COMPLIANCEQUEST
Quality . Compliance . Collaboration . Communication

WHITEPAPER

A 7-Step Guide to Quality & Compliance for Medical Devices Companies

Get to know how a Modern EQMS platform like ComplianceQuest can help

Quality is never an accident. It is always the result of intelligent effort.

– John Ruskin

Leading English art critic of the Victorian era

Introduction

Quality is a key responsibility required of all successful medical device companies worldwide. Quality & Compliance related parameters not only drive operational and financial efficiency but also serve as a competitive differentiator. Why?

- Customers require it
- Regulators demand it
- Competition compels it
- Stakeholders (Employees and Partners) support it.

Are you implementing quality assurance for those reasons alone?

More than any industrial segment, medical device manufacturers need to ensure the quality of their products because they deal with human safety. The accuracy and efficiency of the devices' performance could well be a matter of life and death. The safety and proper performance of the device astronomically increase with each level of the Class that the device is categorized under. Class III device manufacturers are scrutinized more than that of Class II and Class II is scrutinized more than that of Class I.

That's not all. If you are a medical devices manufacturer, here are a few more reasons why you must focus on implementing a platform-based quality system based on best practices:

1. *To reduce manufacturing costs*
2. *To improve productivity*
3. *To increase customer satisfaction*
4. *To increase profitability*
5. *To beat the competition*
6. *To protect your brand reputation and build on the relationships that may take years to create!*

There are several examples of how quality-related errors have cost medical device firms badly. For example,

a. A medical device firm had to recall its Flo Humidification Systems due to malfunction with the potential danger of water entering the respiratory airway, a life-threatening risk in some cases. The FDA classified this as a Class 1 recall.

b. In another instance, non-invasive and invasive ventilators from one manufacturer were recalled due to sound alarm failure, again a mission-critical risk that could have been prevented with a more robust quality process in place. This was also classified as a Class 1 recall by the FDA.
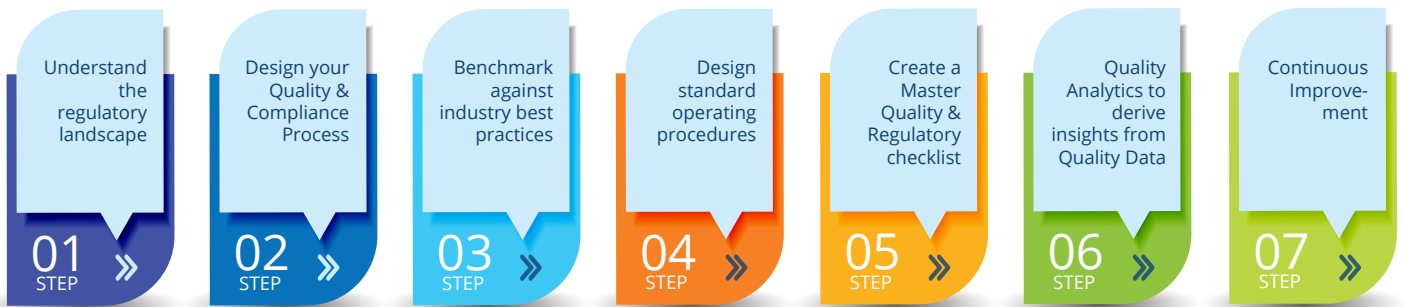
Implementing quality best practices is essential for each manufacturer in more ways than one. An automated, highly integrated and next-generation, enterprise-wide

quality management system such as the one provided by ComplianceQuest can provide deep insights that can go beyond quality assurance and help increase the efficiency and effectiveness of the medical device manufacturer's operations and processes.

Successful implementation requires a simple 7-Step approach:

"Quality is not what happens when what you do matches your intentions. It is what happens when what you do matches your customers' expectations."

