



Quality Management–

What are the essential requirements when selecting a software supplier?

What characterizes an excellent software supplier in regulated environments?

Excellent products? Excellent service? Excellent know-how? Or something more?

As far as quality is concerned, every company has its own approach starting with the “correct” corporate culture and encompassing efficient processes and first-class organization. In general, these are the contexts that you must consider if your objective is to

attain a high level of quality. However, it is critical to realize that these contexts are the result of a host of individual factors. One of the most decisive factors is choosing the right software partner. But what defines this “right” software partner?

How to separate the wheat from the chaff

From the point of view of the company, the common perception that every company is unique is absolutely correct. They have to deal with the peculiarities of their industries, their own recipes for success, their products and services and of course their own histories. Existing company processes generally reflect these characteristics. At the same time, this means that standardized, structured, and systematic mapping of these individual company processes becomes especially challenging.

The pressure exerted on time and resources by day-to-day business means that you often just concentrate on ensuring that work processes function, and on delivering the desired results. However, there are some situations in which this is not sufficient. In these contexts, it is not enough to simply ensure sensible and efficient connection of specific activities. You must check in advance to confirm that these activities even exist and that they are applied at the right points.

Companies from the Life Sciences environment in particular are well aware of this. Many of these companies can boast relevant experience, gathered during many years of product and service provision, projects with partners and customers, and numerous audits. However, some newcomers pursue innovative business ideas or meet market requirements that were not even on the scene a few years ago.

One aspect common to all is that they rely on software systems to meet their specific industry requirements and fulfill all regulatory prerequisites. This means extra effort for the software provider: for example, system transparency cannot be viewed as an administrative control option in the normal sense. The meaning of transparency stretches much further in the regulated context and above all, a software system must be able to guarantee conformity with the regulatory requirements specified in this environment.

Carrying and imparting knowledge

Companies in regulated industries are experts for their products and solutions but this does not mean that they must also possess expert knowledge of all the regulatory requirements that their IT systems have to map. The technical implementation, the "solution" for these requirements, is not generally part of their core business.

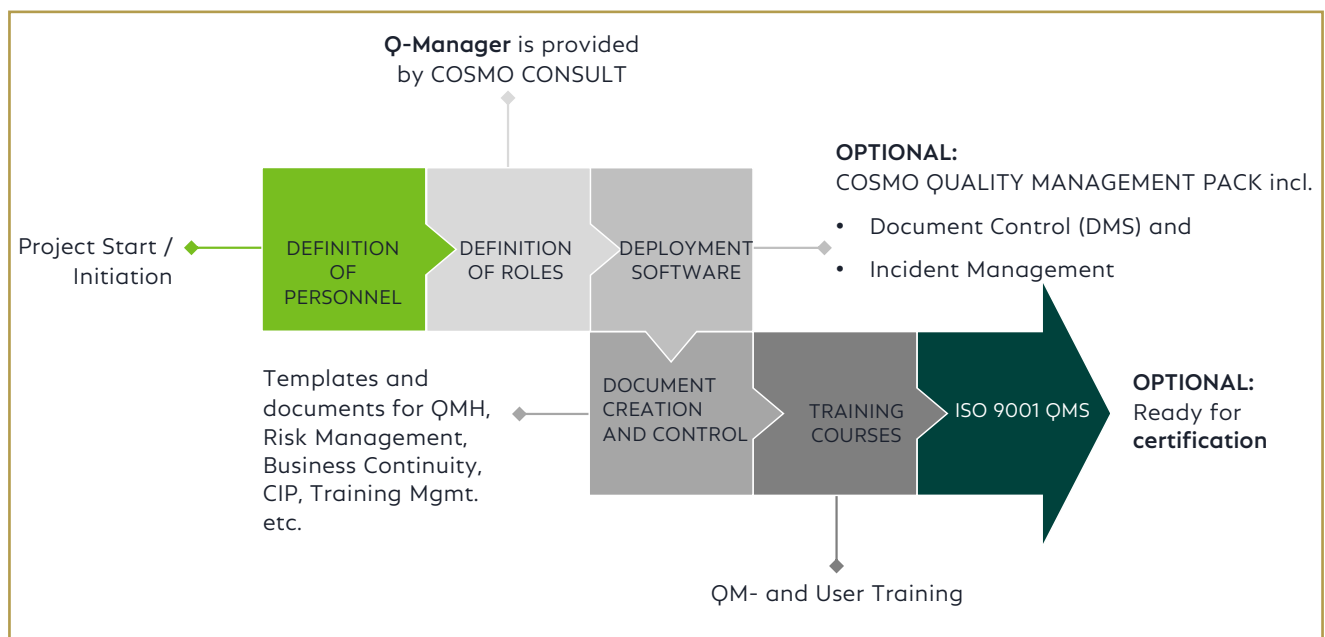
In fact, providing the relevant know-how to customers is the task and core business of the system provider. In regulated environments, system providers are far more than "just" software providers they carry knowledge of a critical area in the affected company. That is why the selection of the right partner is of critical importance.

The implementation and operation of a suitable management system form part of the prerequisites for business activities in regulated environments, showing just how critical the system and partner questions are. Depending on industry typology and market requirements, a range of licensing and approval procedures is

required. A quality management system is obligatory to ensure fulfillment of all specifications, and to allow these to be checked at any time.

It is no exaggeration to claim that software in regulated environments is part of the value chain. In fact, software-supported quality controls and quality assurance are fundamental components of company infrastructure. And successful quality management involves much more: the company must live it as well.

To ensure that this is the case, software suppliers must not only carry knowledge, but have to impart it as well. This starts with comprehensible and regularly updated documentation of system tools, includes detailed training for all employees involved, and goes as far as supporting change processes that have an impact on the corporate culture as a whole. Only those system providers that support this knowledge transfer above and beyond these technical and formal requirements can play a role in regulated environments.



The decisive factor

The selection of the right business solution and a matching implementation partner is decisive when charting the future direction of your company. As has been shown, this applies particularly to companies in regulated industries – especially in the Life Sciences sector. That makes it all the more important for these companies to perform a thorough inspection of their system providers and make their selections based on stringent criteria. But how do you recognize which provider is the right one for a decision of such strategic significance?

Technological expertise, in-depth knowledge in regulated environments, and a clear approach towards conception and realization in the specific context of the company are all necessary prerequisites. But there is something else that you will not find in technical documentation or ranking lists for service providers: the ability of a provider to form a cooperative partnership.

Teamwork is key to establishing efficient, company-wide quality management in the company itself, but also between system providers and users. Only a development and implementation process with full transparency for all concerned allows you to establish a solution that meets all regulatory and functional requirements, whilst remaining understandable and helpful for users. Therefore, it is vital for providers and users to work and communicate closely with one another and align themselves towards common goals.

All companies and decision-makers have their own methods for clarifying whether an intended solution provider will be able to build a cooperative partnership. When confronted with projects that require collective effort, you should certainly choose those providers who do not just give you the right answers, but also ask the right questions.



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