



Prepare to Ignite your Quality Journey



The first stage in the Quality Journey is Ignite. Organizations ready to enter this phase have limited or no automation, affecting core functions such as document control, employee training, and audits.

By automating core quality functions, you can move away from manual documentation and quality processes, the inability to effectively share information thanks to siloed data and inconsistent employee training programs. At this stage, it makes sense to automate your foundational quality management systems, like document control, audit management, change management and employee training.



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Current state

You've started thinking about a more effective approach to managing your quality processes.

You may be in a situation where Management rarely really talks about quality, but the need for enhancing your quality processes and continuous improvement is apparent.

You understand that you have room to improve your quality processes (or you wouldn't probably be here right now). And you understand that you need to manage the risk to quality and your organization. This leads to a number of considerations:

- Manual processes increase the likelihood of human error which can lead to increased audit findings, so exploring options for automation (or expanding any automation that you already have), makes a lot of sense.
- Storing quality policies, information, and documents should be managed so that the appropriate teams can have controlled access to them regardless of location.
- Timely distribution of information and confirmation that employees understand your policies means having a process to track employee training.
- Defining workflows that identify who creates, updates, approves, and needs to be informed about quality processes provides up to date status on every process your organization follows.
- Integrating with other systems (even safety systems) that may exist in your organization leverages the information that already exists. Having to enter data multiple times across systems can lead to errors, as well as having inconsistent information without knowing which source is correct

If you have multiple locations, it is easy to see how each location could have their own quality policies. These inconsistent policies can lead to quality issues, with the inability to spot trends across locations and leverage best practices across processes.

And if all these internal considerations weren't enough, you also have external considerations that need to be addressed:

- Customers requiring adherence to standards and the right to audit your compliance.
- ISO standards, including ISO9001:2015 and ISO14385 which have specific quality requirements and goals.

- Government regulations, such as through the FDA, for additional compliance and documentation requirements.

For organizations ready to enter the Ignite phase, managing non-conformances, corrective actions, and audits can be a challenge. You may be experiencing these hurdles today:

- Responding to internal and external audits can be a time-consuming effort, with a majority of the time just finding the right information to support the audit.
- Addressing findings is critical, yet many times, there is no easy method to track all the findings and the actions.
- Not being able to track and address corrective actions in a timely fashion can lead to increases in production on-hold time, delays in new product introductions (NPI) with a negative impact to sales/cash flow, and an increase in scrap and raw material returns.
- It is difficult to identify systemic issues and understand if your actions resolve them.



The best way to make sure standards are known and followed is by utilizing a successful employee training program.

Even though employees may know how to access documents, many times your system doesn't report who has been trained on the material. You can put your company at risk if all employees aren't on the same page. When that next audit occurs, ISO standards dictate that you need to be able to show who has been trained and who has what level of access to the various documents.

The best way to make sure standards are known and followed is by utilizing a successful employee training program. It's not enough to allow access – you need to be able to track who understands the information. You can't hold employees accountable unless you provide the appropriate training on the standards. So, now is the time to put a complete training program in place through your QMS. You should be able to tie specific documents to specific training programs – this is a good first step in not only making information accessible but making sure everyone understands your processes and quality goals. With the right level of flexibility, you can make sure each employee has access to information that pertains to them. Bottom line with training: you will have an understanding of who has been trained and what additional actions are required to keep your team fully capable.

Recommendations

There are many aspects of a QMS and it's easy to get overwhelmed by the choices and options. Don't feel like you need to implement a broad solution out of the gate, which will more likely lead to failure or a limited understanding of the system's full potential. Start with achievable goals by targeting areas of quick results – document control and employee training are two such areas. Audit and corrective action management can both add significant value.

Many quality practitioners would not prioritize supply chain quality at this juncture – yet. The goal is to start with a successful project that shows the value of automating your quality processes. With that under your belt, you'll be able to expand to include other areas such as supply chain quality, integration with enterprise systems, risk assessment, etc.

To ensure everyone is using the same information you need your documents online, and an easy way to ensure basic controls on your information. A QMS offers improved document control, policy access and training. Increased visibility and training will ensure compliance and create a culture of continuous improvement. Don't limit access, all employees play a role in quality and in managing risk.

It's time to start looking at a centralized QMS that can put structure around how you create and manage all your critical documents. Develop a workflow that shows how a document gets created, reviewed, approved, and distributed. And it's not enough to route documents, you need to track who has been trained on your critical policies and procedures. Don't compromise on quality – today's investments will pay off in the future.

When you start to automate or expand your quality processes, Corrective Action management quickly rises to the top of the list as a function that can provide significant results. Whether you are dealing with non-conformances, audit findings (both internal and external), or supplier corrective actions, having a system to track the issues and actions becomes critical. If you've been audited, you certainly need to show how you are resolving any findings.



Increased visibility and training will ensure compliance and create a culture of continuous improvement.

Without a system to track audit results, it can be difficult to understand the risks and costs associated with not taking action.

Conducting audits is important for continuous improvement. That is why it is essential that your tools are not only configurable to your processes, but also easy to manage and track. The right Audit Management software will allow users to create specific audit plans with multiple audits throughout the year. Setting up profiles for each audit includes integrated checklists, scoring methods and a comprehensive audit report for all audits within the system.

An essential aspect of a QMS is the ability to show management the impact quality has on the organization. Even simple statistics, dashboards and reports can show the value of the quality team.

This builds a culture of quality and continuous improvement. Having analytics can take this even a step further, where you can review current status, drill into the data to uncover detailed insights and even get to the specific situation in your QMS.

If you already have one or more QMS systems in place, now is the time to start thinking about whether that system can help you achieve all of your goals. Make sure you are on a QMS that can expand as your needs grow and adapt as your needs change – now may be the perfect opportunity to upgrade to a QMS platform with a comprehensive application portfolio and the flexibility to adopt to your business as your needs evolve over the long-term.



ETQ quality journey stages

Ignite



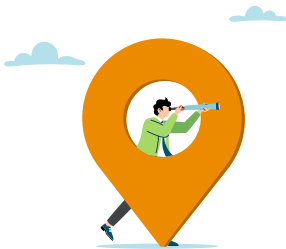
Build a strong quality foundation, streamline processes, and manage documents and training.

Accelerate



Enable process flows between functions and systems, capture data at its source, leverage everywhere, produce actionable information.

Expand



Integrate internal and external stakeholders in the quality process, extend to Health & Safety, and provide value-added analysis.

Transform



Provide competitive advantage by becoming proactive, making quality strategic, with a consistent global deployment.



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