– Guaspari, a notable wine producer

01 STEP	02 STEP	03 STEP	04 STEP	05 STEP	06 STEP	07 STEP
Understand the regulatory landscape	Design your Quality & Compliance Process	Benchmark against industry best practices	Design standard operating procedures	Create a Master Quality & Regulatory checklist	Quality Analytics to derive insights from Quality Data	Continuous Improvement

Step #1: Get the Basics Right: Understand the Regulatory Landscape

Just between January and March of this year, there were 20 recalls of medical devices due to non-compliance and improper functioning of the products. It reiterates the fact that the regulatory landscape is becoming very stringent in demanding compliance to ensure safety. It addresses not just the quality of the end product but the entire process followed from "design to customer service". No defect is being overlooked and the product immediately recalled if it does not meet specifications.

Without a doubt, this can have serious revenue implications for the manufacturer. It can also cast aspersions on their reputation with serious repercussions. For instance, according to a McKinsey report, at least one company saw a 10 percent drop in share price due to a single, crucial quality event such as a major product recall.

A 2017 report shows that the cost of quality is approximately 6.8 to 9.4 percent of industry sales. Considering the annual sales of the industry was $380 billion, this amounts to $26 billion to $36 billion annually. Getting the quality process right on the other hand, costs much less, while also having second and

third-order positive effects on the enterprise brand.

Here we highlight all key regulatory frameworks and the compliance landscape:

FDA 21 CFR Part 11

Part 11 of Title 21 of the Code of Federal Regulations applies to the creation, modification, maintenance, archival, retrieval or transmission of electronic records with proper authentication and authorization. The documents referred here encompass textual content, images, videos and audio files, and include:

- Release and test protocols
- Process and work instructions
- Design drawings, software architecture documentation
- Specifications, request documents
- Records, e.g. production records
- Review protocols

The regulation also covers the nature of digital signatures used, and defines identification codes and passwords.

FDA Software Validation

Following the recall of 3,140 medical device recalls,

where 242 of them (7.7%) were because of software failures, and 192 (or 79%) of that was because of software defects, FDA made software validation mandatory. Whether the software is a component of the medical device used in the manufacturing process, or the medical device itself, it needs to conform to applicable design control provisions. This is to ensure their accuracy, reliability, consistency and performance as intended and the ability to discern invalid or altered records. Early this year, system infusion pumps were recalled due to software and system errors, which could have been avoided with a proper software validation process.

ISO 13485

This International Standard covers every stage of the life-cycle of a medical device from design to development, production, storage, distribution, installation, servicing, final decommissioning and disposal of medical devices. It is also applicable to suppliers or other external parties involved in any stage of the manufacturing process. Certification is optional but can be beneficial. The standard undergoes revision every five years, with the latest revision focusing on risk management and risk-based decision making.

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> *We have implemented CQ in a new medical device startup. The setup and implementation went very smooth and the support from the provider has been outstanding. The system fully supports compliance with ISO 13485.*
>
> ***Some of the reasons why I would recommend the software are:***
>
> - *100% cloud-based*
> - *Allow almost paperless Quality Management System*
> - *Excellent customer support*
> - *Simple set up and implementation*
> - *User friendly*
> - *Efficiency and security*
> - *Accessible cost for small companies.*
>
> "

Laura Granados
QMS Systems Development Consultant

EU's MDR and IVDR

The European Union's revised Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) place a greater demand on manufacturers to significantly change their product development, data reporting and quality assurance processes.

It addresses the classification of medical devices based on risk assessment. New products will need to be certified accordingly while the older ones in the market will have to be recertified based on new norms.

MDSAP for Reducing Audit Costs

The Medical Device Single Audit Program (MDSAP) allows a single regulatory audit of a medical device manufacturer's quality management system and is an aggregation of the requirements of the regulatory jurisdictions of Australia, Brazil, Canada, Japan and the United States. This aims to minimize the regulatory burden on the industry as well as on regulatory resources while aligning regulatory approaches across the globe, unifying technical requirements based on international standards and best practices.

