



# WHITE PAPER: QMS: MORE THAN SOFTWARE

STRATUSG – [UPDATED JANUARY 2022]

## **About StratusG**

Since our inception, we have developed methodologies that aim at rapidly understanding what is at the heart of a project, identifying the issues and root causes associated with the underlying business drivers, and finding solutions that address the root causes. Our guiding principles are simplicity and transparency – to eliminate “consultese” and focus on results.

Our approaches have not only been widely accepted by our clientele, but also often adopted by them. We actively support the transfer and adoption of our methods to our clients to leverage their value beyond our direct involvement.

# QMS: MORE THAN SOFTWARE

## A HOLISTIC QUALITY MANAGEMENT APPROACH:

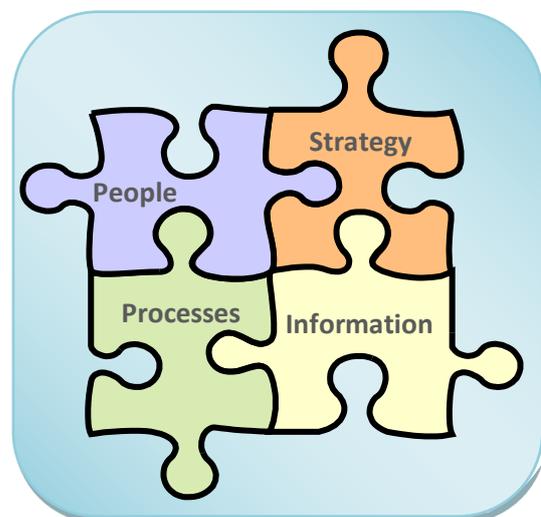
An eQMS software is just one of the many tools that may be employed as part of your organization's overall QMS strategy.

During challenging economic times and with supply chain issues and inflation creating a stranglehold on the flow of goods and services, efficient quality management becomes even more important to the success of your business. Gone are the times of abundance, where manufacturing organizations can afford to absorb the costs of sluggish and non-responsive deviation, change control, and corrective and preventative action (CAPA) processes. To respond to uncertainty, organizations must become leaner in how they manage quality. Time and again it has become clear that those businesses that are the most responsive and able to streamline quality management processes, survive the rough times and thrive in the good times.

Successful QMS is more than a state-of-the-art electronic QMS system (eQMS). It's a holistic approach to implementing a robust and interconnected set of policies, processes and procedures required for ensuring quality in planning and execution of production activities. An eQMS software is just one of the tools that may be employed as part of your organization's overall QMS strategy.

At its core, QMS is about **strategies**, business and regulatory **processes**, **information** management, and your **people**. Strategies provide the road map for robust quality management, business processes are the vehicle that get you from where you are to where you need to be, information about your quality systems is the fuel, and information systems capturing and maintaining this information are the wheels that keep the whole system moving smoothly. The people who work for your organization are the drivers.

Like a puzzle, the Holistic QMS Approach must seamlessly fit together all four of these elements. Realizing that there is always room for improvement, and that internal and external factors change over time, a Holistic QMS Approach allows for adaptation to these changes as part of "process normal".



**Only after understanding regulatory, customer and business requirements, can a sustainable QMS strategy be developed.**

## STRATEGY

Most QMS strategies in their basic form seek to ensure quality with a thorough understanding of regulatory, customer, and business requirements. In order to remain sustainable, the quality management strategy must be achieved while profitability is assured within the confines of resource constraints and/or scarcity.

It is clear then, that to truly develop a realistic strategy, businesses need to understand and analyze these high-level objectives to derive a detailed and aligned set of requirements and business objectives. To do this, organizations must develop the strategic policies, which enshrine the key tenements of QMS as a fundamental “truth” in how they do business.

There are a myriad of approaches to achieving this level of specificity (e.g., [Quality By Design](#), [House of Quality](#), [KANO Model](#), etc.), but regardless of the methodology/methodologies chosen, the resource constraints that the organization faces cannot be ignored. Once you truly understand regulatory, customer, and business requirements, you can align your business objectives, and the constraints faced by the organization, and develop a QMS strategy that will be meaningful; such that your business revolves around clear, measurable, and realistic goals.

