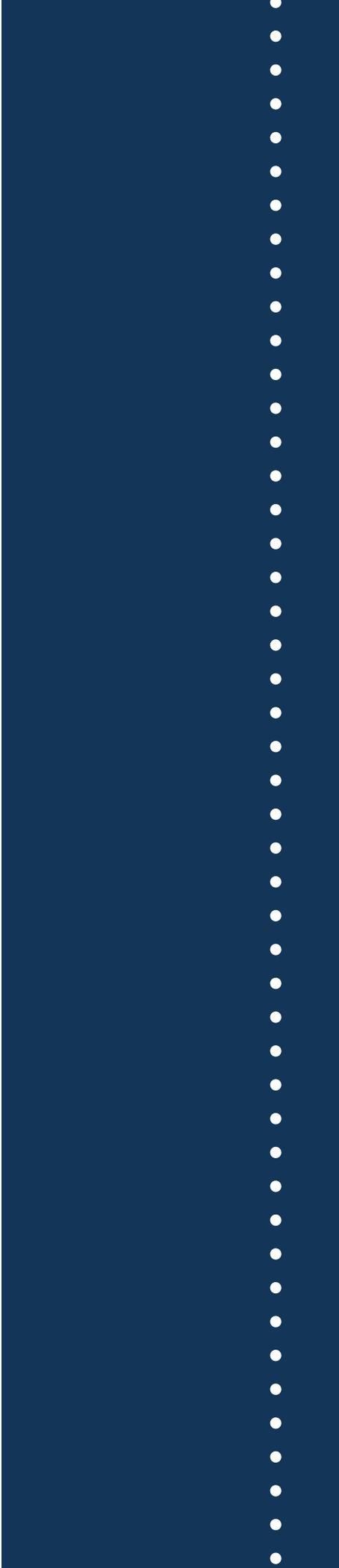




How Smart Quality  
Automation Is Powering  
a New Generation  
of QMS Leaders



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# Introduction

The business landscape is changing, and marketplaces across various industries are becoming more crowded than ever. From medical devices and pharmaceuticals to dietary supplements and wellness products, there's a greater focus on quality management to ensure consumers are protected from unsafe products and practices.

A new crop of regulations are emerging from the FDA and the International Organization for Standardization that will have a major impact on these industries, but these laws could prove challenging to companies in several sectors. Quality management is a complex subject, and it can be difficult to ensure your company – whether it's in the pharma, medical device, dietary supplement, or wellness product industry – is compliant.



# Making Quality Management Manageable

A surprising number of organizations in a wide variety of industries still rely on manual quality management. These processes could involve physical documentation with pen and paper, or they might take advantage of standard office software like Excel.

Manual processes tend to work well in the earliest stages, but they're quickly rendered obsolete after a period of initial growth. As businesses become bigger and must navigate an increasingly complex regulatory landscape, **smart quality automation is the scalable solution that companies need to meet and exceed regulatory benchmarks.**

As opposed to off-the-shelf solutions that require companies to follow predefined processes, smart quality automation allows them to take control of software to automate and digitize existing quality processes.

Most people are aware of the role that quality management plays in areas such as manufacturing, research and development, and shipping and receiving. The manufacturing department must produce a high-quality product for end users that meets the specifications established in the R&D department, and the logistics department can save the company time and money if it spots issues with inputs and outputs before anything is shipped.



# Making Quality Management Manageable

Many off-the-shelf quality management solutions can cover those areas. Only Intellect's software is hyper-configurable to fit your specific business needs and improve efficiency through automated customer feedback. Customers are an essential feedback mechanism in the quality assurance loop, and an influx of complaints about a specific problem may indicate a nonconformance in manufacturing that should be addressed on the production floor.

Automating customer feedback can not only prevent complaints, but it also can continuously improve product quality and safety, minimize product recalls, and create happy and returning customers.

With a smart quality automation solution, companies can exercise full control over what goes into their quality management processes. Complete control of inputs and tracking translates into increased control of the outcome, allowing companies to avoid the costs associated with inferior quality.