For device manufacturers who cater to global markets, being part of MDSAP, which is voluntary, will prove to be cost effective. But still, since Europe is not a part of that, and catering to the different regulatory requirements will mean understanding the variations and conforming, medical device manufacturers face the challenge of coping. This adds the pressure of hiring resources with skills and capabilities, which is both costly and takes the management time away from their core business to focus on compliance issues.

Broadly speaking, to be able to successfully manage the varying demands of the different stakeholders, the organization needs to be on its toes always. Sometimes, it can be a matter of fire-fighting rather than introducing proactive measures. Proactive responses that integrate with the business plans is possible by the implementation of a well-planned out quality and compliance process that is aligned to the organization's maturity level.
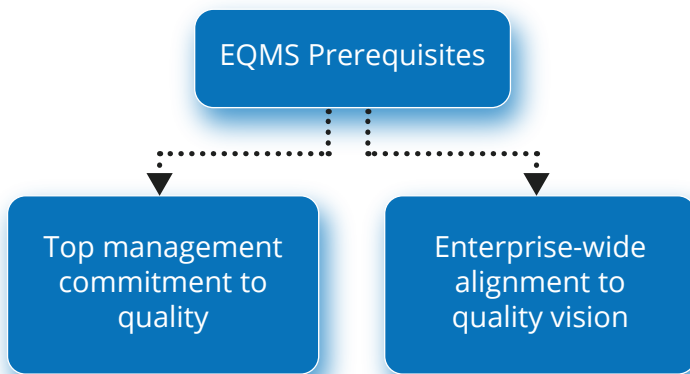
In this blog by ComplianceQuest, we share a brief overview of major trends in the Lifesciences industry and how an EQMS can help.

"Quality is the result of a carefully constructed cultural environment. It has to be the fabric of the organization, not part of the fabric."

– *Philip Crosby, one of the early specialists in quality management popular for his concept of 'Zero Defects'*

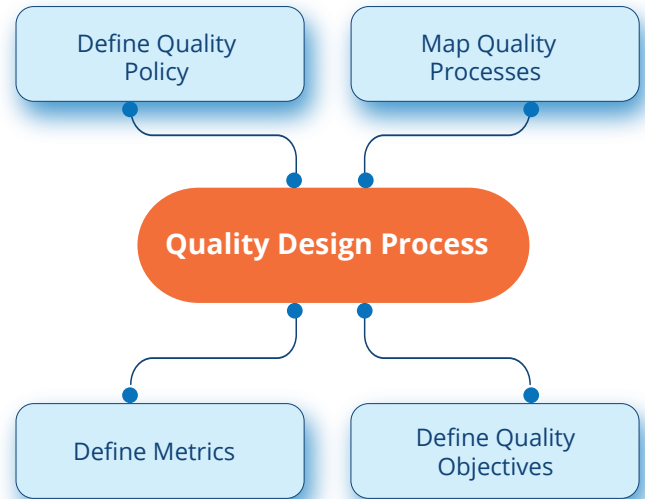## Step #2: Design Your Quality & Compliance Process

An enterprise-wide quality management system like the cloud-based solution from ComplianceQuest can facilitate meeting the quality goals of the medical device manufacturing company. But, before choosing one, an organization must identify its quality goals based on the maturity level of the company. Based on that, it will have to establish a process that meets a few prerequisites.

```
            EQMS Prerequisites
         ┌──────────┴──────────┐
  Top management          Enterprise-wide
  commitment to           alignment to
  quality                 quality vision
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Also, there should be an assessment of the status of the current quality practices and areas that need improvement. This will facilitate the development of the quality goal and designing an efficient but end-to-end quality process. The goals should be delineated as a quality policy and detailed in a quality manual elaborating the scope, procedures, guidelines and checklists for implementation and measures for

continuous improvement.

The policy will delineate the procedures as required by the compliance standard, enabling effective planning, operations, monitoring and control.

