silly, hazard that could arise.

Risk Estimation: Risk Estimation is the process used to assign a numerical value to the laundry list of possibilities you came up with during the analysis. The risk estimation process considered the probability of occurrence and the severity of the harm.

Risk: Risk can be numerical or translated to a scale like low, medium, high, but this is the actual representation of the risk estimation for a given harm. For example, a harm with a high severity but a very small probability of actually occurring may be a low risk.

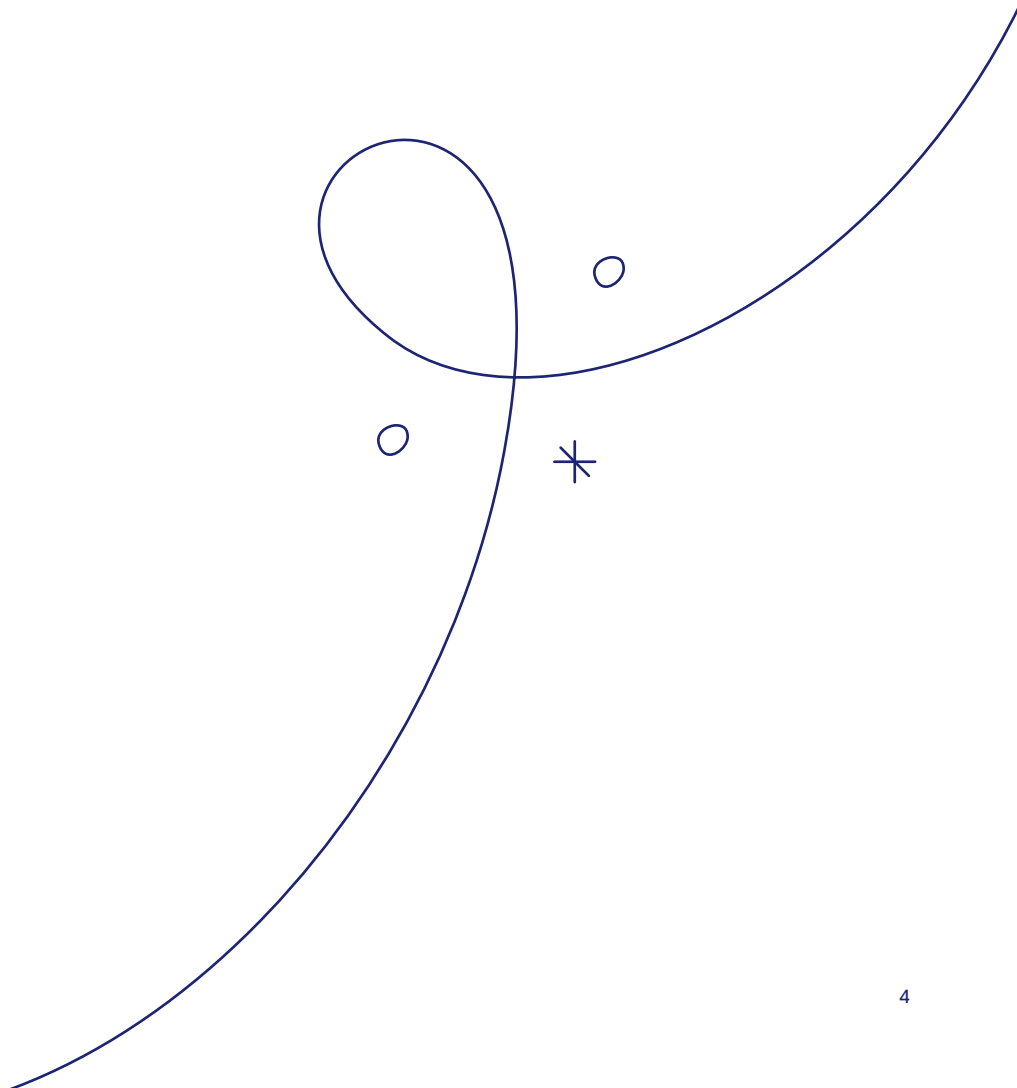
Risk Evaluation: Risk Evaluation is a process of taking the risk analysis and comparing it to a set of predefined risk acceptance criteria. Usually this results in a risk evaluation summary document.

