



# HOW TO ENHANCE THE PATIENT EXPERIENCE WITH QUALITY MANAGEMENT SYSTEMS

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# INTRODUCTION

Healthcare is an intricate and dynamic world where high-quality patient care is the ultimate goal. Quality of care is the degree to which health services increase the likelihood of positive outcomes. From this springs value-based care, which focuses on improving patient outcomes while simultaneously controlling costs.

The rise of chronic disorders, the increasing adoption of eHealth, and evolving government regulations have driven initiatives to digitize healthcare and demand smarter healthcare systems. In 2022, the Smart Healthcare Market was valued at USD 184 billion and is expected to reach around 541 billion by 2032.<sup>1</sup> Ensuring consistent value-based care starts with implementing an effective Quality Management System (QMS).

This whitepaper serves as an essential guide for healthcare professionals, administrators, and service departments that aim to enhance patient outcomes and service quality by implementing a smart QMS. By exploring the evolution of quality management in healthcare, the crucial role of leadership, operational planning, and continuous improvement, this article provides a comprehensive overview of how quality management technology can transform healthcare organizations for the better.



<sup>1</sup><https://market.us/report/smart-healthcare-market/>

# QUALITY IN HEALTHCARE: A BRIEF HISTORY

Quality management in healthcare has significantly evolved over the years, shaped by various standards, regulations, and accreditations designed to ensure the highest level of patient care. Today, it's a thriving market that's projected to reach \$3.31 billion by 2025.<sup>2</sup>

This transformation has been marked by a shift from basic care delivery to a more structured, holistic approach, which involves all facets of healthcare organizations, including service departments. Here's a brief history of quality in healthcare:<sup>3</sup>

## THE EARLY BEGINNINGS

The roots of quality management in healthcare can be traced back to the early 20th century. In the beginning, efforts were primarily focused on improving clinical outcomes through better practices and procedures.

Professional organizations, such as the American College of Surgeons (1913), led to the development of the first hospital standardization program (1918). This is the program that set the stage for modern accreditation and quality assurance processes.

## THE ADVENT OF ACCREDITATION

The mid-20th century marked a rise in formal accreditation bodies. Founded in 1951, the Joint Commission on Accreditation of Hospitals (now called The Joint Commission) became a pivotal player in setting standards for hospital care.

The Joint Commission's accreditation process provided a benchmark for hospitals. These standards focused on improving patient safety and care quality through compliance.

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<sup>2</sup><https://worldmetrics.org/healthcare-quality-management-industry-statistics/>

<sup>3</sup><https://www.accruent.com/resources/blog-posts/quality-healthcare-brief-history>



## THE ROLE OF CMS

Established in 1965, the Centers for Medicare & Medicaid Services (CMS) has also been instrumental in shaping healthcare quality management. CMS administers the nation's major healthcare programs, which include Medicare and Medicaid.

CMS sets the quality standards and conditions of participation for healthcare facilities, ensuring they meet minimum requirements to provide safe and effective patient care.

Over the years, CMS has introduced various initiatives aimed at improving the quality of healthcare. These include programs like the Hospital Quality Initiative and Value-Based Purchasing, which tie reimbursement to the quality of care provided.<sup>4</sup>

## COMMITTEES FOR QUALITY

Although CMS was the first to develop and adopt Conditions of Participation (CoPs) that involved quality, not much has changed. A myriad of committees have been established to directly influence quality in healthcare, such as:

- Peer Review Organizations (PROs)
- Utilization Review Committees
- Professional Standards Review Organizations (PSROs)
- Quality Improvement Organizations (QIOs)
- Agency for Healthcare Research and Quality (AHRQ)
- National Committee for Quality Assurance (NCQA)

## THE ISO 9001:2015 APPROACH

The introduction of ISO 9001:2015 brought a holistic approach to quality management in healthcare.<sup>5</sup>

Unlike earlier standards, where the emphasis was on clinical areas, ISO 9001:2015 focuses on the importance of quality across all organizational processes, including service departments. This universal strategy ensures every aspect of a healthcare organization contributes to patient care quality.

ISO 9001:2015 is based on several quality management principles, including:

- Patient focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

By adopting ISO 9001:2015, healthcare facilities can systematically improve processes/products, meet contractual requirements, enhance patient satisfaction, and achieve better health outcomes. This helps to increase revenue and activity in the global market.

