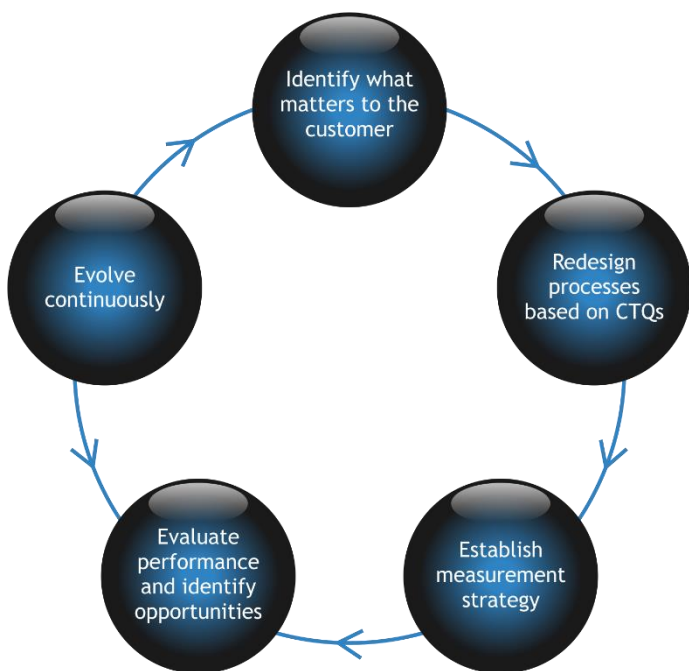




Whyte's guide to **setting up QMS** and avoiding common pitfalls



Organisations for quite some time have been deploying QMS (Quality Management System e.g. ISO 9001:2015*) or some version of it, either to meet the ever-changing competition and customer expectation, to bring down cost of poor quality (COPC), (e.g. rework, escalations, scrap etc.) or for both.

However, in spite of successful QMS deployments, we see companies struggling to reduce PONC (Price of Non-Compliance) and sustain customer satisfaction and loyalty. These issues are highlighted time and again in management meetings, customer churn and survey results.

In this article we focus briefly on how to approach QMS design holistically through five steps inspired by the PDSA cycle, to meet objectives such as process documentation, procedure and responsibilities for achieving quality objectives and adhere to quality management policies. A well designed and deployed QMS helps organisations meet customer requirements while ensuring compliances are met and processes are efficient and effective.

It's no surprise a quality management system should start with specifying customer's requirements. Understanding customer's requirement and aligning processes to meet them has been a cornerstone of multiple improvement projects. While establishing CTQ (Critical to Quality) parameters, one must be equally sensitive to identify CTC (Critical to Compliance), CTP (Critical to Process) and other parameters. SMEs experience and knowledge must be leveraged to this end.

Various Approaches:

- **Lean** – the first among the 5 principles of lean states identify Value, this also forms the foundation for Value stream mapping.
- **Six Sigma** – Six Sigma takes a statistical approach to identify and validate what Value means to customers. QFD (Quality Function Deployment) helps identify quality parameters and the influencers, Hypothesis testing including regression and correlation establishes relationships between dependent and independent variables and Design of Experiment allows factors to be operated at optimal levels
- **COPC** – COPC in section 1.1 (Statement of Direction) advises on adding Quality as one of the directions in which an organization must gauge its commitment to customers and clients. However, while COPC (section 2.4) talks about Quality Management, it does not specify how quality parameters are to be identified and limits it to transaction monitoring.

Why do organisations fail in identifying customer

- Measuring KPI instead of CTQ – In my experience with fortune 500 companies, the biggest misalignments are due to strategies not being translated across layers within the organization, leading to internal processes not being aligned to customer's requirements.

One of the most effective ways to overcome this to ensure each process understand their immediate and ultimate customer. SIPOC, RACI, Escalation & Communication Metrics etc. are some of the tools which provides this view to processes.

- Changes in customer requirements are not captured and sent back across processes – real time or systemic or proactive feedback capture mechanisms in most organisations are broken mostly due to fragmented processes, disorganized responsibilities and lack of end to end view.

Organisations are fast adopting customer survey and analysis mechanisms to bridge these gaps. However, the corresponding change in performance metrics take longer to kick in, this is a failure in PDSA (Plan Do Study Act) cycle that most organisations strive to bridge. Management across industries are spending top dollars to invest in BI & MI solutions. How successful are these deployments and what benefits do these powerful tools bring to that table is a discussion for another time.

Additional Tips:

While exploiting traditional methods of capturing voice of customers, organisations must invest on gathering meaningful insights from social media.

While designing end to end processes or value chain are the best way to go about incorporating changes, often they are time consuming, expensive and disrupts customer experience. Organisations run multiple projects to improve customer satisfaction and experience however, these projects often fail to sustain long term results or fail in the first place. SMEs and departments such as customer advocacy group must partner with consultants for redesigning processes as needed.