Risk Assessment: Risk Assessment is the bigger document that contains both the analysis and the evaluation

Risk Control: Risk Control is the step where the full risk assessment is reviewed and steps are taken to reduce risk to an acceptable level.

Risk Management: Risk Management is the overall process of all things risk. Risk Management is the umbrella term that refers to all of the sub-processes as a whole.

Risk Management File: The records for all things risk management including analysis, estimation, acceptable risk ranges, mitigations, etc.



Getting started with risk management

Managing risk records

Okay, so you're getting ready to start a new design project and that means a new Risk Management File. The first step is deciding how you are going to maintain all of these records.

Options	Pros	Cons
01. Paper — Generate paper records for every risk related document or record and maintain them in a binder. This is messy, but can work if you are in a traditional office setting	Easy to start, traditional	Not feasible for remote work, Higher risk of damage/destruction, Can be difficult to keep continually updated
02. Electronic File/Binder — Think of this as the next evolution from paper. Your records and documents are all maintained in a file folder on a server or in the cloud.	Easy to start, allows online collaboration	Potential difficulties with Part 11 compliance
03. Electronic QMS with Risk Built-in — An eQMS that has a great risk system built-in can allow for linkages throughout the system. You will still need to create documents and records	Online collaboration, Part 11 compliance, Automatic linkage to associated documents and records	Cost of software, learning curve for using software

Developing documents and records

Things you need to develop to set up your risk management system:

Procedures (SOPs, work instructions, etc.)

After reading this primer, buy a copy of ISO 14971 and sit down and get writing compliant procedures, or enlist the help of an expert. You'll want to make sure that your procedures provide enough detail that your team will be able to conduct the risk management activities in a consistent manner.

As a disclaimer, you might write or buy a set of procedures that seems great, but once you get in and do the work of the risk management process you realize the process doesn't work as well as you hoped. That's okay! The nature of quality is to make continual improvements in systems and processes.

You can always open a corrective and preventive action (CAPA) to document the improvement process. Auditors do not look at CAPAs as a bad thing, unless you are opening CAPAs and then not properly addressing them. The 2016 revision of ISO 13485 put more emphasis on preventive actions to encourage manufacturers to continually review systems for possible improvements. This ties in nicely with using risk management throughout the QMS.

These will be the backbone of how you document everything in your Risk Management File. You will also need at least the following basic documents:

Risk management plan

This is device specific and will be your guiding document for ensuring all of your other risk activities take place. This plan must also include your risk acceptability criteria. The Risk Management Plan should be considered a living document that is updated as timelines change. This will be your guide for making sure all of the risk activities are carried out.

Risk analysis document

This needs to capture the who, what, where, and when of the analysis, as well as listing all of the hazards that were identified during the analysis. This could be as simple as meeting minutes with a list of the hazards as the output, or could be much more complex with flowcharts showing the thought process for the analysis. It will really depend on the complexity of your device and manufacturing process.

Risk estimation document

Here is where you will assign numerical values to the hazards that you identified in the analysis. If you have an eQMS there will likely be an integration for this.

If not, a good old fashioned spreadsheet is typically used. There are different styles and methods, so find a way that will work well for you.

Risk evaluation

At this stage, you will compare your estimations to the acceptability criteria from your Risk Management Plan and draw conclusions about the overall risk acceptability. This should be a document that covers not only the numerical analysis, but also offers a synopsis. Your evaluation may come up with risks that are unacceptable and that's okay. Document the risks that need to be mitigated and consider this an action item checklist.

Risk management review

A simple document that should be part of your final phase of Design Controls. This review will document that the Risk Management Plan has been implemented, risk levels are all acceptable, and that plans for post-production risk management activities are in place.

Risk management, step by step

Looking at the list of documents and records above, you may be feeling a bit overwhelmed or still at a loss as to what it actually means to 'do' risk management. Next, let's look at an example using a standard yellow #2 pencil as an example of the device.

Step 1: Planning

First, you'll need to prepare the risk management plan with timelines and responsible people in place. It may look something like the following. Scope: The following plan covers the design, development, and product launch for the Model #2 pencil.

