



HARMONIZING QMS WITH BUSINESS SYSTEMS

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HARMONIZING QMS WITH PLM:

In all likelihood, your company has already encountered difficulties harmonizing quality management systems (QMS) with product life cycle management (PLM) systems. Synergies between engineering, manufacturing, supply chain management, and service will not materialize on their own — even in a closed-loop QMS. In this three-part article, integration between QMS and PLM steps forward as one strategy to improve quality management processes throughout the enterprise.

Leveraging PLM Integration to Strengthen Your Business Case & Win Executive Buy-in

If you can make a strong business case to justify the investment in new QMS capabilities, executives are more likely to buy in. Specifically, PLM and QMS integration is one aspect that you can use to strengthen your business case and win buy-in from top business decision makers.

Closed-loop quality management begins at the highest levels of your organization. Without buy-in from key stakeholders, your quality management initiatives will fall short of your expectations. In a worst-case scenario, cost of quality may actually increase as the result of poor leadership and error-prone software implementation.

Of all enablers of closed-loop quality management, winning buy-in from executives is arguably the most key factor. Along those lines, you must be able to make the case to your organization's leadership hierarchy by highlighting specific synergies and potential improvements over current benchmarks.

PLM & QMS Integration Improves FMEA & CAPA Collaboration

PLM integration with QMS has several advantages for engineering-intensive companies including:

- **Improved communication among engineering, manufacturing, and post-production monitoring**
- **Designing for quality from conception to post-market analysis**
- **Facilitating more efficient corrective and preventative actions (CAPA) based on PLM integration**
- **Automating the workflow of failure modes and effects analysis (FMEA)**

Interestingly, many companies are experiencing substantial synergies stemming from harmonizing QMS with PLM sys-

tems. Automated FMEA processes and PLM-based CAPA can enable faster cross-functional collaboration than ever before. In the past, manual processes have impeded the efficiency of identifying and correcting nonconformances from a value-chain perspective.

Synergies begin to become more visible when functions outside of the engineering domain are able to collaborate faster when you harmonize QMS with PLM systems throughout the enterprise. Given the intensity of competitive pressures, silos of information are no longer acceptable in today's global manufacturing industry; best-in-class organizations have already realized the cost savings of QMS integration with PLM and other business management systems. To harmonize QMS with PLM systems, you should begin by establishing a cross-functional team to benchmark current performance versus the ideal scenario.

Where to Begin: Cross-functional Collaboration in Action

After winning buy-in from the top business-decision makers in your organization, the next most important step is evaluating and benchmarking current PLM capabilities. To achieve the best results, you should look to develop a cross-functional team to conduct this critical analysis. Traditionally, PLM systems have been widely used among engineering-intensive companies. The problem is that in a large, globally distributed organization, disparate PLM configurations can make integration very troublesome, even if your company anticipates quality issues well.

From a cross-functional perspective, harmonizing PLM systems with QMS gives your company the benefit of closed-loop FMEA and CAPA processes. Engineering data can no longer afford to remain idle in isolated silos of enterprise applications. PLM-to-QMS integration only increases the efficiency of mitigating quality management issues as early as possible in the design process.

In short, when you harmonize QMS and PLM systems, your company will be able to document tangible improvements

in FMEA and CAPA QMS processes. To shed more light on a sound QMS implementation, the next part in this article will cover how manufacturing operations management systems fit into the closed-loop QMS equation.

HARMONIZING QMS WITH MOM:

Not surprisingly, manufacturing operations management (MOM) systems benefit from QMS integration. Sound quality management systems touch every level of your organization from conception to post-market monitoring. In an ideal scenario, closed-loop quality management principles can increase your company's ability to respond to and mitigate quality issues early in the design process. However, this situation is not always the case, which places the onus on MOM-to-QMS integration to catch quality issues before products reach the global market.

QMS & MOM Integration on the Front Lines.

One of the key challenges of a manufacturing-intensive organization is how to improve collaboration among shop floor operators and quality testing personnel. MOM systems provide your company with a means to efficiently bring products to market — and, most importantly, on time and at a lower cost.

Time is of the essence on the shop floor. Best-in-class organizations have already discovered how to harmonize their MOM systems with enterprise QMS. On the front lines of a bustling manufacturing environment, operators need immediate — if not real-time — access to any nonconformance notifications. Otherwise, poor quality products may continue to be fabricated despite the immediate call to action.

Pinpointing the root causes of nonconformances is useful for preventing these lapses from occurring in the future. The problem is that your company's critical data may reside in isolated, manual (i.e., paper-driven) quality man-

agement processes. Eliminating these manual processes with an automated QMS will only improve efficiency over the long run.

As touched upon in part one of this series, product life cycle management (PLM) systems align closely with failure modes and effects analysis (FMEA) and corrective and preventative actions (CAPA). Including MOM systems in this QMS equation only creates further synergies throughout the enterprise.

MOM-to-QMS Integration's Positive Effects on Quality Management Processes.