```
  Define Quality        Map Quality
  Policy                Processes
         └──────┐    ┌──────┘
          Quality Design Process
         ┌──────┘    └──────┐
  Define Metrics        Define Quality
                        Objectives
```

Some of the metrics to measure success would be:

a. Financial Performance,
b. Product Quality,
c. Process Improvement,
d. Customer Satisfaction,
e. Market Share, and
f. Employee Satisfaction

Maintaining documents and records of every process and every revision is essential even for compliance needs. While it may seem like additional work, it is beneficial for the organization in the long run and so needs to be part of the process being designed.

Training to be able to follow the quality process at every level is essential for the organization to meet its quality goals. It is not only about having the requisite skills for the task at hand, but also for following the processes as laid down in the policy. A good EQMS will have a robust document management and training solution, one that'll ensure a culture of quality spreads far and wide across the enterprise.

ComplianceQuest is a flexible and scalable EQMS that's designed to serve the Medical Device sector. Visit www.ComplianceQuest.com to schedule a demo or talk to an expert.

Step #3: Benchmark against industry best practices

Business is sometimes about beating the competition to improve your growth prospects. There are many ways to do that, but the one that gives long-term benefits is the battle fought on quality and value proposition. This requires a great understanding of the industry's best practices and imbibing them in one's organization. This could be in quality practices, digital transformation, through collaborations and data management.

Quality and Compliance Practices

The five areas where you can establish benchmarks include:

1. Supplier quality management by tracking and managing global suppliers, establishing metrics for their performance for the purpose of training if they fall short

2. Change management through the enforcement of rigorous change control procedures across the organization

3. Complaint handling by integrating the process from the time of registering the complaint to discharging it, to the satisfaction of the complain-ant or the relevant authorities

4. Electronic medical device reporting (eMDR) by automating and streamlining report submission processes for greater efficiency and accuracy in compliance

5. Corrective and preventative action (CAPA) management to trace the root cause for manufacturing deviations, correct them and implement measures to prevent future product safety issues

Digital Transformation & Automation

To improve competitiveness and keep costs low in these times of high competition and heightened customer awareness, businesses are turning to Industry 4.0 or digital transformation technologies for greater efficiency and productivity. These include:

a. Integration of Internet of Things with telemedicine and telehealth technologies called

b. Internet of Medical Things (IoMT)

c. Wearable medical devices to measure critical health parameters

d. Mobile-ready solutions

e. Leveraging artificial intelligence and machine learning to reduce human intervention

f. Use of augmented reality/virtual reality for simulating situations in medical research for greater accuracy and insights

g. Data management and analytics for gaining insights into current practices, understanding their implications and projecting future trends

According to McKinsey, the use of Industry 4.0 technologies such as advanced analytics, robotics and automation can change the way the life sciences industry works and productivity has increased by 30 to 40 percent in mature and efficient lab environments. Further digitization can improve it to 50 percent, while ensuring better quality and compliance, reducing manual errors and variability and enabling quicker and effective resolution of problems. There can be 65 percent reduction in deviations, 90 percent faster closure times, cost savings due to better compliance, improved agility, shorter testing times and faster releases.

Collaboration & Mobile Readiness

Manufacturers are compelled to shrink time-to-market while keeping their cost of manufacturing low. In a bid to keep costs low, consumers are aggregating their buying through group purchasing organizations (GPOs) or centralized purchasing groups, which is further driving down prices.

On the other hand, it takes a medical device three to seven years of time-to-market on an average, and the cost could range from $31 million to more than $90 million for high risk products and thus averaging a cost of $30M/year on the high end to $3.50M/year on the low end. Any reduction in time to market has a significant impact on the Company's financial performance and thus to the shareholder returns/value.

This is compelling medical device developers to collaborate with contract manufacturers and suppliers to reduce their cost of development and manufacturing and protect them against any delays in supply and

