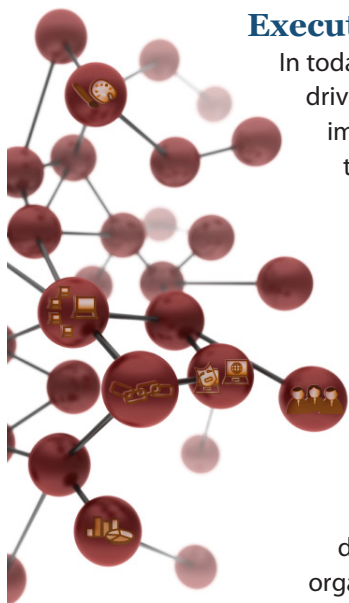




An Insider's Guide to Selecting a Quality Management Software System

Thoughtful Considerations for Selecting
the Right Solution for Your Business





Executive Summary

In today's dynamic and demand-driven market, the need to implement enterprise technology to keep pace with rapidly evolving operational, production, and compliance environments is key to success. In recent years, enterprise technology has become more prevalent in its penetration of all operational areas within a business. It has become so prevalent that it is rare to find a department within an organization that does not have a dedicated enterprise software solution to provide some level of support.

In the case of Quality, this statement rings true. In recent years, enterprise software solutions have become commonplace in many organizations, whether integrated Quality Management Systems (QMS), or Quality Management modules within larger production systems, even down to simple point solutions for Document Control or Corrective Action. Recent reports on top software components for organizations show that Quality Management is at the top of the list. In many organizations, Quality Management and QMS systems are a strategic priority (see figure below). As demand for these solutions grows, so does the vendor landscape—more software vendors are providing solutions for Quality and Compliance Management than ever before.

With a high demand and a large vendor landscape, it sometimes becomes difficult to discern which systems provide the greatest value and guarantee a successful implementation. Many organizations will spend a considerable amount of time and effort in selection of such systems—hiring consultants and assembling selection teams, months of demonstrations and negotiations.

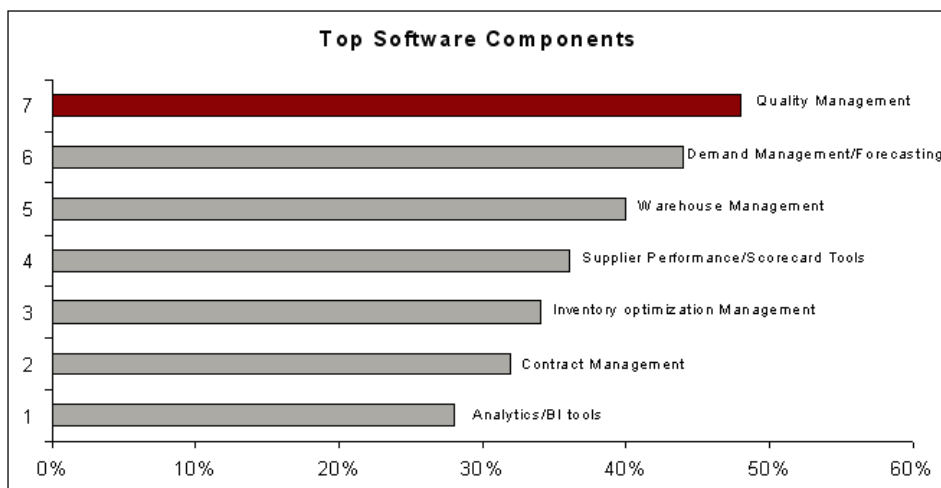
With all the investment put into selecting a software vendor for your business, it is hard to believe that there is any possibility of failure. However, recent

studies have shown that within a sample set of more than 9,000 software rollouts, 71 percent either failed or were late and over budget. Even more staggering, a recent study by Gartner Research revealed that nearly four in ten major software purchases ended up as “shelfware”—software that was purchased, but never implemented. The root cause of such pitfalls is usually attributed to two major issues—the system does not readily adapt to the processes within your business, and the system does not have the technology needed to be implemented and integrated into your existing environment.