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<sup>4</sup><https://www.cms.gov/medicare/quality/value-based-programs/hospital-purchasing>

<sup>5</sup><https://www.iso.org/standard/62085.html>

## Adopting ISO 9001:2015

United States healthcare has been slow to adopt and apply ISO 9001:2015. The reasons often cited include difficulties with implementation and costs. However, this standard is about processes, not assets.

ISO 13485 is the regulation that specifically focuses on the product produced (medical equipment, for example). An effective Quality Management System (QMS) ensures the supporting objectives, policies, data, etc. increase the quality of the delivered product.<sup>6</sup>

## INTEGRATION BY ACCREDITATION BODIES

Organizations like DNV GL Healthcare (a global quality assurance and risk management company) have integrated ISO 9001 into their accreditation processes. The solution combines ISO 9001 with the National Integrated Accreditation for Healthcare Organizations (NIAHO) standards.<sup>7</sup>

This integration helps healthcare providers align their operational processes with globally recognized quality management standards while meeting specific healthcare regulations.

DNV GL's approach ensures patient safety and continuous improvement, making it a powerful model for healthcare quality management (HQM). This integrated accreditation process assesses compliance with standards, encourages innovation, and facilitates best practices in quality management.

The global cost of inefficient healthcare is over \$6 trillion.<sup>8</sup> DNV's accreditation programs streamline processes. The solution directly addresses regulatory requirements for hospitals, such as CMS, provides guidance, and outlines key procedures for clinical specialty organizations across the healthcare sector.



<sup>6</sup><https://www.iso.org/iso-13485-medical-devices.html>

<sup>7</sup><https://publications.ashp.org/previewpdf/book/9781585284474/ch03>.

<sup>8</sup><https://worldmetrics.org/healthcare-quality-management-industry-statistics/xml?pdfJsInlineViewToken=822639729&inlineView=true>

# THE CRITICAL ROLE OF LEADERSHIP IN DRIVING QUALITY MANAGEMENT SYSTEMS

The successful implementation of a Quality Management System (QMS) is crucial to ensuring high standards of patient care, safety, and service efficiency. Leadership plays an indispensable role in the successful deployment and ongoing effectiveness of a QMS.

The biggest detractor of implementing ISO 9001:2015 standards within an organization comes from leadership. That's because it's typically an all-or-nothing process. It involves all aspects of the company that interact with or affect the interested parties.

This can present a daunting perspective to leadership, and it's understandably overwhelming. However, these fears can be faced head-on once a full understanding of the process and outcome is developed.

## WHY LEADERSHIP INVOLVEMENT IS CRUCIAL IN A QMS

Why is leadership so important when it comes to the successful implementation of a QMS? Here are a few reasons:



**Resource Allocation:** Successful QMS implementation requires adequate resources, including access to funding, personnel, and technology. Leaders need to responsibly allocate these resources to ensure the QMS is well-supported.



**Direction and Vision:** Leaders are the ones who provide the direction and strategic vision required for a QMS to complement business goals. These are the people who define quality objectives, set priorities, and ensure the technology seamlessly integrates with the broader missions and values of the healthcare facility.



**Stakeholder Engagement:** Leaders engage with various stakeholders, including patients, staff, and regulatory bodies. They must ensure the Quality Management System meets the diverse needs and expectations of the facility. They must communicate the benefits and progress of the QMS to establish a deeper trust and a more enthusiastic buy-in across the organization.



**Oversight and Accountability:** Leadership is responsible for monitoring QMS performance, reviewing progress, and making necessary adjustments. They set the tone for quality standards, encourage compliance, and foster an environment where employees are empowered to contribute quality initiatives.

## STEPS FOR IMPLEMENTING A QUALITY MANAGEMENT SYSTEM IN HEALTHCARE

Implementing a Quality Management System in healthcare is a strategy aimed at enhancing safety, patient care, and operational efficiency.<sup>9</sup> It provides a structured framework for standardizing systems, optimizing service delivery, and fostering a culture of continuous improvement.

A successful QMS ensures organizations can effectively meet regulatory requirements, address quality issues, and drastically improve the patient experience.

