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# Smart Manufacturing and Advanced Quality Management **Hexagon and ETQ** **1+1=3**



Few industries have been as transformed in the last 20 years as the manufacturing sector. For more than a century, the manufacturing paradigm remained the same: raw materials in one end of the factory, finished product out the other end. From the coal fired plants of the Industrial Revolution to the mid-20th century wonder of Detroit's automobile manufacturing assembly lines, change came to manufacturing in increments and at a slower pace than sectors such as banking and healthcare.

Today, however, manufacturing is on the cusp of a significant evolution that will impact not only how products are made but how the manufacturing branch of an organization can serve as a catalyst to significant corporate transformation. Key to this leap is the collection, analysis and sharing of data from across the manufacturing spectrum. Whether you look at modern manufacturing through the lens of Smart Manufacturing, Industry 4.0, Quality 4.0, the Industrial Internet of Things (IIoT), or artificial intelligence and machine learning, the undisputed foundation of what's to come is ubiquitous, relevant, democratized and actionable data which will be used in the service of delivering better products at lower cost more quickly and consistently to markets around the world.

In the manufacturing realm, the desired future state may be autonomous manufacturing, depending on the industry and context. With human workers filling the most value-added roles that cannot be handled by technology alone, the

factory floor of tomorrow will be able to run 24/7/365, be self-sufficient, self-monitoring, self-optimizing and self-repairing to create a harmonious cycle of continuous improvement. All of this is driven by the collection, analysis, delivery and utilization of data from all points in a fully connected and integrated manufacturing ecosystem. This ecosystem extends beyond the shop floor to internal constituencies like product design and engineering and external stakeholders such as suppliers, logistics partners and even customers.

Before that future state can become reality, we must recognize that there are several gaps that must be filled in order to usher that scenario into being. First and foremost, there are data gaps. Even in the world's most advanced factories, there are still too many discrete and disconnected systems creating siloes of information -- the bane of efficiency, productivity, profitability and in some cases a hinderance to achieving the potential of autonomy and digital transformation.

One of the more critical gaps to the fulfillment of the Smart Manufacturing promise is the gap between finished product quality control (QC) and in-process quality assurance (QA). By filling this gap with the kind of advanced technology that can automate the process of delivering QC data to a comprehensive QA software platform -- also known as a Quality Management System (QMS) -- we can catalyze a virtuous cycle of continuous improvement and drive quality concerns further upstream in the manufacturing process. That technology and the integration capabilities needed to help close that gap are available today.



# Global Challenges to Manufacturing and Quality Management

One of the reasons for the rapid growth in interest in Smart Manufacturing and automated QMS is that manufacturing and quality are under pressure from a variety of sources today. Even before the massive disruption of the COVID pandemic, supply chains were pressured by a host of environmental and political changes which collectively made the routine and reliable outsourcing of materials and components a challenge. Once the pandemic took hold and work of all sorts was forced to move to a remote and no-contact environment, those challenges were only amplified.

Add to this stack of hurdles a fast-changing world where consumer expectations of product selection, availability, quality and safety are on the rise – and the social media, legal and financial implications of failure are quicker and more painful – the job of simply making things has become ever more difficult.

Similarly, on the quality side of the manufacturing lifecycle, challenges abound and some of these are self-inflicted. As business have grown more complex and geographically dispersed, companies have created siloes of disconnected systems, processes and information. Data that may be crucial to overall product quality is languishing in disparate databases, SharePoint files or even on paper in filing cabinets. Aging legacy systems have failed to keep up with growth, and dynamic scalability is only a dream for many fast-evolving companies. Too often, a “checklist” mindset to quality has arisen in which companies do just enough to stay ahead of increasing regulatory burdens. Meanwhile consumer demands and sharper scrutiny also yield the same rapid negative response to quality failures, the consequences of which can be existential threats to many companies.

A recent Capgemini study found that 68% of organizations surveyed had already initiated Smart Factory projects yet only 14% characterized those initiatives as “successful.” Why? Because there were ongoing challenges in converging IT and operational technology (OT) systems and functional profiles. Those that were successful found that their key success factors were: 1) addressing quality issues sooner in the manufacturing process (“efficiency by design”) 2) focusing on maximizing manufacturing productivity (“effectiveness in operations”).