This paper will discuss a few of the key considerations when selecting a software vendor, some pitfalls to avoid, and technical considerations for ensuring the software system is a good fit for your business. We will make the business case for each consideration, and describe some of the technological points when selecting a software vendor.

Flexibility to Adapt to Your Business Processes

Probably the most important consideration is the ability of the system to adapt to your existing business processes, and be flexible enough to change and improve as your processes change and improve. This may seem like a simple statement, but many times software vendors build their systems around a generic, best-practices approach that cannot be changed without substantial time and cost. These vendors want you to adapt your processes to their software, not the other way around. If your company has spent years developing and fine-tuning business processes, and upon purchasing a software system, you find yourself re-engineering your proven processes to fit within the software system's limitations, you have compromised your efficiency.



- **The Business Case:** Do not compromise. Find a solution that is truly flexible and configurable, and can configure all aspects of the software, including workflows, forms, fields, reports, business rules, even the look and feel. Configuration should also be easy for non-technical administrators. Graphical tools such as drag and drop will enable administrators to own the configurations of the system with limited to no programming knowledge required. In many cases, the cost of changing your operations as a result of an inflexible software package outweighs the cost of the package itself. Careful and thoughtful attention to the software's flexibility is key to a successful implementation.
- **Technically Speaking:** This level of flexibility is often hard to discern with a simple demonstration. Make the vendor dive deep into the product, even configure your existing processes for you. Software vendors often take a generic approach to workflow and forms so that they can sell to the "masses." Many vendors will usually develop the product and "hardcode" certain elements, making it easier to mass-produce, but also making them less flexible. By requesting a "proof of concept" you can uncover any walls in their level of flexibility, and truly see if their software will fit your business needs. Understand whether the configurations are really just configurations, or customizations, which make future maintenance and upgrades much more difficult. Identify how quickly you can make common configurations, like giving different paths through a workflow, adding new sections on the form, defining sub-processes that run in parallel or automating steps in the process. Uncover the number of configuration options to make sure that flexibility is not just skin-deep. Ask the vendor how many of the customers have been able to implement their system without making any code-level customizations.
- **The Business Case:** As software vendors move away from the client-server model, they have to make a choice on how they present their product. Many software companies invest their development in creating a truly Web-based experience, whereby all the forms, workflows, even the administration is conducted through a Web browser. Other systems choose to use "workarounds" to mimic a Web-based experience, utilizing third-party middleware or tools to get the job done, and requiring installation of the software on every computer both for using the software and for more complex tasks like configuration. These Web-enabled solutions often sacrifice functionality and flexibility for speed to market, and often fall short of their Web-based competitors. Be careful to identify the pitfalls of Web-enabled—much like an inflexible system, Web-enabled systems often will look good during the demonstration, but once you try to implement it, the software system will fall short of your goal. Furthermore, some of the middleware used to Web enable these systems often come at an additional cost above and beyond the license price. So, in effect, you are paying for two software systems to accomplish your goals—one for the system, and another for a middleware to make it work over the Web.
- **Technically Speaking:** There are many flavors of Web-enabled: Citrix, Adobe Forms, Java Applets, even Macromedia Flash. All of these tools have their drawbacks. For one, these types of Web enablers are proprietary tools, independent of the software vendor. As a result, the vendor becomes reliant on their technology to make the system work—any changes or discontinuation of the tools can impact the software's ability to work. Another drawback is the ability to take full advantage of the Web in usage of the product. For example, a system built using a third-party tool such as Adobe Forms will work over the Internet, but will only allow "read" access. Furthermore, any data within the Adobe form will not be part of the structured data that resides in the database—in other words you cannot query or report on the data. It is simply residing within attachments in the system, sectioned off from the rest of your data.

