CANNON QUALITY GROUP LLC

Risk Management Process:

Medical Device Best Practices & Requirements to Control Risks to Users, Patients and the Environment

A Practical Guide

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Introduction

Medical device companies of all sizes are often concerned about speed-to-market, new device clearance, overhead costs to maintain compliance, lack of certainty on what is needed to maintain compliance and fear of non-compliance consequences. Given numerous regulatory bodies, including the FDA, MHRA (UK), EU MDR, ISO, TGA to name a few, compliance to standards is key to bringing new medical devices to market with success.

Most medical device companies are audited by regulatory bodies at least once per year depending upon their geography. Incorporating a solid Risk Management Process can not only mitigate regulatory risk but also deliver peace of mind to all stakeholders in the enterprise as they launch new products.

Whether you are still using a legacy, paper-based quality management system (QMS) or an electronic Quality Management System (eQMS), risk management is critical.

In general, the Risk Management Process should be applied throughout the lifetime of the device.

Working as a team enables the identification of risks and the implementation of effective risk control measures. This results in a device that is safer for users, patients, and the environment.

The deliverables for the risk management process are interwoven within the Design and Development Process, as risk management is considered throughout the development of a device and whenever changes are made to a device.

In order to succeed in mitigating an organization's risk, it is critical for medical device companies to create a risk management plan for review and also take a condensed approach in which everything is done at once and built into the design and development process. Risk Management cannot be an afterthought and needs to put user, patient and the environment safety first.

Defining Risk

Risk is a combination of the probability of occurrence of harm and the severity of the harm.

It is both required and best practice to consider and control risks to users, patients, and the environment throughout the lifecycle of a medical device.