Activity	Responsibility	Timeline	Reviewers
01. Initial pre--design analysis			
02. Data review for estimation			
03. Develop risk acceptability criteria and add to risk management plan			

Activity	Responsibility	Timeline	Reviewers
04. Develop evaluation metric for residual risk and add to risk management plan			
05. Post-design risk analysis*			
06. Apply risk estimates*			
07. Risk evaluation*			
08. Risk control & mitigation*			
09. Verification of risk controls			
10. Develop post-product pisk metrics			
11. Risk management review			

**Repeat steps 5-8 cyclically until all risks have been mitigated to an acceptable level or a risk-benefit analysis determines that residual risk is acceptable given the expected benefits. Remember: Your risk management plan is a living document. Update it as necessary. Adhere to document and record controls when updating.*

Step 2: Analysis

Once you have (at least your first version of) your risk management plan in place, it's time to get to work on risk analysis. Let's use some examples using our #2 pencil device model.

There are many different risk analysis techniques that can be used. For an initial risk analysis before you have a finished or even prototype device to look at, a less structured approach might be the best fit. This approach will allow your team to come together to discuss the device and may also be helpful in introducing additional considerations for the device development.

So for this example we know we want to make a pencil, but we don't yet know what that manufacturing process really looks like, what the final materials will be, or where it will be used. This is where using risk early can be beneficial to the overall development process. We know we want to have some sort of a coating on the outside of the pencil, but we don't know what material we want to use. If we discuss the risks and benefits of the different options now we can save time and money down the road when we realize we picked a material without thinking it through completely.

Here's an example thought process: A paint coating on the pencil is nice, but where will the pencil be used? Is it going to be a hazard if the paint flakes off? Can we include any design or markings on the painted surface that we need to? There is usually a metal component that attaches the eraser to the pencil. What are the risks if that metal breaks off? Can the metal cut anyone? Can the metal interfere with other devices in the environment that use magnets? What about users that are allergic to certain metals?

The initial spit-balling of ideas can then be translated into a formal risk analysis like below:

Hazard	Hazardous situation	Potential harm
Pencil coating	Flakes off	Contaminates controlled environment
	Difficult to print on	Illegible markings
Metal clamp	Sharp edges	User is injured
	Magnetic interference	Nearby devices disrupted
	Biocompatibility	User allergies to metal
Eraser material	Biocompatibility	User allergies to material

Complete the analysis by documenting exactly what device it applies to, who was involved in the analysis, and when the analysis took place.

Step 3: Estimation

This is where things start getting tricky. Estimation can be qualitative or quantitative, but where possible there should be some rationale for the estimate.

For medical devices that are based on similar existing devices, it may be possible to pull some risk estimation data from published scientific literature, clinical trial data, or publicly available adverse event reports. But how do you estimate the risk that someone will use an expired product or that manufacturing debris will remain in a fluid pathway?

For risks introduced through the manufacturing process, statistical data can be gathered from the quality control system to help inform your estimates. For user based risks such as off-label use, or incorrect use, usability studies can be conducted. Another source of risk estimation data is expert opinion.

For the below example, a numerical scale of 1 to 5 has been used for the estimation, where 1 is incredibly unlikely and a 1 in severity is practically harmless. In practice in industry, there's often also a column for Detectability, which identifies how easily the hazard is detected prior to use as a means to prevent the harm from occurring.

Hazard	Hazardous situation	Potential harm	Probability of Occurrence	Severity	Comments
Pencil coating	Flakes off	Contam-inates controlled environ-ment	3	1	Not designed for controlled environments
	Difficult to print on	Illegible markings	3	2	Manufacturing data indicates 3% of units have poor print quality; Unclear printing could result in selection of the wrong hardness pencil (ex. 2 instead of 2B)