Various Approaches:

- **Lean** – Lean is known for making processes more efficient. However, lean tools can contribute significantly in making processes effective by building quality into the process and lead to cost reduction. Correlation between the changes made and customer experience and satisfaction should be statistically studied, one of the many reasons practitioners use lean and six sigma together to derive meaningful results.
- **Six Sigma** – Six Sigma helps in this phase especially with the various approaches and tools at its disposal to manage both DMAIC (Define, Measure, Analyse, Improve and Control) and DMADV (Define, Measure, Analyse, Design, Validate) projects.

Why do organisations fail in redesigning processes

- Improvements in silos most often fail than creating a tangible impact – While process level defects can be looked at in silos, meeting changes in customer requirements often require a holistic approach. Improvements in silos, without aligning subsequent processes lead to Inventory / Backlog and contradict multiple lean principles such as Pull, Waste Reduction etc. while not making any significant improvements on customer requirements or experience.
- Traditionally organisations invest heavily on technology, this gives them leverage only for a defined period due to ever changing technology landscape. Organisations must invest in “Modular” technology which can be changed or modified in parts rather than overhauling the entire system. RPA (Robotic Process Automation) in recent times has been playing a pivotal role in integrating technologies faster, better and cheaper. Future looking organisations are already riding the RPA wave to sustain long term benefits while maintaining agility.
- High focus on documentation while low focus on documentation penetration – While organisations traditionally invest heavily on documentation of processes and procedures keeping certifications and standards in mind, the focus on making the documents usable and ensuring that the documents are used is not given enough emphasis. Training and operations teams must be engaged during documentation process to ensure documents are fit for purpose and are used by operators. Technology must be leveraged to intertwine documented process vis- a-vie process execution.

Additional Tips:

Design thinking, lateral and parallel thinking may add new dimensions to process redesigning.

Most if not all organisations agree with the importance of having measurements in place, its common place to see them have no major contribution to customer experience and satisfaction. An example would be processes who consistently meet the quality performance score but scores poorly on Customer surveys, or worse even, processes with high quality score and good customer survey score (e.g. C-Sat, D-Sat, NPS etc.) but high customer churn. In case a process does not play a significant role in customer satisfaction or customer churn, the existence of such processes must be re-evaluated only exception being statutory or regulatory.

Various Approaches:

- **Lean** –Toyota 3M model focuses on Muda (Waste in the process), Muri (Unreasonable burden on people or machinery) and Mura (un-leveled workload), QMS must be designed keeping in mind these guidelines. Lean also provides multiple methods and tools for enhancing quality of output, techniques such as Poka Yoke allows zero defect processes.
- **Six Sigma** – QMS must have a robust MSA (Measurement System Analysis) plan defines along with defined action plan in case of variations. Most service based organisations have diluted down the process of establishing MSA in quality functions. Some examples are (i) incorrect sampling - sample numbers are agreed and changed to keep clients happy rather than going by statistical sampling methods based on data type, inherent variation, margin of error etc. (ii) Quality Audit Form are most often inconstant with end objective of the process and business (iii) Only quality teams accountable for calibrations – the importance of calibrations cannot be stressed enough in the scope of setting up a QMS. Calibrations in quite a few organization have been reduced to an activity that quality team is solely responsible for. Quality is everyone's responsibility and Operations, Training, HR and other functions must be part of calibrations as needed (iv) Incorrect calibrations done – Most often calibrations are not done based on statistically defined parameters, e.g.
 - Recommended operators or sample sizes are not studied to make meaningful observations.
 - Important statistics such as Tolerance vs total variation are ignored amongst other key statistics
 - Gage R&R is the primary method to evaluate calibration especially in-service industry. There are multiple ways to study the MSA e.g. X bar & R, X bar & S, Anova etc. QMS must be designed keeping in mind the process and data. Interrelationship of quality metric with customer satisfaction and customer churn must be studied, using statistical tools. Fatal and non-fatal parameters must be assigned based on these relationships unless statutorily mandated.
- **COPC** – COPC standard especially while designing QMS for service oriented organisations must be referred. COPS provide a laundry list of measurements and recommends calculations for these. Few sections that must be looked at are section 1.1, 2.4 along with Table F. This will help organisations design fit for purpose audit forms.

Why do organisations fail in creating an effective MSA Plan

- Importance of MSA not explained to Operations – The importance of MSA and the impact it has on customers is not explained to various functions. Time and effort must be dedicated to ensuring all relevant functions are aware of the importance of MSA
- Low priority given to MSA – KPIs must be defined and adequate weightages must be given for all functions that play a role in MSA this includes Quality, Operations, Training, HR etc.
- Lack of Governance – MSA is a mundane activity as it is primarily designed as a maintenance activity, hence often time the governance is not followed.
- Follow through of MSA not robust – Action planning for quality control or quality assurance as part of the Next step is not well defined leading to even lower focus on MSA.
- What does great quality mean to the employees – employees must understand implications for non-compliance and COPQ and rewarded or penalized accordingly.