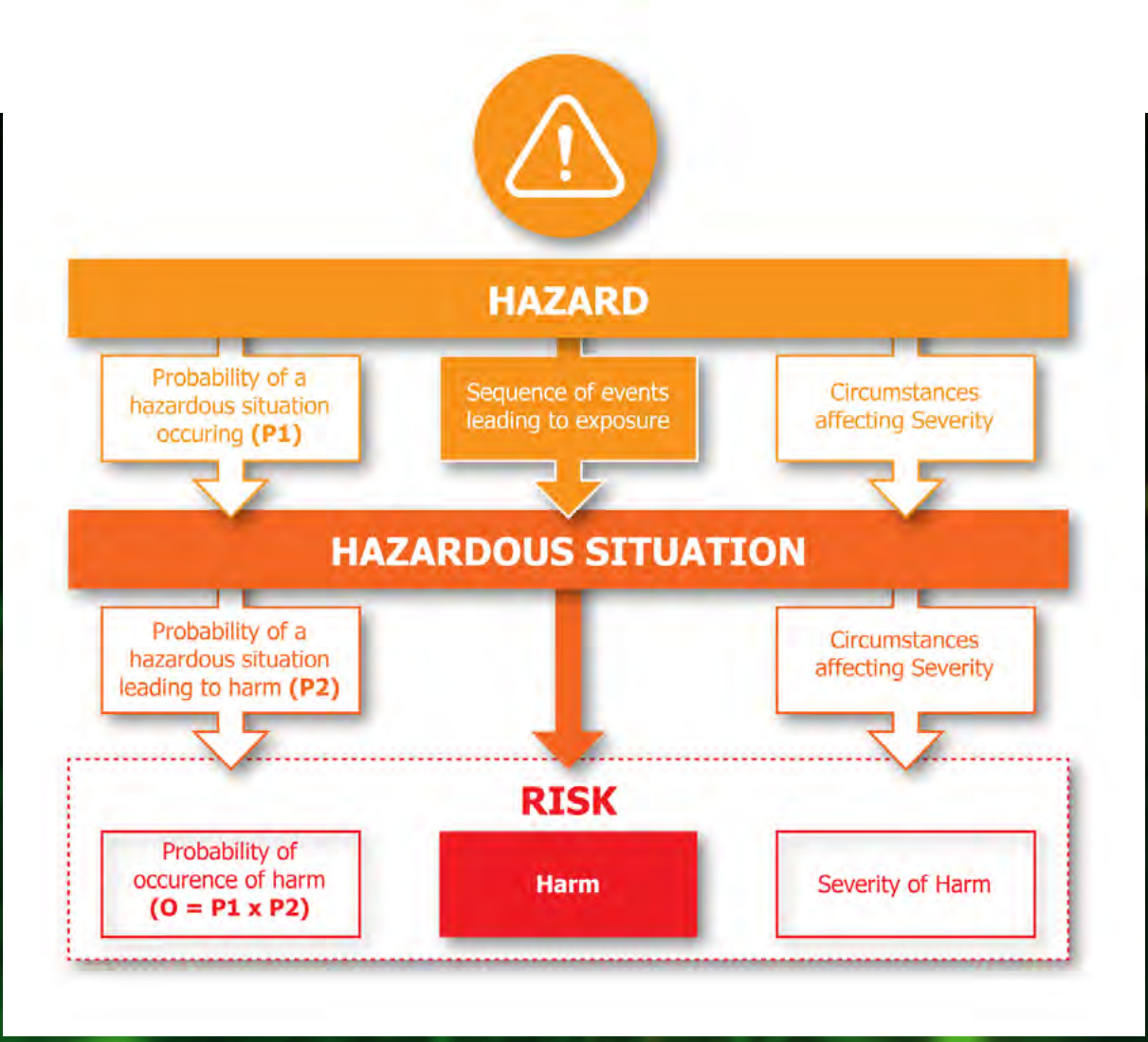
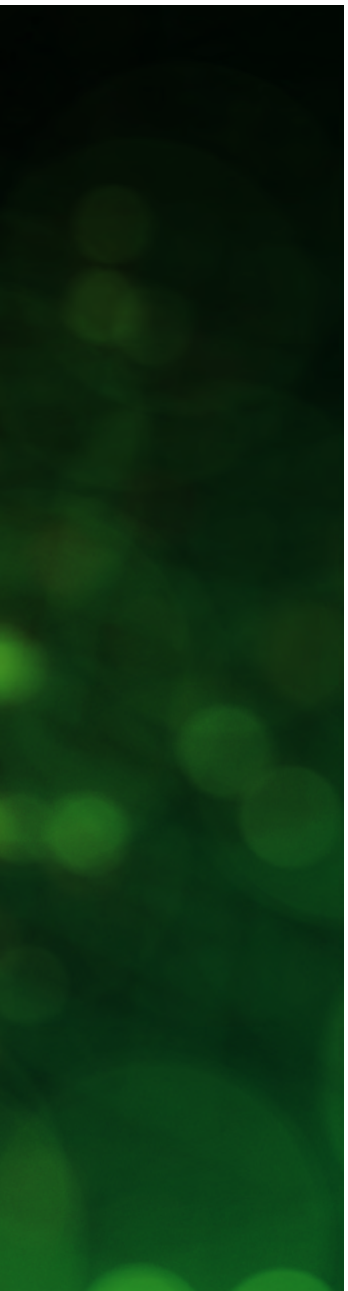


Figure 1.1

5 Best Practices for Managing Risk

The five best practices for managing risk while common sense are critical to avoiding the burden and threat of non-compliance. They include involving stake holders, starting from the top of the organization, communication, deciding on clear risk management processes, and creating an iterative risk monitoring process. Imperative to these best practices is starting the process early, in the design and development phase.



Involve stakeholders. In order to effectively manage risk, stakeholders need to be involved every step of the way, beginning with an initial risk assessment. Stakeholders can include people such as managers, clients, employees, shareholders, unions, etc. Many of these individuals may be key personnel and are key to the company's Risk Management processes. Each of these individuals represent different roles and responsibilities within the organization, thus giving you a holistic representation of all of the aspects of the business and each risk that comes along with it. It is imperative to encourage stakeholders to help improve the continuous risk process by getting them involved in answering the question, "What keeps you up at night?"

Start from the top. The second risk management best practice – and an important step in any successful Risk Management program – is creating a strong risk culture. Risk culture is defined as the values, beliefs, and attitudes about risks by a common group of people. It is the responsibility of management and the board of directors to clearly communicate the company's culture and set the tone for compliance from the top. Management buy-in is critical to ensure that the importance of risk awareness is emanated throughout the entire organization. A good question to ask as a leader or team is, "What is our company's risk culture?"

Communication. The third best practice in risk assessment and risk management is communication. Communicating risks throughout the organization is another important aspect of Risk Management. Key risks, or risks that would have a high organizational impact, are identified and monitored by all departments. Any new risks are identified, assessed, and mitigated properly. Creating awareness of risks through communication to the entire organization is critical to a successful risk management process.