Web-Based versus Web-Enabled

The Internet has made the world much smaller. Organizations are building Intranets and Extranets into their global network, and the need to have systems in place that not only utilize the Internet but also thrive on it is key to success. Following this lead, enterprise software vendors are building tools that move away from the old client-server models to a thin-client interface, allowing for more flexibility in a global environment. There are software vendors that are Web-based and some that are "Web-enabled." Knowing the difference between the two can provide a key differentiator in your selection of the system.

Look-and-Feel: Making the Software Your Own

One of the more overlooked issues when selecting the software is the ability to "brand" the system with your organization's look-and-feel. While many ask whether the system can be configured to meet their changing needs, the ability to change the colors, logos, fonts, and general layout of

the navigators, forms and reports is usually an afterthought. Many systems will offer some level of configurability, but this will usually not extend to the layouts themselves. End users must contend with the vendor's look-and-feel, which will be foreign to them. The ability to control all aspects of the software's user interface helps user-acceptance of the software, and user buy-in is one of the major contributors to a software implementation's success. In the age of Web-based applications, vendors can demonstrate flexibility by complying with Web user interface standards. Furthermore, they should be able to provide this control without the need to customize the software. When selecting a system, have a well-defined set of user interface requirements that will make the system work for you, and ensure that the system is able to meet those requirements without having to do extensive development.

- **The Business Case:** User buy-in will skyrocket if the system uses familiar colors, layouts and concepts. There are systems in the market that provide 100% configurability of the user interface (the presentation layer), so that the system can be modified, without programming, to match the exact user interface standards implemented in other Web-based systems, such as the company's intranet, or even the company's external website. The ability to "brand" the system is a critical part of evaluating whether the new system will be a good fit.

- **Technically Speaking:** When looking at how extensively the system's user interface can be configured, look to systems that provide direct access to the presentation layer using standard web page design tools. This usually means the ability to change the layout without affecting the software's functionality. Also, make sure that all aspects of the user interface are configurable, so a consistent look and feel can be implemented throughout.

Making Sense of the Data: Reporting, Searching and Analytics

When you automate using a QMS, there is an enormous amount of data created. Without some means of easily accessing the data, the QMS makes it extremely difficult to derive trends and insights on the quality system. Users are left to their own devices to manually filter out the data, or even export the results into an external system for reporting. This is a time-consuming effort, and can lead to time management issues in finding the data, filtering the data and reporting on the data. Software systems will often offer some means of search capabilities, but this comes in many ways and may require administrative intervention. Having search capabilities is often not enough—the system should be able to search not only at the highest level, but also search on multiple criteria and search within records, or even within attachments embedded in records. At the same time, reporting on the data

Before You Begin...

While this paper will talk about specific considerations when selecting an enterprise QMS solution, it is important to touch on a few generic points when selecting a software system. Below is a summary of best practices when selecting a software vendor.

1. Do your Research: When you begin the selection process, you should do your homework. Identify the top vendors in the market, identify the different technologies within the different vendors and understand the typical components/modules. By identifying and understanding the market, you can speak to the vendors with more authority and expertise.

2. Don't "Over think" the RFP: The key to a successful Request for Proposal (RFP) is not in creating a copious feature list; it is focusing on solving a business need. The key to an RFP is differentiating one vendor from the next. Overly generic features that focus on functions often provide detail on products, but little visibility into how the product solves a business need. Center your RFPs around the key business needs, and let the vendor explain how they can solve this need through their product.

3. Keep your "shortlist" Short: Often, many companies will move forward in the selection process with more than three or four vendors, which can push the selection timeline out too far.

Limit your shortlist to three or four, and have a selection team evaluate and conduct research. Case studies, research analysts and peers can provide valuable information in this selection. Also, consider the vendor's corporate fit to your business—a good relationship with a vendor can go a long way.

