



WHITEPAPER

The Top 5 QMS Implementation Best Practices

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Life science organizations must ensure that the manufacturing process of their products and processes follow specific requirements, managed by a Quality Management Solution (QMS). A digital QMS can automate nearly all processes of an organization and streamline compliance, no matter how complex the organization's manufacturing processes are.

Yet establishing and implementing cGMP compliance processes can often be a challenging task. [Strategically implementing a QMS](#) is essential to ensure project governance structure, project joint team structure, and the underlying assumptions for a proven, repeatable, and successful rollout.

The following are the top five best practices for successful QMS implementation.

1. Project Governance

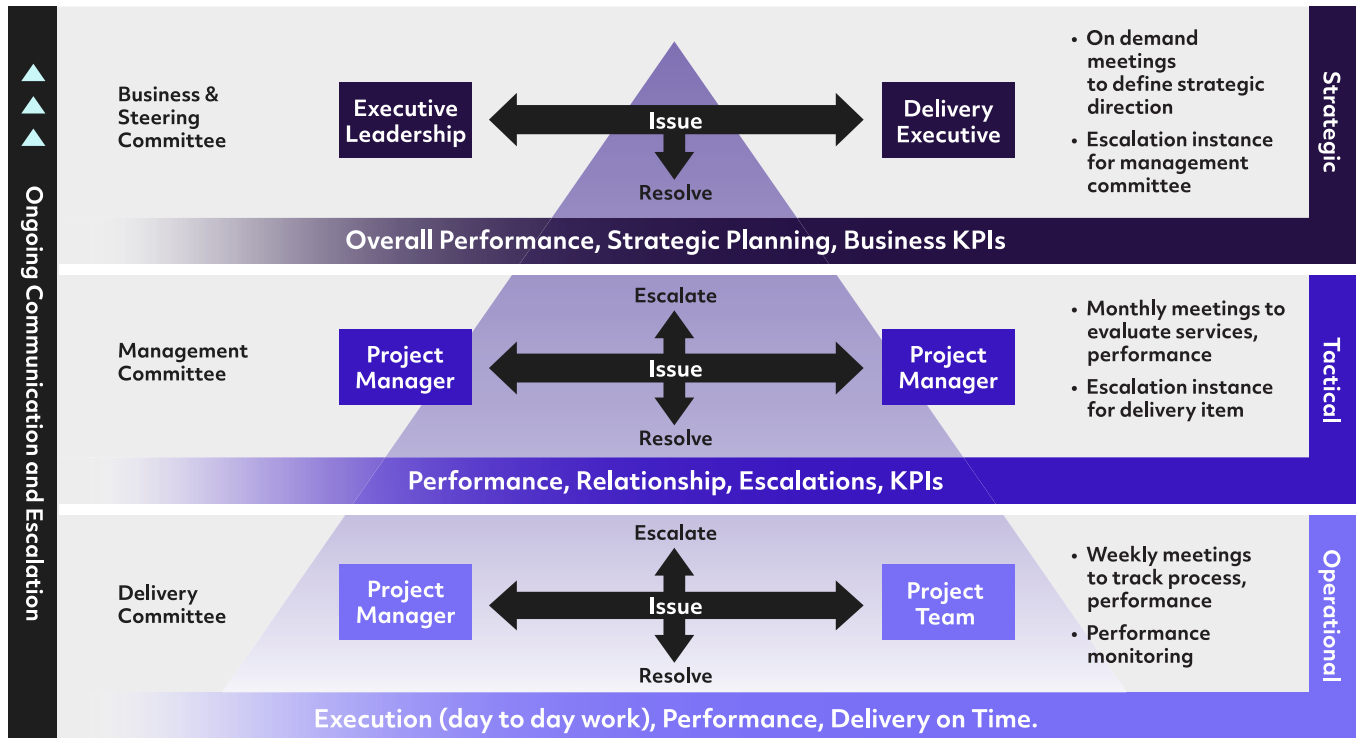
Clearly documenting employee roles and responsibilities is a simple and effective step to streamlining QMS implementation at your corporation. A robust management framework built on a logical structure and capable of reproducible results can provide security to an organization in the form of Project Governance. This organized documentation of roles and responsibilities associated with a business's usual activities can offer crucial data to help with decision-making.

Benefits to developing and implementing a Project Governance plan include increased accountability, clarity in communication, and enhanced decision-making capabilities. By building this into the QMS at the start, an organization sets a solid foundation for future success.



To achieve Project Governance, executives, committees, and employees at all levels must be properly aligned.





2. The Elements of Project Governance

Project Manager/Management Office (PMO)

A project manager is an essential member of the project governance structure and is responsible for day-to-day activities and resources. This role serves as the initial escalation point to account executives and project sponsors.

A single point-of-contact is essential to any project. One sole project manager as the touchpoint for all departments leads to clearer communication, reduced human error and redundancies, and higher customer satisfaction.

Executive Leadership

An assigned account executive is recommended for [QMS implementation](#) oversight. An experienced delivery executive is crucial to the effective management of multinational accounts, and is advised to participate in steering committee meetings and executive checkpoints. This role serves as the final escalation path.