Decide on clear risk management policies. Developing clear risk management policies is the fourth best practice in risk management success. Questions to answer should include:

- Is the Risk Assessment policy clearly documented?
- Are the roles and responsibilities clearly defined?
- Are there clear policies and procedures defining mitigation of any and all identified risks?
- Is there a Business Continuity Plan and an Incident Response Plan in place that map out how the organization will handle and overcome any unforeseen risks?
- Are these policies communicated effectively to all employees?

Having these clear policies developed helps identify all potential risks that could affect the organization, the likelihood and impact of those risks, how the risk is mitigated and prevented, and how new risks are monitored and managed.

Create a Continuous Risk Monitoring Process. The fifth best practice is to set up a process that continually monitors risk. In order to manage risks, risks must be identified. Once the initial risk assessment is performed and the proper controls are in place to mitigate and address these risks, the next crucial step is monitoring. Clear monitoring processes must be established to ensure that any and all risk mitigation efforts are working and effective. This is a crucial aspect of any Risk Management process.

Risk Management, the process of determining what the risks are to the organization and creating steps to mitigate those risks, is critical to the business. It's a continuous and constantly evolving process.

Risk Management Process Overview

Risk Management is incorporated and must be considered at every stage of the development life-cycle AND the defined lifetime of the particular software or device.

Risk Management can also be implemented after production, however, this increases the risk. For example, a recent Cannon Quality Group client with a global reach received recurring FDA 483 warning letters for product combinations and was threatened by a shutdown. It had moved from manufacturing in-house to a model of outsourcing products from overseas, but remaining the manufacturer of record. They needed to resolve the issue fast. A major aspect of the challenge the distributor faced was the fact it was a mixed business with thousands of SKUs of which only a small percent were under regulations. However, the part of medical devices products under FDA scrutiny were a serious threat to the company because it could be shut down and thus impact all of its other non-device products revenues.

Had the company implemented a risk management process earlier, and integrated it into the decision process for this transition, they could have avoided the threat of a shutdown to the entire operation and stress of receiving FDA 483s.