Here are the essential steps for successfully deploying a QMS in healthcare settings:

- **Planning and Assessment:** Assess current processes and identify areas for improvement. Develop a detailed plan for implementation that outlines the timeline, objectives, responsibilities, and resources required.
- **Stakeholder Buy-In:** Secure commitment from top stakeholders to champion the QMS. This means verbal support and active participation in planning, resource allocation, and oversight.
- **Staff Engagement and Training:** Thoroughly train employees on QMS standards, tools, and processes. Engage them in the implementation process to encourage their input and buy-in. This also helps to foster a culture of continuous improvement and stronger accountability.
- **Policies and Process Design:** Develop standards, policies, and procedures that align with best practices and regulatory requirements. Make sure to document everything to ensure consistency and clarity.
- **Active Implementation:** Roll out the QMS implementation in phases, starting with pilot departments if necessary. Be quick to monitor progress, gather feedback, and make any tweaks or adjustments as needed.
- **Evaluation and Monitoring:** Establish KPIs (key performance indicators) to monitor the effectiveness of the QMS. Conduct regular audits and reviews to assess performance and identify any areas that may need attention.

Feedback and data from monitoring can be used to drive strategies for continuous improvement. Empower healthcare staff to identify and implement changes that enhance quality and efficiency.

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<sup>9</sup><https://www.accruent.com/resources/blog-posts/multi-part-overview-quality-management-systems-qms-healthcare-part-2>





## REDEFINING ROLES AND ENHANCING THE PATIENT EXPERIENCE THROUGH QMS

While increasing revenue is a top goal for 2024, improving the patient experience is a close second.<sup>10</sup> In a recent poll by HFMA, 70% of respondents say increasing revenue is a top priority, followed by improving the patient experience (60%) and reducing costs (55%).

A well-implemented QMS helps service departments in healthcare settings significantly enhance the patient experience by addressing quality issues and redefining traditional roles.



**Shifting From Reactive to Proactive Roles:** Service departments can shift from a reactive, problem-solving stance to a proactive, quality management position. This means they are better at anticipating issues, standardizing processes, and implementing preventative measures.



**Addressing Quality Issues:** An efficient Quality Management System provides a structured approach to identify, analyze, and address quality issues in healthcare. This includes (but is not limited to) root cause analysis, corrective actions, and preventive measures to avoid recurrence.



**Enhancing the Patient Experience:** A strong QMS is always focused on patient-centered care. This guarantees services are delivered on a consistent basis. Improving process efficiency reduces errors and enhances communication. In turn, patients receive higher-quality care and an enhanced experience.

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<sup>10</sup><https://www.hfma.org/cost-effectiveness-of-health/financial-sustainability/while-increasing-revenue-is-a-top-goal-for-2024-improving-the-patient-experience-is-a-close-second-specially-for-large-health-systems-hfma-poll/>

# OPERATIONAL PLANNING AND CONTROL MECHANISMS IN QMS

How can an organization support the QMS policy and develop operational guidelines for execution? Once the goals have been defined, a healthcare facility must decide how it will support and execute those objectives.

In general, the organization must identify and provide the resources needed to develop, implement, manage, and improve the QMS program.

To properly execute a QMS plan, leadership should consider:<sup>11</sup>

- Capabilities of and constraints on existing internal and external resources
- People: who's available and who's needed to implement and operate the QMS
- Infrastructure (buildings & related utility needs)
- Equipment (hardware, software, assets, etc.)
- Transportation resources
- Communication and information needs

Effective operational planning and robust control mechanisms ensure quality standards are consistently met, and that an organization can adapt to changes, while maintaining high levels of service delivery.



<sup>11</sup><https://www.accruent.com/resources/blog-posts/multi-part-overview-quality-management-systems-qms-healthcare-part-3>

## COMPONENTS OF LEADERSHIP AND OPERATIONAL PLANNING WITHIN QMS

Central to the success of any Quality Management System are two critical components: leadership and operational planning. Leadership within QMS provides the vision, direction, and commitment needed to foster a culture of quality. Operational planning translates leadership's vision into actionable steps, ensuring that quality objectives are met consistently.