The account executive helps ensure that project risks are identified, prioritized, mitigated, and resolved in a timely fashion.

Steering Committee

A project-specific Steering Committee can resolve issues and drive decision-making. To ensure productivity, this committee should focus on engaging in strategic discussions and framing alternatives, as opposed to receiving general status updates. Monthly meetings are recommended, but should be adjusted to suit the needs of each individual project.

Delivery executives are often effective advisors to Steering Committees, compiling key factors to manage, developing a matrix for analysis, and submitting monthly written progress reports. This role helps ensure that all obstacles are dealt with promptly and as they arise.

Status Reports

Project-specific status reports should be prepared on a weekly basis, or as requested by customer sponsors. At a minimum, such reports should include schedule and milestone status, issues and resolutions, and risks and proposed mitigations. These reports ensure that all stakeholders in the project are updated regularly.

Daily Flash Meetings

Bringing together core team members to review progress, determine focus areas, and boost morale doesn't have to take long. Fast-paced, highly-focused "flash" meetings should not exceed 30 minutes in duration. Encouraging all teams to participate ensures a sense of camaraderie, which leads to improved teamwork and higher productivity. A team that works together wins together, resulting in success for the company.

3. Developing Implementation Strategy

A solid strategy for QMS implementation can give an organization a headstart in productivity. By preparing everything and planning for every eventuality, a firm sets itself up for a quick and easy eQMS integration.

When implementing a digital QMS implementation strategy, there are four necessary steps: Design, Deploy, Control Measure, Review/Improve.

The key to developing a successful implementation strategy begins with an analysis process to map and define:

- **Design Implementation Approach:** evaluate current status, define stakeholders, determine effort phases and timeline, choose methodology/approach (big bang; by division; by capability)
- **Define Strategy:** eQMS structure, scope, responsibilities, establish templates, commission translations, outline customer resources required by role and time
- **Deploy eQMS:** cloud access, training tools and manuals, systems and metrics
- **Control/Measure and Review/Improve:** collect and analyze data, streamline processes, improve customer experience

Planning and executing a well-planned eQMS implementation strategy allows an organization to:



Achieve organizational goals



Reduce human error



Increase customer satisfaction



Improve internal communication



Achieve scalable growth

4. Implementation Resource Allocation

Improvement requires investment. Taking the time to implement a QMS requires a project team for successful deployment. Bringing together the necessary skills and experiences from varied backgrounds and competencies will ensure a smoother rollout of an organization's eQMS system.

Planning each step, including the amount of resources dedicated to the project, can make or break a QMS implementation. It is crucial to allocate sufficient resources to ensure a smooth transition for staff and customers.



5. Implementation Stages

In preparation for the QMS implementation, organizations should carefully consider the four stages of implementation:

A. Training Approach

This requires effectively educating the workforce with a knowledge transfer strategy, in which internal staff are imparted with the capability to train fellow employees.

For System Administrators

Training system administrators via knowledge transfer typically involves a walk-through of the system and overview of any customizations made for the organization. This overview should provide a clear idea of the technical design, environmental configurations, solution configurations, and any migrations.

For End-Users

Train the Trainer sessions provide a walk-through of the fully operational system. They should be designed around an organization's Standard Operating Procedures (SOPs).

Role	Training Material	Training Delivery Mechanism	Tools Used
System Administration Customer Solution Support / Administrator	System Administration Guide	Hand over session – Knowledge and Responsibility transition	Video Conference
End-User Process Owners / SMEs	User Manuals SOPs	End-to-End Training sessions	Video Conference

B. Data Migration Strategy

Data is priceless, so ensuring proper management of an organization's information is essential when implementing eQMS. Developing a data migration strategy within the IT department or with an eQMS provider can reduce the risk of data loss or leakage.

The benefits to a proprietary quality records management tool are:

- Completed master document spreadsheet (or)
- 3rd party legacy system extract containing all metadata
- Native master documents in shared, accessible location
- PDF rendition of documentation revision in shared, accessible location

Working with a data migration specialist can help ensure data integrity and accuracy, so that no issues are encountered during migration.

C. Validation Strategy & Services

Working with an eQMS provider can streamline implementation and adapt to client-specific configurations. Such a service may also include a full suite of validation documentation. It is always recommended to follow the GAMP 5V-Model standard for computer system validation.

GAMP stands for Good Automated Manufacturing Practices, and provides guidance, principles, and processes for manufacturers to ensure pharmaceutical software meets required quality standards. This methodology can be used to test for defects in the system, ensuring product quality and a smooth transition. Manufacturers are better able to monitor product quality, maintain data integrity, and ultimately protect patient safety.