4. Control the Evaluation process: As the vendor selection process continues, make sure that your company is driving the evaluation. Vendors tend to show features and tools that may not be related to your business, simply because they are "flashy" and "sizzle." Keep the process focused on your specific needs. Furthermore, be aware of any last minute deals by vendors who fear they may lose the business. Do not sacrifice functionality for price—you may lose in the long run.

5. Do not let politics get in the way: There is a great deal of subjectivity that can arise when reviewing applicable vendors. Whether it is a personality conflict, a prior experience or internal politics, it is important to keep your vendor rankings objective, so that any outside animosity does not distract from the software's capabilities.

comes in many flavors. Many software vendors consider reporting an afterthought in the development of their products—usually partnering with third party tools to help make sense of the data, but with only limited integration between the two systems. Others will embed reporting tools directly into their product, providing a more integrated method of pulling data across records within the system. When selecting a software solution, determine the types of searches and types of reports you need to generate, and require that the vendor is able to create such searches and generate the reports you need.

- **The Business Case:** Reporting is going to be a driving factor in getting the right information to management. Without the ability to report on the data, and create visibility into Key Performance Indicators, management will be blind. Reports requested by management need to be created quickly, so look for systems that let users create report templates quickly and effectively. Furthermore, make sure the system either has its own proprietary reporting tool, or seamless integration into your existing tools. Often, having systems that outsource reporting to a third party requires a separate license for the reporting tool (Cognos, Crystal Reports, etc.), as well as a steeper learning curve for the administrators and users, which can drive up the cost to purchase the system.
- **Technically Speaking:** Having a robust search is important to the success of a QMS. Many companies leverage the Google philosophy in searching not only the metadata within a record, but also the content stored in attachments. Furthermore, searches should also have the ability to drill down on multiple search criteria (i.e., search or sort within search results), so that results can be filtered. When dealing with thousands of records, this is a critical feature for many organizations. For reporting, the ability to have an integrated reporting tool built into the system is important, not only for ease of use and to eliminate jumping from one application to the next, but to also avoid the administrative costs associated with maintaining and upgrading the third party tools. One test of a truly integrated reporting tool is the ability to go directly from a graphical chart generated by the report tool to the actual quality records represented by the chart, with just a few clicks.

Tying Systems Together Using Integration

Operational areas no longer live in silos when it comes to business systems. Whether they are production systems, financial systems or quality systems, the ability to interact, collaborate, and coordinate across the business is key to

uncovering any gaps in processes, and creates visibility from one operational area to the next. It is of paramount importance to be able to integrate your systems. When looking to select a system, keep in mind the integration options available within the solution. Avoid solutions that claim integration, but will only do basic integration “lookups.” While this is powerful and eliminates some degree of double-entry of data, true integration will not only pull data in from production systems, but will also push data back to those systems, such as nonconformance issues, overall cost of quality activities and more.

- **The Business Case:** Having true integration can give your business visibility into other systems within the enterprise, allowing for faster resolution to quality issues, no lost production resources waiting on quality-related issues and better collaboration between operational areas. Systems that can open up the QMS into this level are key in having a truly integrated system.
- **Technically Speaking:** It is important that the system have a robust integration layer built into the product. Simple database tables that bridge the gap aren't always effective—housing your data in a temporary table repository can be a workaround to successful integration. Ask about standards-based Application Programming Interfaces (APIs) that will pull data in and update records within other systems. Furthermore, you should examine what business systems you already have (SAP, Oracle, VisiPrise, etc.) and ensure that the system has the APIs to connect with your systems seamlessly.

Taking Quality to the Enterprise: The True Meaning of Scalability

Ultimately, your QMS may not serve a single site, especially if your organization has multiple facilities. As more and more companies scale their systems to span the enterprise, it will become necessary for the QMS to follow suit. When selecting a software system, think about the long-term goals on how you plan to scale. It may not be an immediate need, but having the ability expand your QMS beyond your four walls to include other facilities, or even suppliers and customers can make a difference in the system's long-term value. Watch out for false scalability promises—some systems will claim scalability, but have no real experience in the matter. A scalable system must obviously be technically capable of handling the load of additional users, but that is only half of the picture. The scalability of administration is equally important and can be much more expensive to fix later if not considered up-front. Look for customer references that have scaled the system to a level that is equal to your business, specifically in the ability to

delegate administration to different levels in the organization, across the entire enterprise. Truly scalable systems include location-based administration that extends beyond simply managing different user groups, to enabling location-specific configurations and dynamic filtering of location-specific data.