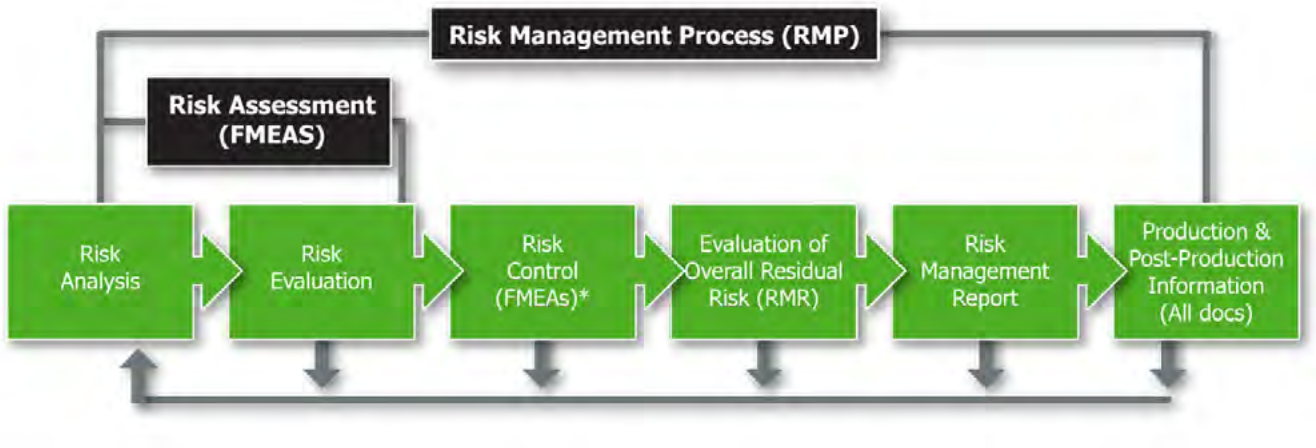
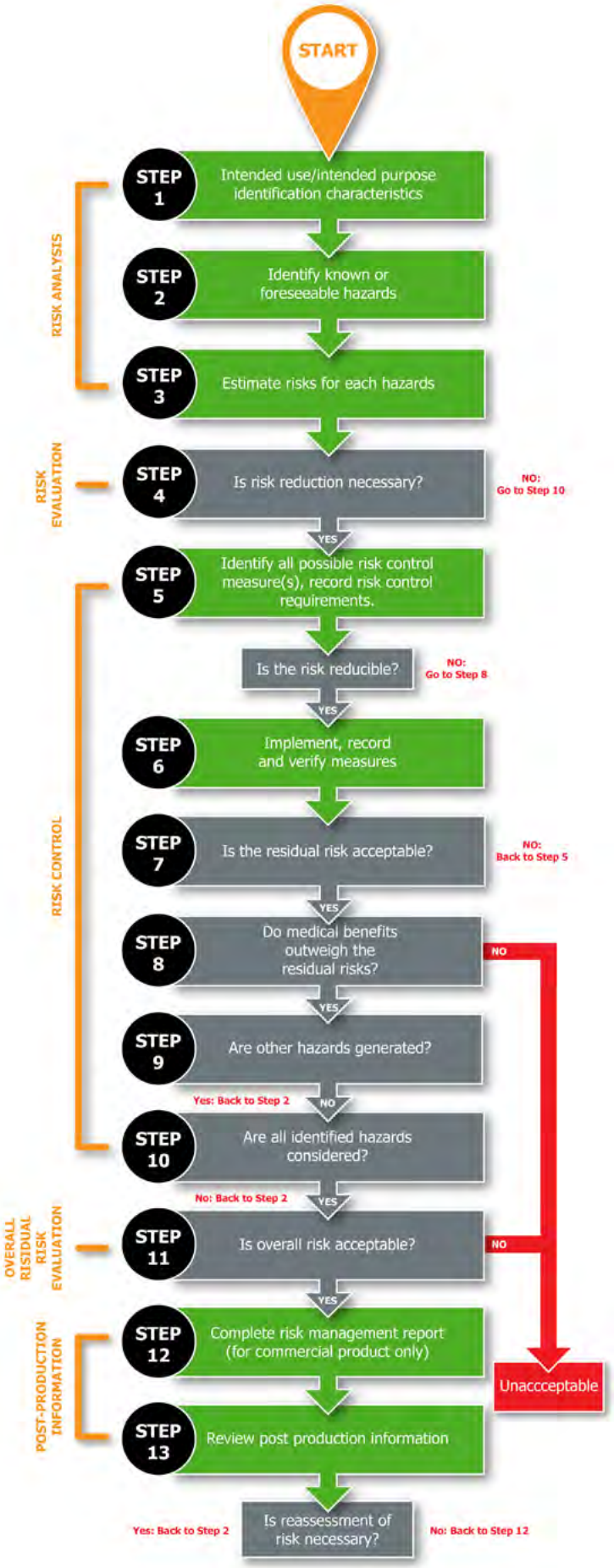


Figure 2.1: Failure Mode Effects & Analyses


START
STEP 1
Intended use/intended purpose identification characteristics
STEP 2
Identify known or foreseeable hazards
STEP 3
Estimate risks for each hazards
RISK ANALYSIS
STEP 4
Is risk reduction necessary?
NO: Go to Step 10
YES
RISK EVALUATION
STEP 5
Identify all possible risk control measure(s), record risk control requirements.
Is the risk reducible?
NO: Go to Step 8
YES
STEP 6
Implement, record and verify measures
STEP 7
Is the residual risk acceptable?
NO: Back to Step 5
YES
STEP 8
Do medical benefits outweigh the residual risks?
NO
YES
STEP 9
Are other hazards generated?
Yes: Back to Step 2
NO
STEP 10
Are all identified hazards considered?
No: Back to Step 2
YES
RISK CONTROL
STEP 11
Is overall risk acceptable?
NO
YES
OVERALL RISIDUAL RISK EVALUATION
STEP 12
Complete risk management report (for commercial product only)
Unaccceptable
STEP 13
Review post production information
POST-PRODUCTION INFORMATION
Is reassessment of risk necessary?
Yes: Back to Step 2
No: Back to Step 12

Risk Analysis

Risk Analysis is the identification of hazards and should consider risks associated with:

- the foreseeable use of the device
- reasonably foreseeable misuse, i.e., "use in a way not intended by the manufacturer, but which can result from readily predictable human behavior."