production challenges. Proactive collaboration is proving to be a key risk management solution, leveraging the resources of the partners to cut down on overheads.

For effective collaboration, the following Partner traits are essential:

a. An understanding of the capabilities and market reach

b. Commitment to collaboration

c. Driven to manufacturing safe and effective devices

d. Risk management capabilities

e. Transparency

Seamless integration of processes between the collaborating teams and mobile-readiness has become important.

> ## ComplianceQuest is above the rest!
>
> *As a long time life sciences Quality Systems professional and leader, I have been exposed to many different Quality System tools and implementations. Some of these implementations have been nightmares with timelines that drag on and resource drains that can never be regained. ComplianceQuest, however, stands tall in my experience as a true cloud-based, SalesForce eQMS application that is quite ready to go, out of the box. With minor configuration and data migration, it is ready to fit any business model. Powerful analytics and real-time collaboration are at your fingertips within weeks, not months or years! I have witnessed these transformations first hand and hands down, ComplianceQuest is above the rest!*

Tim Bright
Director of Regulatory Affairs & Quality Assurance at IsoAid

Step #4: Well Established Standard Operating Procedures

A documented Standard Operating Procedure (SOP) lays down the rules for how tasks must be completed in your organization. Also, the subject matter experts along with the resources responsible to carry out the activities identified in SOPs must work collaboratively to create robust SOPs. By following this will;

a. Give a structure to your quality systems and processes

b. Ensure the delivery of services and products consistently every time

c. Demonstrate compliance by ensuring strong document management, internal audits, and effective CAPA processes

d. An EQMS like ComplianceQuest can aid the automation and digital transformation efforts of a medical device firm, by delivered a flexible, customizable and scalable EQMS platform. Based on your specific business needs for quality and compliance, the tool can be customized and designed for your process.

The Quality Leader & Team's Role

The responsibilities of the quality leader are not restricted to motivating his team to implement quality assurance but bring about an enterprise wide change in the attitude of all employees across functions. By establishing a quality policy, laying out standard operating procedures and providing training, he ensures that all employees are:

- Equipped with information on safety, health, environmental and operational information that can help them discharge their role effectively, aligning their actions to the quality goals

- Diligently following quality control in their respective functional areas consistently

- Completing their tasks as scheduled, with minimum downtimes

- Ensuring socially and environmentally responsible manufacturing practices to protect the surroundings and contribute to community development

- Complying with the company and government regulations
- Following the checklist

Rest of the Organization

Quality is not the responsibility of the quality leader or his team alone. While they provide an overall direction to the quality efforts of the organization, it has to become part of the DNA of business that the existing employees and newcomers also imbibe this culture and implement it without fail. The senior manager of the functional area must lead from the front, ensuring documentation and process control. With the cost of quality what it is, taking ownership of their processes and ensuring quality at every step of the way is critical to reducing errors, time to market and improve customer satisfaction.

"Quality is the best business plan."

– John Lasseter, former chief creative officer of Walt Disney Animation Studios & Pixar

50,000+

Users in the Medical Device sector use ComplianceQuest to power many different quality and compliance processes within their enterprise.

Join Them! Visit www.ComplianceQuest.com to schedule a demo.

Step #5: The Master Quality & Regulatory Checklist

In early 2020, a Video Laryngoscope Adapter was recalled due to the display of images in reverse. A simple check before sending the product out would have prevented this problem. All it needed was a checklist with an item 'Check image quality'.

The airline industry has long used checklists to help pilots and aviation professionals deal with unexpected snags. Atul Gawande, a doctor, actually authored a book titled 'The Checklist Manifesto' to help doctors and healthcare service providers avoid manual mistakes while treating patients. He suggested hospitals and healthcare providers develop a checklist strategy much like Boeing, the aircraft manufacturer, does. Our suggestion is not different. We strongly recommend to quality leaders to build a checklist strategy to ensure key steps and done and ticked off.