- **The Business Case:** Scalability is an issue often overlooked, since many companies often are concerned with the “here and now.” But factoring in scaling the system beyond a single facility can potentially save your company a good deal of money in the long-term. For example, if you purchase a system that cannot scale beyond your site, and in 2 years you find that other sites are looking to use the QMS, you may have to purchase another system to accommodate this need, or spend development dollars in forcing the system to scale. Beware of false scalability claims—many vendors believe they can scale the system, but it is never often proven. The concept of scaling a single QMS across multiple facilities is a fairly new trend, and many vendors are not prepared for the task. Technological issues, localization issues, standardizing processes, compiling data from multiple sites for reporting—these are critical factors that must be taken into account when looking to scale a software system.
- **Technically Speaking:** Scalability can be a complex task, requiring multiple facets of integration. Many facilities want to keep their individual processes, but corporate wants to standardize the data for enterprise reporting and process consistency. The ability to implement and administer a system at this level often requires database integration, application integration, and more to make the system consistent across the enterprise. This complex nature of multi-site deployment often leads vendors to create extensive custom development to integrate data, or to find ad-hoc “workarounds” to circumvent a multiple site deployment, such as repository tables, or replication of databases on a scheduled basis, or manual export of site data and manual import into a roll-up database. While these may accomplish the task, they fall short of the true goal—real-time collaboration and data visibility. Look for a system that has a centralized administration tool that uses location profiles, user profiles and keyword profiles to standardize elements of the system at an enterprise level. Also look for the ability to configure workflows, forms, and reports by location, so that the unique needs of individual sites or regions can be met without disrupting processes in other locations. The benefit is that data is centrally stored, individual sites have access to their data and their

processes, and the enterprise is able to collect data across facilities in real-time, creating a truly visible QMS that spans the entire organization.

Know your Audience: End Users

Typically, the team selecting a software system is made up of multiple areas—IT, Quality, Operations, Purchasing, and more. More often than not, the participants are manager-level, and are making the decision on behalf of themselves and the end users. The end users, while most likely the highest volume user, are more than likely not involved in the ultimate decision. Many software systems will have the technology and process management needed, but once implemented, the end users are lost. It doesn't look familiar; it doesn't look and feel right, and requires significant adjustment to get used to. Look and feel may not seem like a “deal breaker” but it can be a hindrance in the learning curve for many users, and cause delays in getting implemented and effective. Many software vendors do not come from your industry. In fact, many come from a technology background, and never take into account the user experience. The result is a software system that is technologically advanced, but completely “un-user friendly.” When selecting a software system, take into account the end user's experience. Make sure the software can easily be configured to help the end user—whether it is familiar forms and layouts, even colors that match the corporate look. If you are replacing an existing system, see if you cannot match the new system's look and feel, even the form layouts to the old system.

This can make the transition much easier, and make the end users more productive right from the start.

- **The Business Case:** Consider the learning curve when you adopt a system for your end users. A system that feels familiar and intuitive can speed time to train and get your employees productive. When a system is rigid and inflexible in design, user interface and process, your end users will cringe every time they have to use it. They may even reject the system and revert back to old ways. Having a system in place that either matches an existing system, or even familiar Internet fodder (i.e. Google, Yahoo, Amazon, etc) can make users more productive.
- **Technically Speaking:** As stated before, many software vendors come from a development background—they probably have never set foot on a shop floor, interacted with typical end users or understood the very processes they were developing. Look for vendors that have a background beyond development. Vendors that

come from Quality and compliance know quality and compliance, plain and simple. Furthermore, make sure the system has the backend tools necessary to adopt a familiar look and feel. Simple style sheets and configurable layouts can make the difference. Silly as it may seem, changing colors and graphics on a QMS can enhance the end user experience, and provide an environment for better productivity.