Risks should consider Design and Use Processes as defined by a risk management plan and initial drafts of a Hazard Analysis or Failure Mode & Effects Analyses (FEMAs) developed by Engineering, Quality Assurance, Clinical Affairs, and Risk Analysis teams.

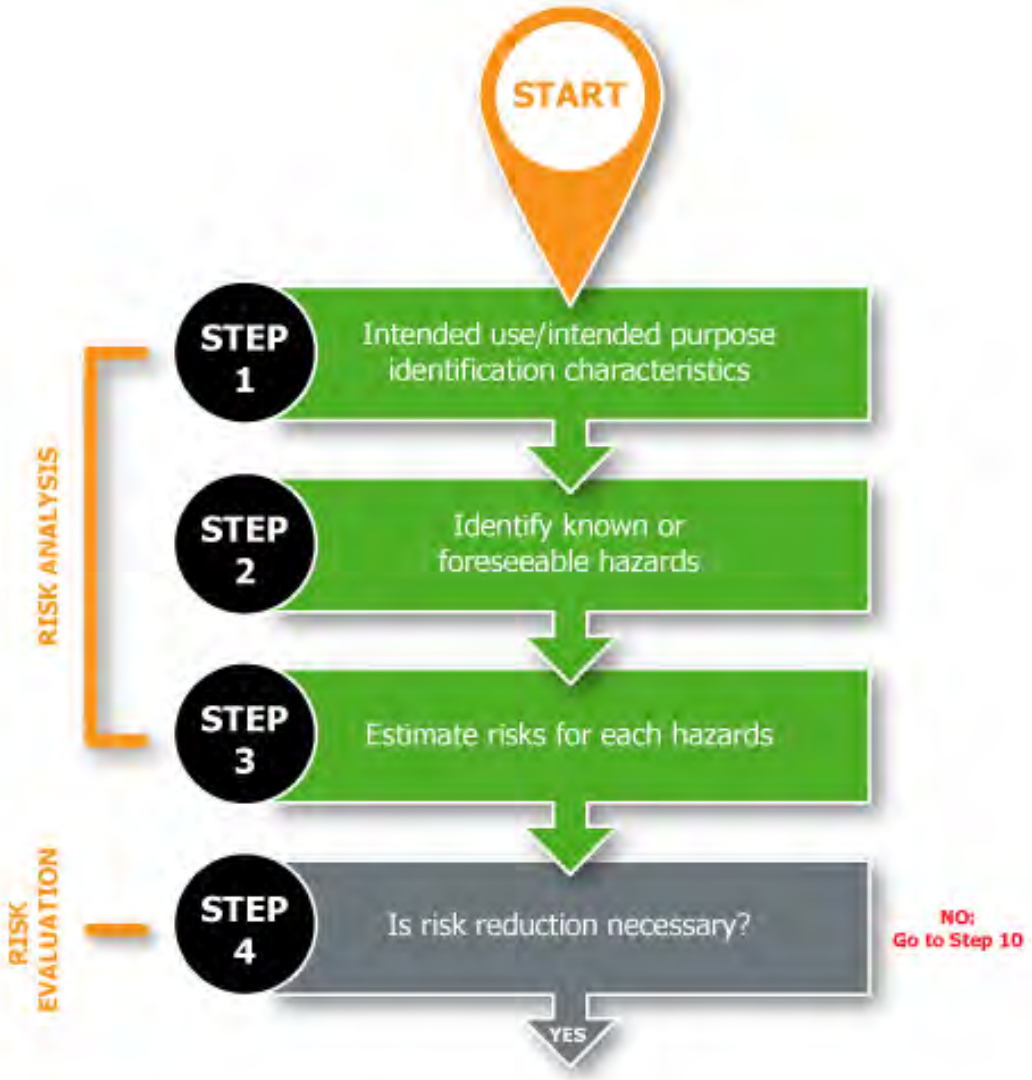


Figure 3.1

Risk Evaluation

Risk Evaluation involves comparing the estimated risk against predetermined acceptability criteria and a predetermined scoring scheme. The goal is to assess all identified risks for acceptability and to identify where efforts should be focused in order to reduce or control the most pressing safety risks.