### Commitment to a Strategic Mindset

Leaders should articulate a clear vision for quality that aligns with the mission and goals. This establishes the direction for all quality initiatives and ensures every team member understands the importance of quality in their daily work.

This also requires leaders to provide adequate resources (like funding, technology, and personnel) to support QMS activities. This includes investing in training, tools, and systems necessary for quality management.

Lastly, open and consistent communication from leadership reinforces the importance of quality standards. It also keeps everyone informed about QMS initiatives, progress, and outcomes.

### Operational Planning and Standardization

Establish SMART goals. These are clear and measurable objectives for quality improvement that align with a strategic vision. Goals should be specific, achievable, relevant, and time-bound (SMART).

It's also wise to develop standardized procedures and processes to ensure consistency in service delivery. This may include developing process maps and documentation that guides staff in effectively performing their duties.

Part of planning is also identifying potential risks to quality and patient safety. This helps to develop strategies to mitigate those risks. A proactive approach prevents issues before they arise.

## IMPORTANCE OF CONTROL MECHANISMS

Central to any effective QMS are powerful control mechanisms. These tools and processes are designed to monitor, measure, and enhance quality across all healthcare operations. Control mechanisms are essential for identifying areas of improvement, mitigating risks, and ensuring compliance with healthcare regulations.

### Monitoring and Measurement

It is critical that an organization monitors the effectiveness of QMS processes. Establish KPIs, and regularly track and analyze these indicators to identify trends, successes, and areas of improvement.

### Audits and Reviews

Conduct regular internal and external audits to maintain compliance with established standards. Reviews should be systematic and involve feedback from all stakeholders.

### Feedback Loops

Implement systems for continuous feedback from staff, patients, and key stakeholders. Use this information to drive continuous improvement initiatives.

### Corrective Actions

Develop a structured approach for addressing deviations from quality standards. This can include root cause analysis, implementing corrective actions, and monitoring performance.



## CREATING A CONDUCIVE WORKPLACE ENVIRONMENT

Approximately 50% of project failures can be attributed to inadequate stakeholder engagement?<sup>12</sup> What is the key to 100% stakeholder buy-in for QMS implementation? Creating a workplace that encourages feedback and actively listens.

Foster a culture where employees feel empowered to take ownership of quality initiatives. People who are interested and engaged are more likely to contribute to and support QMS efforts.

It's also important to provide ongoing training and development opportunities to ensure staff have the skills and knowledge required to adhere to quality standards.

Creating a welcoming environment for change also means promoting a positive and collaborative space. Recognize and reward contributions to quality improvement, encourage teamwork, and facilitate open communication.

## THE BENEFITS OF PROPER QMS SUPPORT

The effectiveness of a good Quality Management System hinges on the support it receives. Proper QMS support transforms a good system into a great one. This works to drive continuous improvement, enhance operational efficiency, and foster a culture of quality across the organization.

Some of the top benefits of proper QMS support include:

- **Increased Employee Satisfaction:** Offering staff continuous training and development opportunities improves competencies and increases job satisfaction. Employees who are involved in meaningful quality initiatives feel empowered and valued, leading to higher morale and lower turnover rates.
- **Improved Service Delivery:** Standardizing processes and creating effective control mechanisms ensures consistent and reliable service delivery, which enhances patient care and satisfaction. Streamlined processes also reduce waste and inefficiencies. This allows healthcare providers to deliver services more effectively and at lower costs.
- **Organizational Outlook:** A commitment to quality will enhance the organization's reputation, helping to build trust with patients, regulatory bodies, and other important stakeholders. High-quality standards set the organization apart from competitors, attracting more patients and partnerships. Additionally, adherence to regulatory requirements and standards minimizes the risk of legal issues and penalties.

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<sup>12</sup><https://iquasar.com/blog/why-stakeholder-engagement-matters-building-stronger-connections-for-success/>

# AUDITING AND CONTINUOUS IMPROVEMENT IN HEALTHCARE QMS

It's critical that an organization takes the time to define how, where, and when specific processes are to be monitored, analyzed, and evaluated. This is important if the facility hopes to determine if the QMS is effective.