Conclusion

There are many systems in the market today, all with various levels of functionality and features. Some vendors focus on a specific niche, some are more generic. All of them have similar features, but in many cases selecting the right vendor falls into a single requirement—what is right for your business. In this paper, we talked about some select features to look for when selecting a vendor for your business:

- 1. Flexibility:** Beware of systems that claim flexibility, but are limited in the depth of configuration to meet your needs. Do not compromise. Have the vendor use your business processes and configure a few sample workflows and forms related to your business.
- 2. Web-Based versus Web-Enabled:** Keep an eye out for systems that claim they are Web-based, but use middleware to accomplish the task. This type of “Web-enabled” interface can cause functionality issues, and make for difficulties in retrieving, searching and integrating data. Make sure the system is a truly Web-based system and uses a single technology to accomplish the task.
- 3. Look and Feel:** Look for systems that are able to match your company's branded image, without programming. Many systems will claim their configurations can be made to the look and feel, but often fall short in allowing layout changes. Having a system match your company's look will make the system less foreign to the end user, and make them more productive and comfortable with the system.
- 4. Reporting:** Make sure the system has robust reporting and searching tools, so that you can find data and trend data with ease. Many vendors will claim they have reporting tools, but through a third party license agreement, driving up the cost of the system. Furthermore, make sure that the system can generate the reports you want. Without proper reporting the data becomes useless to you.

5. Integration: Systems that can integrate across your enterprise can dramatically improve operations. Look for systems that can integrate data from production systems and push and pull data, providing true real-time communication. Many systems can fall short of advanced integration, and usually have limitations. Consider the systems you interact with and ask for a demonstration on how the vendor plans to integrate with your other systems.

6. Scalability: Whether it is an immediate need or a long-term goal, factor in the ability to scale to multiple facilities, contract manufacturers, suppliers and customers. Many vendors offer highly customized “workarounds” to manually sync data from one site to the next, sacrificing real-time visibility and standardization in the process. Look for systems that are able to provide a central location for managing locations, sites, keywords, access rights and processes—ensuring each facility is able to conduct business in their terms, but provide a real-time rollup of data to the enterprise.

7. The End User Experience: Consider your end users when selecting a software system. End user productivity is key to a successful implementation, and comfortable users are happy users. Many vendors do not understand quality and compliance as you would, and develop products that are functional, but not end user friendly. Look for configurable systems that can match a look and feel of familiar systems in your organization, or even mimic legacy systems you are replacing. Simple colors and styles can make the difference. Finally, look for a vendor who understands your business. For example, a vendor primarily focused in Pharmaceuticals may not know what a discrete manufacturing process will entail and vice-versa. Look for vendors who have a background in your industry and see how their product will map to your business.

As you go through the selection process, consider these points, but more importantly, make sure that you build a list of requirements for your system. Having a well-defined set of requirements will provide you with the guide to evaluate a software system. If they are able to meet your requirements, then there may be a fit. Finally, do not be afraid to make the vendor prove their solution to you. Request proof of concept demonstrations, have them configure your sample business process, and pose tough questions. If they are able to respond to your requests, then you can mitigate any risks of a bad investment and ensure a successful implementation.

About EtQ

EtQ is the leading Quality, EHS and Operational Risk and Compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. Founded in 1992, EtQ has always had a unique knowledge of Quality, EHS and Operational Risk and Compliance processes, and strives to make overall quality operations and management systems better for businesses. EtQ is headquartered in Farmingdale, NY, with main offices located in the U.S. and Europe. EtQ has been providing software solutions to a variety of markets for more than 20 years. To learn more about EtQ, visit www.etq.com or blog.etq.com.



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