During the risk evaluation process, *updated* Failure Mode & Effects Analyses (FEMAs) developed by Engineering, Quality Assurance, Clinical Affairs, and the Risk Analysis teams during the Initial Risk Assessment phase are recommended and should be required to mitigate safety risks.

Risk analysis can be a tricky process. Teams can really "what if" anything and when you get into a team environment, sometimes it can turn into a bit of a competition to see what you can find as possible risks. The risk analysis aspect can turn untenable unless you really leverage the risk evaluation process. This is where teams can flush out those really rare or impossible scenarios.

For example, we have a client in the pediatric space that has both hardware and software (embedded and app) which can get interesting in a risk development process. This client's engineering and scientific teams really took pride in debating potential risks, and locked into the process and the productivity potential of the process once they started working with the evaluation scoring. This step in the risk evaluation process helps the team laser focus and flush out where their development and mitigation energies can be prioritized to improve productivity.

Figure 4.1

Risk Control

Risk Control is the process by which risks are reduced to or maintained within acceptable levels. The goal is to improve the safety of the device through design, for example, new design requirements or labeling, including warnings in instructions for use (IFU) or other labeling.

During the risk control process, updated Failure Mode & Effects Analyses (FEMAs) as well as any design/testing documentation (as necessary) developed by the Engineering, Quality Assurance, Clinical Affairs, and the Risk Analysis teams should be leveraged to help improve the safety of the device.

The sooner the risk process is started in the design process the more risk measures can be integrated into the design with a minimal impact on the overall program timing. In scenarios where risk management isn't integrated early and control measures need to be implemented later in the design process, it drastically impacts timelines and product goals and can delay time-to-market. In addition, the result can be a product that has "band-aid" solutions causing a less ideal product released to the market versus a well integrated solution with risk control included into the sleekness of the design. Incorporating risk control early in the design process, is inherent in the scientific process and good development hygiene.

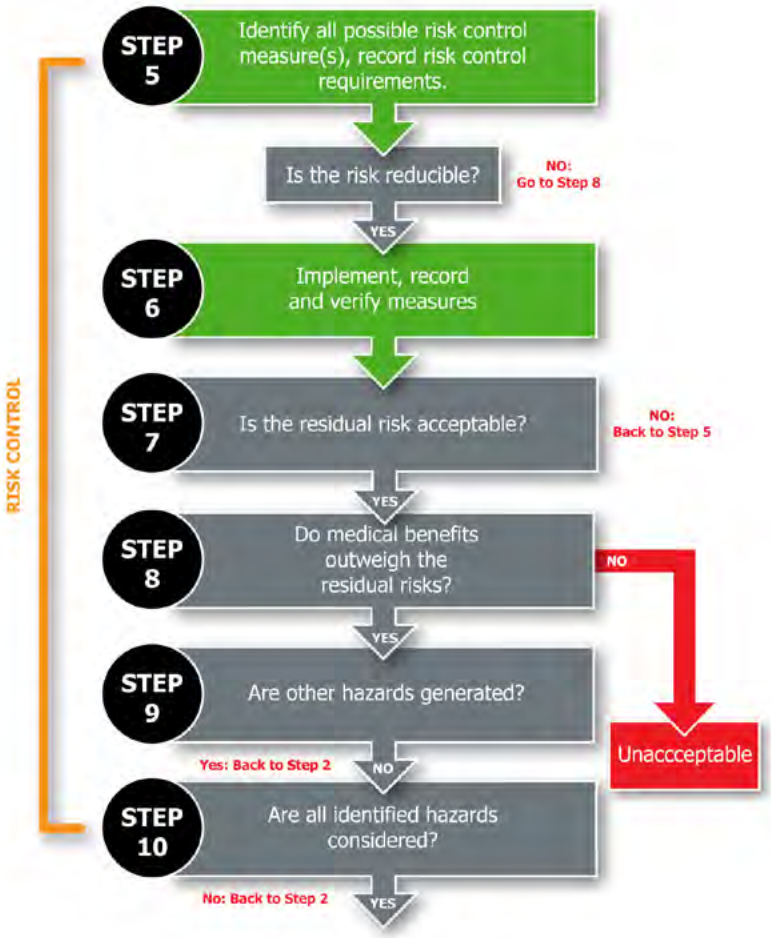


Figure 5.1

For example, most of Cannon Quality Group startup companies develop their product ideas with risk as part of their process and find implementing a structure early on aids their development process. Risk control can be a competitive advantage for startups by helping speed-to-market, ensuring quality and designing an ideal product.