**Aligning business processes and procedures with the QMS strategy is a key part of the Holistic QMS Approach**

## BUSINESS PROCESSES

Your business processes add value to your product or service; this is the value (real or perceived) that your customers experience when buying and using your products or services. QMS-specific processes seek to deliver value in the most cost-effective way while ensuring the quality of your products meet the highest standards.

One of the biggest areas of waste we typically identify in QMS processes is the overprocessing of QMS-related activities, which ultimately lead to unnecessarily long lead times. Overprocessing is often caused by the involvement of too many departments or persons in resolving/managing deviations, change controls, or CAPAs and processes that are far too complex. This traditional (i.e., conservative) approach, while understandable, has the effect of stymieing innovation and responsiveness to ever changing external factors. Shouldn't the elimination of non-value-added process steps be a key feature of the continuous improvement of QMS processes?

At the opposite end of the spectrum, the compartmentalization of QMS processes (i.e., silos) leads to a lack of communication within the organization and we end up in a scenario where the right hand doesn't know what the left hand is doing.

In the worst-case scenario, we see organizations that suffer from both afflictions mentioned above, leading a sort of QMS "stagflation", in which processes are bogged down due to a lack of communication and bloated with non-value-added activities.

Aligning your QMS processes with your QMS Strategy, by maximizing value added activities, minimizing wasteful activities, and ensuring good communication and shared information ensures that the benefits of your holistic QMS approach are optimized.

By allowing for constant updates and improvements to your QMS processes, you will ensure the continuous improvement of production quality into the future.

**eQMS software will only add value if the processes that they support are well defined and in alignment with your overall QMS strategy.**

## INFORMATION MANAGEMENT/SYSTEMS

QMS has become a term that is often used when talking about eQMS software systems. With all the various fancy “eQMS systems” out there, together with all the hype around process automation, integration, and digitalization, it is easy (and not uncommon) to fall into the trap of thinking “if we only had a top notch eQMS software system, all our QMS troubles would be solved”.

As we have seen, eQMS software is not the answer in and of itself. eQMS software is however a powerful tool to manage processes and procedures and to collect, manage, and analyze information about your QMS.

Without having a sustainable QMS Strategy that is supported by well thought out QMS processes, an eQMS software project is nothing more than noise or perhaps a façade, which obscures the underlying challenges that organization faces regarding quality management.

If the organization goes through the effort of developing a Holistic QMS Approach, extracting the requirements of eQMS software (including user, business, regulatory, integration, and technical requirements) is a far simpler exercise. Once those requirements crystallize, the process of selecting the appropriate eQMS software becomes merely semantics, and the implementation will have a much higher likelihood of supporting the overall QMS Strategy.

[this would be the place to plug TrackWise, but I must be honest, I don't feel comfortable doing so. TWD kind-of sucks. I feel like, if we plug one vendor, we are losing credibility around the whole concept of being vendor agnostic.]

**A Holistic QMS Approach must be transparent, so that people at all levels of your organization understand how they fit in, and so that they are aware of the criticality of the quality management.**

## PEOPLE

Returning to the previous metaphor, no matter how good your road map, vehicle, fuel, and wheels are; you are never going to get there in an efficient manner without a motivated and talented driver. A motivated driver will get there as quickly as possible but may not take the best route. A talented driver will take the best the best route but may not get there quickly. A motivated and talented driver will strive to take the best route and will get there as quickly as possible.

Ensuring that your people are appropriately motivated (i.e., incentives), and posses the appropriate talent (i.e., training) will yield the results desired in an efficient way by enabling your organization to achieve the goals of successful QMS program.

A Holistic QMS Approach must be transparent, so that people at all levels of your organization understand how they fit in, and so that they are aware of the criticality of quality management.

## SUMMARY

The Holistic QMS Approach involves:

- Development of a QMS strategy
- Alignment of business processes and procedures to the strategy
- The management of information about your processes
- Developing a motivated and talented workforce

Regardless of where you are in the realization of a Holistic QMS Approach, **StratusG** can help by being a partner in your journey, as we have been for many customers who have started down this road.