– Capgemini Study, “Smart Factories Set to Boost Global economy by \$1.5 trillion by 2023”



Under these circumstances, realizing the future vision of autonomous manufacturing may seem daunting. However, there are solutions available today that digitize the quality management process and provide an unprecedented degree of integration across the manufacturing lifecycle to bring the vision of Smart Manufacturing into clear and achievable focus.

## What is Automated Quality Management?

An automated Quality Management System (QMS) is an enterprise software platform that defeats all the challenges posed above. QMS platforms are workflow-based and provide intelligent routing to move quality related events through various areas of an organization. They are used by quality-centric companies to ensure product and service excellence and to adhere to compliance standards demanded by industry or regulatory bodies. QMS software eliminates the siloes and disconnections that stand in the way of maximum performance, and the best systems gather, analyze and communicate critical data that helps companies make better decisions, faster.

The impact a modern, cloud-native QMS can make on most any organization is felt in the reduction of non-compliance events and failed audits, more streamlined operations in every aspect of manufacturing, a reduction of warranty, scrap and rework costs, and the ability to use exemplary quality as a strategic tool to grow and protect revenue.

### A QMS delivers benefits across the entire product life cycle.

**Product Design:** to design quality in the product at the outset

**Supply Chain:** to ensure receipt of high-quality goods from suppliers

**Manufacturing:** to manage in-process quality during manufacturing and assembly

**Logistics:** to ensure the delivery of quality goods to customers and distributors

**Sales:** to sell products at their very best

**Post Sales:** to gather information and feedback from customers on product performance



Ultimately, a QMS supports an organization's ability to resolve quality issues early and meet customers' expectations for quality and safety. At the same time, the QMS is a catalyst for continuous improvement and a foundation for digital transformation.

## Smart Manufacturing and Automated QMS In Concert

As we noted earlier, Smart Manufacturing and advanced QMS can do brilliant things for organizations on their own. Together, however, they bridge the data gap and are transformative in ways that deliver immediate and long-term strategic benefits which we will delineate in the next section. First, let's look at a manufacturing use case in depth.

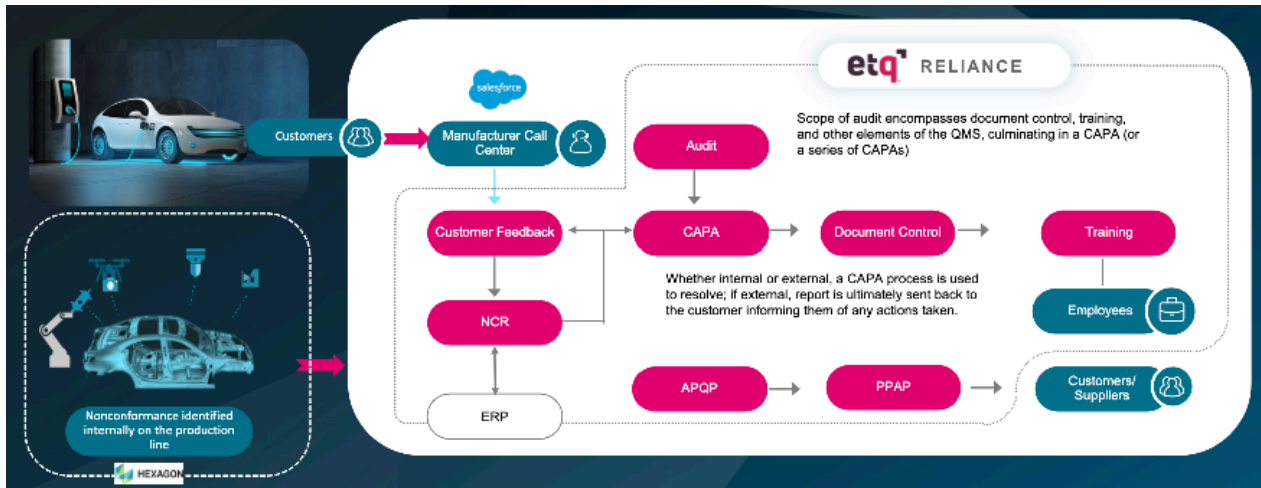
Many nonconformances may result slowly, over time as components on an assembly line begin to drift out of tolerance. Or they may result from poor quality product delivered by a supplier. Regardless of the source, once a nonconformance is identified by metrology, machine vision or other monitoring and measurement systems an action must be taken to halt or modify production of the now faulty product. Today, this action is most often taken by manufacturing professionals and handled manually or with only limited technological help.