Hazard	Hazardous situation	Potential harm	Probability of Occurrence	Severity	Comments
Metal clamp	Sharp edges	User is injured	2	3	Consumer data for similar pencil indicates 5 complaints out of 100,000 pencils sold for injuries from the metal clamp
	Magnetic interfer-ence	Nearby devices disrupted	1	1	Metal used is nonmagnetic
	Biocom-patibility	User al-lergies to metal	1	5	Available medical data indicates allergy to selected metal occurs in 1 of 100,000 people
Eraser material	Biocom-patibility	User al-lergies to material	1	5	Available medical data indicates allergy to selected metal occurs in 1 of 100,000 people

Note: Prior to completing the estimations you will need to define the acceptable risk levels in the risk management plan. Similar to the estimation, you may look to industry sources for data about typical risks to identify what is acceptable. The acceptability criteria for a manufacturing process risk may be different from a risk to the patient or device user. This is also where you will define how you will identify estimations, quantitative, qualitative, or both.

Step 4: Risk evaluation

At this stage, you'll be looking at the risks and determining if they meet the acceptability thresholds. If a certain hazard is identified as being unacceptable, risk control measures may be implemented. These are changes to the design, packaging, labeling, training program, manufacturing process, etc., that will be implemented to attempt to reduce the risk occurrence. These mitigations must be verified for implementation and effectiveness, and that verification must be documented within the risk management file.

For this example, we're going to say that the metal used can potentially cause a life threatening reaction for those with the rare allergy. Since it's life threatening we want to mitigate the risk if at all possible. Some possible mitigations we might consider would be changing the type of metal used for the clamp, coating the metal so it is not able to cause a reaction, or putting a warning label on the packaging for the pencils notifying the user of the potential allergen.

It would then be up to the design and development team to determine if a material change or coating makes sense. If the material change doesn't make sense, some sort of usability testing may be necessary to ensure that the labeling on the product is prominent enough to alert users to the potential danger.

Hazard	Hazardous situation	Potential harm	Probability of Occurrence	Severity	Comments
Metal clamp	Biocom-patibility	User al-lergies to metal	1	5	Available medical data indicates allergy to selected metal occurs in 1 of 100,000 people

The analysis, estimation, evaluation, and control steps may be repeated in iterative cycles until the risk is finally brought to an acceptable level. This cycle may also need to be repeated at different phases of the design process as new information about the device and manufacturing process become available.

Step 5: Risk management review

Finally, you've reached the final phase of design controls and the device is ready to be released.

As part of your final design phase review you will need to complete a formal Risk Management Review. The Risk Management Review is simply checking to make sure that the Risk Management Plan has been fully implemented, that the residual risk of the device is acceptable, and that the Risk Management Plan has been updated to include methods and plans for post-production risk activities.

These post-production plans will include identifying sources for collecting data that will be included in future risk analysis and estimation activities. Possible sources include Nonconforming Material Reports, Complaints, Literature Reviews, clinical data, process control data, user feedback, or any other source that may provide useful data.

The Risk Management Plan should also be updated to include defined triggers and timelines for reviewing and updating the Risk Management File. At a minimum, the risk analysis and risk estimation should be reviewed annually and a new Risk Evaluation prepared summarizing any risk data that has accrued. Defined triggers to require a risk analysis and risk estimation review may include: recurring customer complaints, recurring material non-conformances, or a complaint indicating a severe risk.

If there are any design changes or process changes the risk analysis and risk estimation should also be reviewed. This should be built into your change control system as an automatic trigger.

Top tips for success

01. Look in other areas of the standard for risk management inspiration. ISO 14971 has an annex with some great examples of hazards that you may want to consider for your design project. The hazards list in Annex C is a great starting point if you still aren't feeling confident with identifying hazards and harms.

02. Start with a plan. Trying to just "do risk" without a Risk Management Plan and procedures in place is a disaster waiting to happen. It's a controlled methodical process, so start with controls in place.

03. Don't be intimidated. Risk can seem overwhelming and confusing, so you just have to get in there and start writing hazard statements until it starts to make sense. If the grid is difficult to comprehend, write sentences first to help get the process started. For example, "If the pencil coating doesn't properly adhere during drying it could flake off and contaminate a clean room."

04. Don't forget to routinely review your risk materials. Doing the initial pre-market risk management process will get you to market, but if you stop there you are at risk of noncompliance during an audit or FDA inspection. There's increasing focus from international regulators on post-market surveillance and therefore post-market risk analysis. Make sure that you build a system that keeps regular risk review from falling to the back burner.