At this phase, we're checking on the pulse of the QMS and doing something about poor performance. Audits work to improve the quality of care.<sup>13</sup>

## THE IMPORTANCE OF AUDITING THE ENTIRE QMS PROGRAM

Going through and auditing the entire QMS program is a fundamental component of quality management in healthcare. It serves several key purposes:

- **Verification of Compliance:** Auditing the entire QMS program ensures compliance with all internal policies, industry standards, and regulatory requirements. This verification helps to identify any gaps or deviations that need to be addressed.
- **Measuring Performance:** Audits provide an objective assessment of the QMS performance. It will highlight areas of strength and ones that need improvement. This type of measurement is crucial for maintaining high-quality standards.
- **Risk Management:** By identifying non-compliance and potential risks early, audits will help mitigate issues before they grow, ensuring patient safety and operational efficiency.
- **Continuous Improvement:** Audits facilitate continuous improvement by providing greater insights and relevant data that drives corrective actions and enhances the QMS.

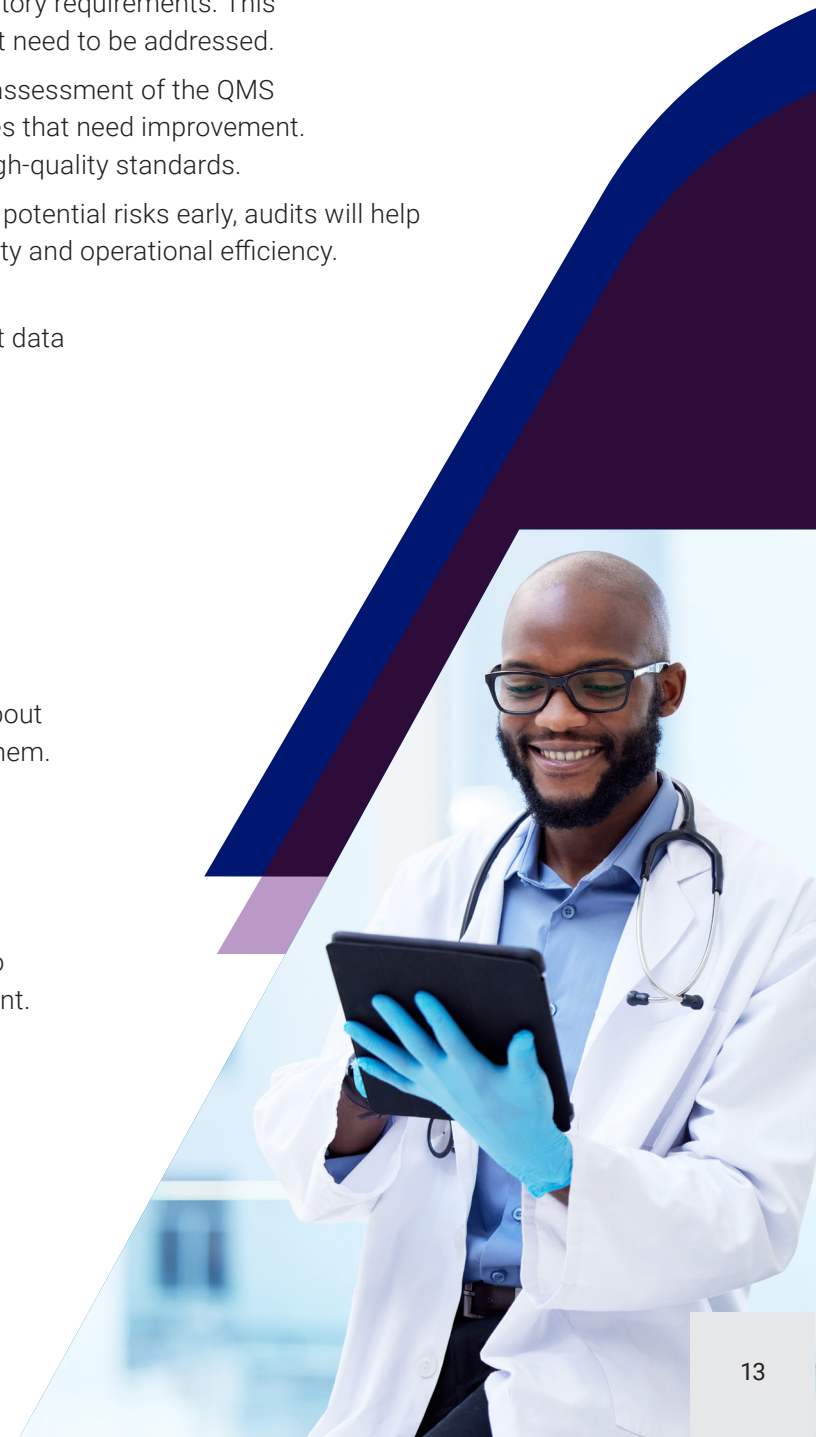
## COMPLIANCE WITH INTERNAL DOCUMENTS AND STANDARDS