Additional Tips:

Defining KPIs does not guarantee successful results, adequate time and resources must be made available to enhance chances of meeting targets.

4

Evaluate performance and identify opportunities

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Organisations across industries are moving away from traditional dashboards and quickly adopting to the flexibility provided by the modern-day MI/BI (Management Information & Business Intelligence). These tools equip stakeholders with information they need to make decisions on the go. Organisations must have a well-defined action plan to ensure changes are implemented as planned.

Various Approaches:

- **Lean** - Lean recommends processes such as single piece flow and Kanban to enhance detection of defects on the assembly line itself, minimizing defects from reaching the customer. These instances can be captured to evaluate performance of upstream processes. This however must not replace the need for a separate QMS. Lean also propagates the use of visual signals or Andon board to help identify areas that need attention.
- **Six Sigma** – Most organisations measures performance based on arithmetic averages, while six sigma professionals prescribe tools such as Control charts to measure true performance. Control charts measure averages, variations, defects, defectives etc. They provide an insight into changes in performance that can be

attributed to changes in processes. These observations along with other special causes must be studied in focused groups to identify root causes and subsequently mitigations. Besides these other statistical observations derived from MSA should also be shared in a QMS dashboard.

Why do organisations fail in evaluating performance and identify opportunities

- Performance not captured to provide meaningful insights – performance data are most often evaluated in silos rather than holistically to provide insights into customer experience and subsequent events.
- Data captured mostly focuses on averages and not variations that play a critical role in customer experience. Also impact of changes before and after implementation are not studied thoroughly before changes are made to procedures.
- Non-availability of information for key stakeholders – proactive reporting goes a long way in mitigating risks, carve out action plans and establish procedures. Often management dashboards do not provide definitive insights that would enable decision makers to act fast. Creating a meaningful dashboard which looks at performance, risks, insights and models future enables decision makers to take decisions based on data and adds to the confidence of operations.
- Incomplete or broken RCA (Root Cause Analysis) practices – In most organisations RCA is conducted by Quality teams, while in fact RCA must be owned by operations and quality may only play the role of a facilitator. Roles must be defined with authority to make changes holistically based on findings. All special causes must be subject to rigorous RCA.

Additional Tips:

Rewards and recognition is prescribed by most management gurus and helps in culture change while enabling targets to be met.

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Evolve continuously

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Organisations are constantly reinventing themselves based on customer demand and market trends. It is imperative for internal frameworks and procedure to be agile to accommodate these swift changes with least interruptions. Hence, procedures, accountabilities and governances must be created to evaluate performances, understand business insights and act accordingly. Change management plans and testing are also vital components to sustain a competitive edge in the market.

Various Approaches:

- **Lean** - Value Stream Mapping must be done periodically to ensure value is created throughout the process flow. Opportunities identified must be prioritized and actions including projects must be initiated accordingly. Unfortunately, most companies still act based on the age-old philosophy of not fixing things until they

break, this makes processes and business reactive rather than proactive and future ready.

- **Six Sigma** – Six Sigma provides an array of statistical tools to identify opportunities and prioritise them based on criticality and urgency. Top management must invest time and resources to ensure opportunities are adequately used to keep the competitive edge.

Why do organisations fail in evolving continuously

- Lack of commitment from Top Management – All strategic changes must be driven at the highest level within the organisation. Top management must play an active part in shift in culture and enhancing adoption across organisation. QMS may look like a lot of additional activities without meaningful or tangible results to operations and other functions, however management must ensure that the organisation is made aware of the PONC avoidances, change in customer experience, client relationship and other benefits associated with QMS.
- Budget for a thorough QMS deployment and sustenance – Management must ensure adequate investment in QMS and demand meaningful insights. Management must also ensure adequate resources and technology is made available for a thorough deployment.

Additional Tips:

Driving a dedicated Kaizen initiative allows organisations to identify more improvement opportunities, helping in engaging the workforce in the journey.

In conclusion, the objective of QMS should not contradict the 3rd point in Deming's principle, "Cease dependency on inspection to achieve quality". Partial deployment of QMS may do more harm than good and cause reputational loss at the least for the business as well the project manager. Lack of thorough and detailed deployment of QMS becomes another fad in the organisation and fades away rather than becoming an instrument to make businesses more profitable and customers more satisfied. QMS must be created and deployed with a vision to keep organisations future ready and agile.

**Other standards related to quality management systems include the rest of the ISO 9000 family (including ISO 9000 and ISO 9004), the ISO 14000 family (environmental management systems), ISO 13485 (quality management systems for medical devices), ISO 19011 (auditing management systems), and ISO/TS 16949 (quality management systems for automotive-related products).*