05. Integrate risk management throughout your QMS. Once you have a handle on how risk management works you can start to see the value of using risk throughout the QMS. You can use risk to prioritize efforts in all areas of your QMS.

A few examples of what you can do by assessing risk across the QMS:

- Document/change control – assign priority and approval requirements
- CAPA – assign priority level and range of actions that are appropriate to address the corrective and preventive action(s)
- Supplier controls – assign level of control required based on
- Internal audits – determine audit frequency
- Management review – assess overall risks within the QMS
- Production – determine inspection requirements, determine maintenance/ calibration intervals

Make sure all of these QMS processes have processes built in to trigger a review of the design risk management file when appropriate. Now you're ready to get out there and build a successful and compliant risk management system to optimize processes, reduce time to market and cut costs.

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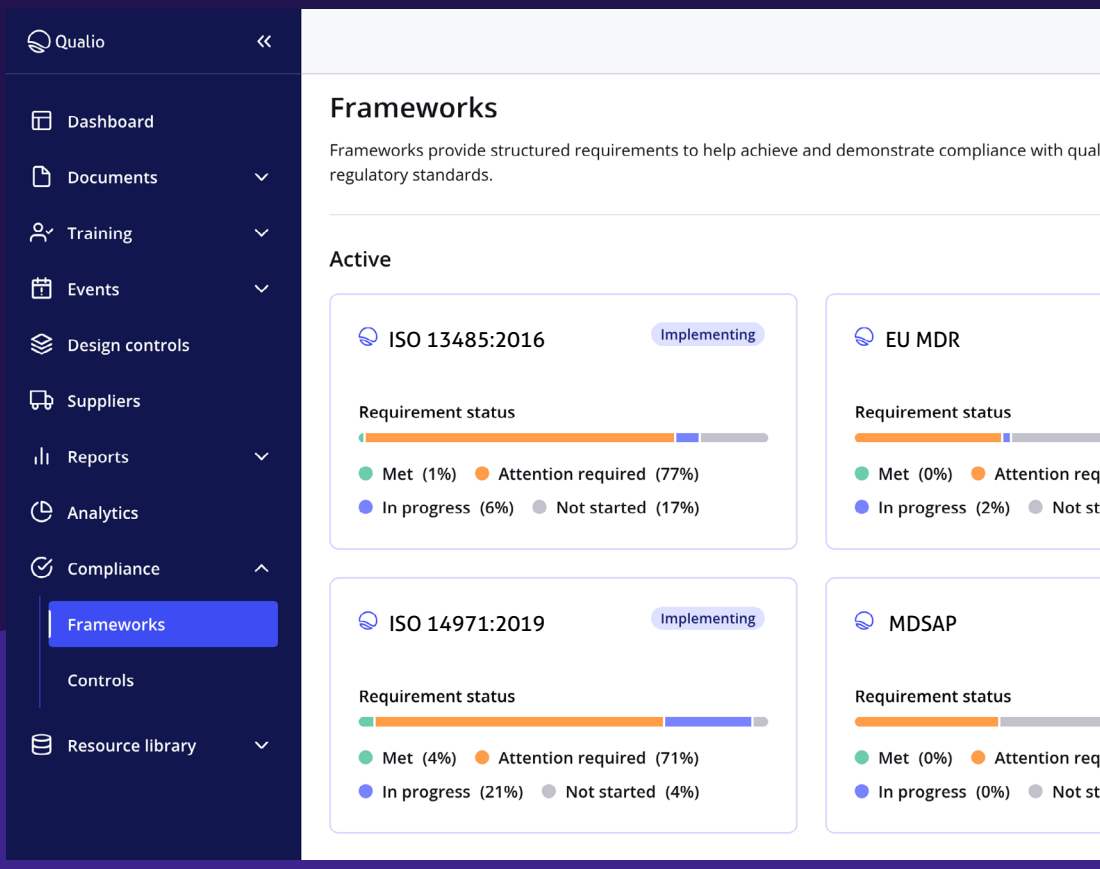

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