As an effective method for preventing nonconformances from reoccurring on the shop floor, CAPA processes alongside MOM systems benefit from QMS integration, too. For manufacturing-intensive organizations, MOM integration is arguably the most important pain point. In an automated QMS, the advantages of harmonizing QMS with MOM systems surface in unforeseen ways.

Harmonizing QMS with MOM systems allows your organization to more effectively benchmark the cost of quality. Ideally, establishing a baseline of current capabilities will help improve cost of quality, but aside from cost benefits, MOM-to-QMS integration also helps improve statistical process control (SPC) and hazard analysis and critical control points (HACCP).

Specifically, by integrating and automating HACCP processes, your organization may actually improve compliance over time. Also, automated HACCP processes can help your company locate areas of weakness during production. As such, synergies with nonconformance/CAPA process become even more apparent.

The Next Step: Beyond QMS & MOM Integration.

MOM-to-QMS integration certainly has several benefits when automating traditionally manual quality management

processes. Fine-tuning the synergies created by harmonizing QMS with MOM systems and PLM systems is the next step.

In the past, your organization may have experienced much difficulty eliminating manual quality management processes. The reasons for this difficulty are many, but essentially, they all boil down to the problems that disparate QMSs create. Harmonizing QMS and MOM systems enables your organization to rid itself of slow, error-prone manual CAPA and HACCP processes.

Nonconformance/CAPA processes cross several different functions within a typical enterprise. Without utilizing QMS as a hub of data exchange and collaboration, your company will likely achieve minimal results when trying to find optimizations in manufacturing operations. To make closed-loop quality management a reality, you need to note that manufacturing operations management (MOM) systems benefit from QMS integration, too.

MOM systems and nonconformance/CAPA quality management processes go hand in hand. In a fully harmonized QMS, MOM systems touch PLM systems via increased data exchange and collaboration. To tie all QMS aspects in this series together, you need to include supply chain management (SCM) into your planning.

HARMONIZING QMS WITH SCM:

In many ways, supply chain management (SCM) systems close the loop on quality management processes. By including SCM integration in your quality management software stack, your company can tie PLM systems together with MOM systems via enterprise quality management systems (EQMS). Supplier quality issues can potentially derail a time-crunched production schedule, so harmonizing QMS with business management systems (QMS + SCM) becomes crucial for efficient quality management.

Benefits of SCM Integration with QMS

When you harmonize your QMS with SCM systems, you can improve your organization's upstream visibility. Also, your organization's ability to respond proactively to supplier quality issues improves with QMS integration. The benefits of SCM-to-QMS integration stem from efficient data sharing and a single location where you can see supplier quality performance via real-time scorecards.

When you align your QMS to collect supplier data automatically, your company can calculate defect rates more efficiently as well as improve complete and on-time shipments. Taken as a whole, SCM integration with QMS increases transparency, which allows your company to harmonize SCM with PLM and MOM systems as well.

Another synergy created via QMS-to-SCM integration revolves around corrective and preventative actions (CAPA). Mitigating quality management issues outside of your organization is problematic, to say the least. However, by integrating supply-chain data with QMS data, you can improve CAPA related to investigating, resolving, and preventing external nonconformance.

In the ideal situation, more efficient upstream visibility in concert with supplier-specific CAPA allows your company to reduce the occurrence of nonconforming materials reaching the shop floor. Also, improved SCM capabilities afford your company the benefit of more accurate risk assessments as the presence of supplier data becomes more integral to the complete quality management equation.

Integrating All Elements of Manufacturing with QMS.

Previously, this article touched upon the benefits of harmonizing QMS with PLM and MOM systems. Expertly config-

ured supply chain management systems close the loop on quality management processes by accounting for external pressures.

Synergies created by harmonizing QMS with PLM, MOM, and SCM systems is an overarching theme in this article. Essentially, QMS solutions act as a hub of information exchange and cross-functional collaboration. Not surprisingly, both of these benefits have been very difficult to achieve using the paper-driven methodologies of the previous century.

For instance, nonconformance and CAPA data rest in silos of applications, business processes, and quality management processes. A fully harmonized enterprise QMS pulls and integrates the right data from the right applications at the right time. Real-time integration and interoperability among disparate software solutions would not be possible without a central QMS to facilitate automated cross-functional collaboration and data exchange.

Some might argue that SCM systems are the missing piece of the quality management puzzle. Supplier quality issues are notoriously difficult to mitigate quickly, which only highlights the improved efficiency of enterprise QMS. To close the loop on quality management throughout the enterprise, you should not overlook SCM systems as a potential opportunity to create synergies among quality management processes. In short, the general idea is to bring external quality management pressures into the fold to harmonize the benefits of QMS.

At the end of the day, harmonizing QMS with PLM, MOM, and SCM systems creates synergies in quality management processes throughout the enterprise. Through increased data exchange and collaboration, best-in-class enterprises are utilizing QMS to stand apart and break new ground in holistic, closed-loop quality management.

IQS

 info@iqs.com

 800.635.5901

 24950 Country Club Blvd. #120, N. Olmsted, OH 44070 - USA

iqs.com



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