Overall Residual Risk Evaluation

Overall Residual Risk Evaluation makes the determination of whether the overall benefits of the device outweigh the risks of the device. If it is determined that the overall benefits outweigh any residual risks, then the device is considered acceptable for release.

The process should include a comprehensive Risk Management Report provided by the Quality Assurance, Clinical Affairs and Engineering teams.

Figure 5.2

Post-Production Risk Mitigation

The following risk mitigation processes are recommended to ensure ongoing risk management success:

- Periodic review of product quality trends, e.g., bug reports
- Supplier quality audit assessments
- Customer complaint and feedback handling protocols
- Ensuring design changes on commercial products are evaluated from a risk management perspective
- Updating of the risk management framework (RMF) as new risks are identified and existing risks are further understood

Figure 6.1

Summary

The Risk Management Process should be applied throughout the lifetime of the device.

Working as a team enables the identification of risks and the implementation of effective risk control measures. This results in a device that is safer for users, patients, and the environment.

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About Cannon Quality Group

Cannon Quality Group provides outsourced Quality Management System solutions that are efficient and compliant. Cannon's number one priority is delivering QMS solutions that make sense for the stage and goals of its clients' business. 88% of past clients are still in business and 30% have been acquired or gone public. Cannon Quality Group's mission is to be **the Change in Quality.**

Our Quality Management Services

ISO 13485:2016 & FDA 21CFR820

If you're in the MedTech industry, you know you must comply with the rigorous standards set by different organizations. The ISO 13485:2016 is specific to medical devices and imperative for products going to market. By having your device meet all the requirements set by this standard as well as FDA 21CFR820, you can be sure your medical device will meet the extensive safety and performance requirements for consumers, suppliers and more.

Supplier Audits

A Cannon Quality Group shared supplier audit can save your company up to 50 percent by splitting the auditor cost with other companies needing the same information. CQG can also perform supplier audits on short notice for clients who find themselves in a pinch.

Internal Audits

Regular auditing of your internal processes and procedures is a cornerstone of good quality management. You can meet your requirements for internal auditing more easily by hiring Cannon Quality Group's experienced auditors to come in and give you a fresh perspective on your quality system or perform a gap analysis.

QMS Implementation and Maintenance

Allow our quality team to fine tune your medical device's QMS system. We'll implement a simple, risk-based system while you focus on other mission-critical tasks for your company.

Quality Projects

Cannon Quality Group is comprised of experts who can mesh with your company's workflow and goals to help you complete quality projects such as ERP implementation, post-audit remediation, and more.

Controlled Environment Room (CER)

If you are considering building a Controlled environment room at your facility, Cannon Quality Group can help you every step of the way up through validation to ensure your room is compliant with all relevant requirements. If you're looking for a CER in the meantime, we maintain our own CER in Redwood City, CA.

Founders Club Memberships

When you become a member of Cannon Quality Group's Founders Club, you'll gain access to our shared space facility which is equipped and ready for testing. Complete with a controlled environment room, this area offers storage space, a CDA system, lab benches, and has an ISO Class 7–certified CER.

FDB Certification/Audits

When you need a quality management system that meets the standards of the California Food and Drug Branch, you can count on Cannon Quality Group. Whether you need to prepare for certification or require a professional audit to completely review your current quality system, we can be of service.

First in Human

To prepare for such a milestone, you must first secure IDE approval (Investigational Device Exemption), which requires quite a bit of documentation. Cannon Quality Group helps you navigate the proper documentation and will ensure that you have what is necessary for approval.

FDA Audits/FDA Clearance/QSR Compliance

Are you ready to file your submission and want to ensure you have a quality system in place that can stand up to the scrutiny of the FDA? Cannon Quality Group is well versed in the rules and guidelines set forth by the Food and Drug Administration and can help make sure your product and quality system are up to code.

Complete Outsourcing

While quality control and assurance are important to your company's success, we understand it is not your core business. Cannon Quality Group represents a chance for you to have the most simple, effective QMS procedures in place without having to hire your own department. We can take on entire projects and also offer interim and part-time staffing options.

Contact Us

Contact us online or call us today to learn more about our quality management systems solutions.

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