However, by including a digital connection between those monitoring and measurement systems and the QMS, a nonconformance report (NCR) can now be generated autonomously and handled within the QMS system without human intervention. The NCR may trigger a corrective action (CAPA) which also updates information in the company's enterprise resource planning (ERP) system to automatically put a hold on a particular batch or lot of the effected product, so it will not escape the factory. If the CAPA resulted in the need to modify documentation of any sort – bill of materials, specifications, testing criteria, supplier information, labelling guidelines and much more – the QMS' document control system ensures each one is updated, version controlled and communicated to all appropriate stakeholders. The QMS will also ensure via its training management application that the right





## Quality Control Identifies Issues/management to autonomously initiate workflows that address quality issues



employees are trained and certified on the new materials and procedures. So, a manufacturer's employees are always up to date on the latest tools and procedures and all training records are kept digitally.

In just one example of this process in action, a global climate equipment manufacturer has managed to cut manufacturing cycle time by more than 400 hours per month just by creating a digital connection between their MES and QMS to automate their system of recording nonconformances. Prior to automation, the company used a manual card system to collect and record nonconformances – not all of which were ultimately acted upon – which resulted in several missed opportunities to prevent product from escaping the factory with quality flaws. Today, not only is the company saving time and allowing employees to engage in stronger value added activities other than manual card entry, but they have also improved their finished product quality and are reaping those benefits as well.

Bear in mind, product quality issues may also surface outside of the manufacturing facility via customer feedback collect and stored in a firm's customer relationship management system (CRM). A digital conduit from the CRM to the QMS also can initiate and drive the above process to the same result.

When the manufacturer initiates an audit or is subject to an external audit, all this information – NCR, CAPA, document control, training, customer feedback – is digitally stored, accessed and easily analyzed within the QMS. This eliminates much of the frustration, time and expense of manual audit preparation but also creates a lasting digital information trail that will be used to drive continuous improvement.

# Data is the New Oil – Advanced Analytics is the New Refinery

All manufacturing processes throw off huge amounts of data. As we have noted, often this data is lost, siloed or blocked from methods to make it easily beneficial to the manufacturer. QMS-based advanced analytics – including machine learning and artificial intelligence algorithms – makes all this information fully actionable and available to the right people at the right time, both inside and outside (suppliers, partners, etc.) the organization as appropriate. It builds an autonomous feedback loop into the manufacturing process and drives quality consideration further upstream to catalyze continuous improvement and provide the fuel for an organization's digital transformation effort across the enterprise.



## Industry Agnostic Benefits Now and Tomorrow

Advanced QMS and Smart Manufacturing is in place today in organizations of all sizes, from digitally native startup in electronics, medical devices, alternative energy, and automotive to global market-leading manufacturers in pharmaceuticals, food and beverage, and aerospace and defense. They have all realized the individual benefits of the two platforms and the most savvy are beginning to focus on the future value of integration of these two platforms.

**Leading organizations of all sizes in most every market understand the immediate benefits of Smart Manufacturing technologies and advanced QMS software working together. In the short term, organizations will see an immediate ability to:**

- Deliver higher quality finished product
- Reduce scrap, rework, waste and warranty costs
- Boost brand image, brand value and customer loyalty

**Slightly longer term, these platforms in concert will enable them to:**

- Truly integrate their enterprise software “stack” with quality management as the hub
- Create a more efficient product design and manufacturing lifecycle
- Speed new product introduction and legacy product updates
- Enact better informed, faster and more targeted responses to market dynamics

Ultimately, the fulfillment of the integrated vision will be transformative to these firms, as it empowers global manufacturing harmonization, delivers ubiquitous and democratized data access to the proper stakeholders in a firm’s entire ecosystem, enables the move from predictive to prescriptive AI-powered decision making, and creates the foundation for digital transformation.

As the world continues to evolve and the business environment is subject to a host of new dynamics – many of which we cannot predict today, as recent history has shown – the goal of an autonomous factory seems less like a pipe dream and more like a necessity. The tools exist today to make it a reality that delivers measurable short-term benefits and provides a pathway to excellence in the future.

[Learn more at ETQ.com](https://www.etq.com)

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