D. Environment Strategy

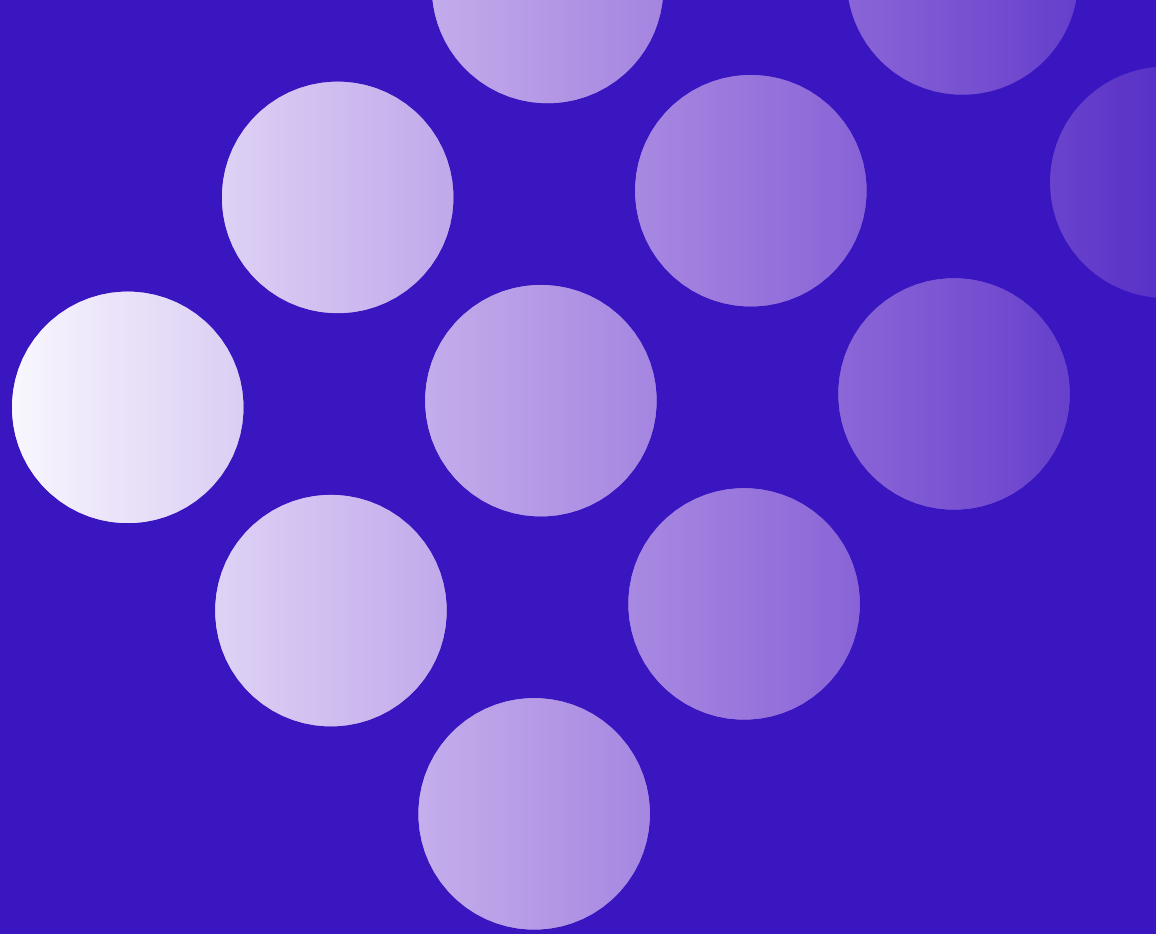
An eQMS supplier can configure systems to suit an organization's needs first in a development sandbox, and with assumed gated deployments. It is important that the client completes system reviews. Following client approval, the configuration should be locked. It is at this stage that any changes to the configuration should be validated.

Once the validation is completed successfully, then the configuration changes are ready to be released to the production environment.

6. Employee Resources

Updating a Quality Management System results in major changes in employees' day-to-day activities. As such, it is advisable to provide relevant personnel with the necessary training, tools, and resources for learning a new system and its interfaces.

Even the most extensive strategy and testing phase may still result in necessary adjustments during the early stages of any system implementation. The organization's workforce will be largely responsible for uncovering and voicing these required changes, and will ultimately pay off in enhanced productivity within the new system.



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7. Conclusion

Undergoing an eQMS implementation can be intimidating. However, if approached correctly, and with the right partner, the implementation process need not be daunting and can set your organization up for scalable growth and provide a major opportunity to digitally transform the organization.

The benefits of a cloud based eQMS are extensive and compelling. Choosing the right technology vendor to help guide you through the implementation process can help ensure a smooth transition to an automated quality management system.

Following the tips outlined here, quality and compliance professionals will reduce risk and costs, and will be set up for scalable growth.

For more information on Dot Compliance's QMS implementation best practices and ready to use QMS solutions, visit us at [dotcompliance.com](https://www.dotcompliance.com)

Dot Compliance offers the industry's first ready to use Quality Management Solution powered by the Salesforce.com platform. The Dot Compliance solution suite includes an extensive set of off-the-shelf ready eQMS and compliance pre-configured processes, that enable customers to deploy quickly and cost effectively. Trusted by hundreds of companies worldwide, Dot Compliance is driving Quality 4.0 innovation across the life science industry.

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