

The ETQ Decision Criteria Checklist is designed to help you identify key considerations and QMS software capabilities that you and your team should keep in mind as you evaluate potential QMS partners. The checklist should be compared against your goals and be modified to precisely fit your unique objectives and environment. The suggested checklist items below were developed based on hundreds of hours of collaboration with ETQ's QMS customers as well with industry analysts who are often called upon to guide prospective QMS buyers.

Generally, we find that a comprehensive QMS offers customers a range of benefits that can be grouped in four areas. It is helpful when working through your Decision Criteria Checklist to keep these global strategies in mind. A world class QMS should always:

- Reduce risk of non-compliance
- Streamline operations
- · Reduce costs
- Grow and protect revenue

While the decision process often centers on features and functionality of the QMS, we urge you to consider the overall strength of your QMS partner and their ability to help you achieve long term success.

OMS PRODUCT CHECKLIST

As you review potential QMS solutions, use this checklist to ensure the QMS can deliver your "must-haves" to get the maximum business value from your new deployment. In general, you'll want a QMS solution that is flexible enough to not just meet your needs today but can grow with you as your needs and business requirements evolve. Your prospective partner's QMS solution portfolio should also be a comprehensive solution with the ability to handle all your critical QMS processes such as supplier quality management, risk management, audit management and training management, among others. In addition, today's QMS must incorporate flexible reporting and, better yet, offer advanced analytics.

Specific checklist must-haves include: Data migration: You'll have some quality data on hand already and, likely, a lot of it. Make sure the vendor can provide a method for cleanly moving all of your relevant data into the new software with a minimum of disruption to your organization. Document control: The heart of the QMS solution is typically document control, so vet this capability fully. You'll need a solution that manages the creation, distribution and archive of all critical documents in a centralized and controlled framework. Make sure workflows can be easily modified. Corrective and Preventative Action (CAPA) management: CAPA workflows help define, address and manage the root cause of nonconformances to help prevent future recurrences. Training Management: This is a vital baseline requirement to ensure that all staff, in all locations, are fully trained and up to date on certifications and other requirements. Change management: To be in business is to be comfortable with change. A solid change management solution helps automate and closely manage your environment in times of change or disruption. Supplier Quality: Supply chain quality means end-product quality. So, supplier quality management and collaboration are critical. The most efficient way to manage supplier quality is in your QMS, even allowing suppliers access to your QMS to participate in workflows, such as managing Supplier Corrective Actions (SCARs). Further, regulated businesses should track supplier audits and findings in the QMS as a means of maximize supplier quality visibility. New Product Introduction: Building great products means integrating quality as far upstream in the development process as possible and including quality in every step, from design to delivery. A robust NPI capability makes this possible. Failure Modes and Effects Analysis (FMEA): FMEA gives your organization a structured approach to spotting possible quality or safety failures that may exist within a product's design or within the manufacturing process.



COMPANY CHECKLIST

You'll want to know as much as you can about your prospective QMS partner. From financial stability to post-sales onboarding, training, support and guidance, your partner must be more than "just a software company." Some corporate background checklist items to consider include:

\bigcirc	Company history and heritage in the QMS industry	\bigcirc	Customer support, online training programs and on-going customer success managers
	Company financial stability		to guide you as you expand your usage and take on new processes after your initial
\bigcirc	Track record of projects similar in scope to		deployment
	yours		Easy access to other customers who use the same QMS, ideally via online networking or a Community-type portal as well as virtual and in-person conferences
\bigcirc	Experience in your specific industry		
	Global reach and capabilities if your organization is widely dispersed		
\bigcirc	A compelling and realistic product roadmap		High customer retention rates and positive customer references with long-term customer accounts.
	Ability to virtually implement and support your deployment		
	Partnerships with adjacent technology firms for both infrastructure and end-user software		

This Decision Criteria Checklist is a strong set of guidelines but don't let it be a generic substitute for a careful and detailed analysis of your organization's cross functional requirements and quality culture fit. You should modify this list to best match your environment (just as your QMS should!) and fully scrutinize your potential partners to determine the optimal long-term partner for your organization.

About ETQ

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