Measuring the success of a QMS also means ensuring compliance with internal documents and standards.<sup>14</sup> This can involve:

- **Training and Education:** Continuously educate staff about internal standards and the importance of adhering to them.
- **Documentation Review:** Regularly review policies, procedures, and protocols to ensure they are up-to-date and reflect important best practices and regulatory requirements.
- **Performance Metrics:** Use metrics and benchmarks to measure compliance and identify areas for improvement.

<sup>13</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8011742/>

<sup>14</sup><https://www.accruent.com/resources/blog-posts/multi-part-overview-quality-management-systems-qms-healthcare-part-4>



## ESTABLISHING AN AUDITING PROGRAM

The best way to establish a QMS auditing program is to start with a plan. Develop a comprehensive audit plan that outlines the scope, objectives, criteria, and schedule of all audits. Then, assemble a skilled and knowledgeable audit team that understands the QMS and relevant standards.

Systematically conduct audits using standardized checklists and tools. Lastly, document any audit findings and develop a plan of action that will identify and address issues.

## CONDUCTING MANAGEMENT REVIEWS

Management reviews are critical for overseeing the effectiveness of the QMS. Leaders should hold regular meetings to assess QMS performance and progress. Analyze the data from audits, performance metrics, and feedback to quickly identify trends and places for improvement. This will help an organization make more informed decisions about resource allocation and policy changes.

## THE CONCEPT OF CONTINUOUS IMPROVEMENT

Continuous improvement is a core principle of QMS, and starts by establishing mechanisms for receiving and acting on feedback from staff, patients, and other stakeholders. This will help to identify the root causes of non-compliance or quality issues.

Continuous improvement also requires implementing and monitoring corrective actions to ensure they effectively address the identified issues. Additionally, an organization should be encouraging innovation to continuously enhance efficiency and quality.

## THE ROLE OF QMS IN COMPLIANCE

A well-implemented QMS plays a crucial role in ensuring compliance by:

- **Standardizing Processes:** Ensuring all processes are standardized and consistently followed will reduce variability and errors.
- **Regulatory Alignment:** Keeping the organization aligned with current regulations and standards through regular updates and audits.
- **Documentation and Traceability:** Maintaining comprehensive documentation that provides traceability and accountability.

## THE RIGHT PROGRAM

Implementing a Quality Management System (QMS) in healthcare is a transformative initiative that significantly enhances patient care, operational efficiency, and overall service quality.

One of the most important advantages of this modern technology is to achieve and maintain compliance with ever-changing regulations and to maintain high standards during performance audits required by regulatory agencies, such as The Joint Commission, CMS and DNV GL.

Accruent tools provide the training, features and data needed to get this right. They can help you establish a QMS program. To see how Accruent's purpose-built healthcare CMMS can help you support and document your QMS program, [reach out](#).



## FINAL THOUGHTS

Leadership commitment and a structured approach to operational planning are critical for the successful deployment and sustainability of a long-term Quality Management System.

Regular auditing and a focus on continuous improvement ensures that the solution remains effective and compliant with evolving standards and regulations.

By fostering a culture of quality, engaging staff, and utilizing powerful control mechanisms, healthcare organizations can achieve remarkable improvements in service delivery and patient outcomes that will positively influence everyone involved.

In 2025, all Medical Equipment manufacturers doing business in the United States will be required to meet the updated 21 CFR Part 820 (Quality System Regulation) requirements. The new changes, in effect, incorporate the ISO 9001 and ISO 13485 Standards, and having your CMMS as an integral part of your organization's QMS program is more critical than ever before and can be the difference between compliance and non-compliance.

## SPEAK TO A SPECIALIST



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