Mistakes are often made by missing, simple-to-do but manual steps. The checklists outline the quality standards and product requirements that everybody down the supply chain is expected to meet, be the suppliers, the workers on the shop floor, the finance team, the procurement team and even the frontline sales team to customer service. Secondly, it helps in ensuring that the product satisfies customer expectations by establishing objective criteria.

Share a detailed quality assurance checklist with your supplier in advance, giving them time to come up to speed or inform you in case of any deviations.

Design a Single Checklist Across all Regulatory Frameworks

As we saw, every region has its own set of regulatory requirements, not meeting which can end up in penalization as well as product recalls. But manually remembering and checking to ensure compliance can be difficult as well as prone to errors. A checklist for regulatory compliance can make all the difference in reaching your product to the intended customer and should be part of your SOP before shipment.

For the checklist to be effective:

a. It should be clear and direct, making it easy to read and understand

b. If you are importing supplies, get it translated into his language for reinforcing clarity

c. The checklist template should be all-encompassing and include:

   i. *Packaging requirements including the material being used for packing, labeling, product specifications*

   ii. *Product requirements such as the specifications, the material and construction, color, markings and labeling*

   iii. *On-site tests and checks that your product and packaging need to pass such as barcode scan check, carton drop test, function test or hi-pot test*

Step #6: Quality Analytics for Deriving Insights from Data

Having an enterprise-wide automated quality management system provides medical device manufacturers access to data from across functions. This is a goldmine that can be used to understand trends, problem areas and forecast the future for improvement and devising business strategies.

Gold Source of Quality Data

A good EQMS is a data mine that can validate and authenticate data collected, organized and stored in a database with a dashboard for reports. Data modeling tools can help identify bottlenecks to quality and even give a direction for appropriate solutions.

a. A customized dashboard for every function

b. An early warning system for potential problems

c. Up-to-the-minute information

d. A consolidated view across the systems

e. An easy to use, drag and drop report builder

f. Integrated security to control access to data based on requirement and authorization

g. A robust reporting schedule

h. Generation of customized reports

i. Collaborative feedback

Step #7: Continuous Improvement in a Loop

The quality journey is not a one-time affair. Nor is it stagnant. A more aware customer and an equally aware regulator are constantly upping the demand on the medical device manufacturers to become stringent in applying the rules, to make cheaper, safer and better products. The regulators keep revising the expectations, and the manufacturers have to keep track of the changes to implement them following these seven steps again.

A good EQMS like the one from Compliance Quest allows its customers a bird's view and a detailed view of the various processes, their progress and their efficiency, enabling:

a. Compliance

b. Flexibility and scalability

c. Automation

d. Configurable workflows, user interface design and object design

e. Mobile-readiness

f. Multi-lingual readiness

g. Reports and analytics

The enterprise quality management system from ComplianceQuest leverages the cloud-based platform from SalesForce.com and is built to meet Quality 4.0 requirements through its 12 modules:

1. Audit
2. CAPA
3. Change Management
4. Complaints handling
5. Document Management
6. Equipment Management
7. Incident Management
8. Inspection
9. Non-conformance Management
10. Risk Management
11. Supplier Management
12. Training

Life Sciences is a special area of focus for ComplianceQuest, which has the required experience and expertise to understand the unique needs of the industry and provide bespoke solutions.

At ComplianceQuest, we've helped over 50,000 users across the life sciences domain and manufacturers alike in automating their EQMS process with a flexible and scalable solution. Our scalable platform is elastic to serve firms of various sizes - Fortune 500 companies to start-ups and mid-size companies.

Write to marketing@compliancequest.com to request for a demo.

About ComplianceQuest

ComplianceQuest, an innovative 100% cloud-based Enterprise Quality Management System solution company, provides an enterprise grade solution platform that streamlines quality, compliance, content and collaboration management initiatives and strategies across your enterprise and globally based supply chain networks. ComplianceQuest helps accelerate manufacturers and distributors to accomplishing their most challenging quality, compliance and supplier management goals.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today.
- Visit www.compliancequest.com • Email us at info@compliancequest.com • Call us at **408-458-8343**