# The High Cost of Low Quality

One would think that quality would be nonnegotiable in the aerospace and aviation industries, but a New York Times report suggests that Boeing's manufacturing facility in North Charleston, South Carolina, consistently **prioritized production speed over quality.**

In the plant that produces the 787 Dreamliner, manufacturing employees filed a slew of complaints about tools left on aircraft and the use of faulty or defective parts; the New York Times even reports that planes have gone on test flights with loose tools in their engines. Boeing denies that the plant is experiencing any issues, but the allegations illustrate the intense scrutiny directed toward quality management.

The good news is that emerging technologies in the quality management space are leading to cost reductions and productivity increases. According to **a McKinsey & Company report**, digitization and automation can spark a 30% to 40% increase in productivity and a 50% reduction in quality control costs.

# Consistency is Key

After quality control concerns emerged from a plant in Dadra and Nagar Haveli, India, an FDA investigation reportedly found quality control deficiencies in the manufacturing processes of Sun Pharmaceutical Industries Ltd.

**According to a report**, part of the concern stemmed from a lack of written production procedures designed to maintain consistent drug strength and quality – two factors that are vital to achieving positive patient outcomes.

These shortcomings demonstrate the importance of concrete procedures that can be monitored by a quality management system as well as the need for supply chain transparency.



Samsung recalled 2.5 million smartphones at a total cost of \$5.3 billion.

# The Power of Hyper-Configurable Quality Management

A focus on quality is vital across industries, but many businesses drop the ball because of manual quality management. With a smart quality automation system, your workflow will be easier to manage and less prone to human error. As a result, you'll enjoy the following benefits:

## 1. Avoid Astronomical Lawsuits

When you have a tight handle on quality, you avoid the types of mistakes that end up in the courtroom. There are no positive outcomes from a liability lawsuit, and it can do permanent damage to your reputation regardless of fault. With the right quality management system in place, you can reduce risk as much as possible and look out for your customers' best interest.

You can never eliminate risk, but the ability to point to a robust quality management system and a stringent focus on compliance could save your company in the event of an accident. At the same time, customer safety isn't just about good business sense — it's the morally correct thing to do.

## 2. Eliminate Expensive Waste

There's a reason that waste is the bane of manufacturing. Creating a product, building it out, and then having to scrap it because it's not up to par is a great way to waste resources and frustrate your employees. In some cases, the costs associated with low quality can be catastrophic. Almost everyone remembers **Samsung's recall of the Galaxy Note 7**. After 96 devices overheated or caught fire, Samsung recalled 2.5 million smartphones at a total cost of \$5.3 billion.

While it's impossible to avoid waste entirely, you can drastically reduce it by implementing effective quality assurance measures at each step of the manufacturing process. When mistakes do occur, quality management can pinpoint where problems arise and highlight whether the issues are part of a pattern. If so, a quality manager can intervene and alter the process in a way that produces better results moving forward.

# The Power of Effective Quality Management

## 3. Constantly Improve Quality

When your organization is consistently working to resolve issues with quality, you'll see continuous and robust improvements that ripple throughout your company. Reduced waste, improved customer experiences, and lower customer service costs all stem from quality improvements.

Marketing research consistently proves that **the highest-quality brands** enjoy more repeat purchasers. Meanwhile, customers will quickly notice a slip in quality — tell their friends about it. Research from the White House Office of Consumer Affairs suggests that they'll share their experience with **nine to 15 different people**.

Many executives are frustrated by the complications and complexities of compliance, but the companies that make the upfront investments necessary to adhere to regulations can end up seeing a substantial return. Compliance isn't just a box to check; rules exist for a reason, and meeting compliance standards shows that your company is committed to product quality, ethical production, and customer safety. Treat compliance as a competitive differentiator, and you may be surprised by the positive response from your customers.

Compliance essentially is about maintaining a standard of quality. According to technology company First Insight, quality has surpassed price as **the most important factor** consumers consider before making a purchase. A cheaper product will appeal to just 38% of potential customers, but a product of higher quality attracts 53% of buyers.



Unsatisfied customers will share their experiences with an average of nine to 15 people

# Is Your Quality Management Solution Giving You A Competitive Advantage?

As regulations continue to spring up governing all kinds of industries, the companies that are slow to respond will have a hard time staying in business. Organizations that take a proactive approach and rely on smart quality automation will reap the rewards and come to see compliance – and the resulting increase in quality – as a competitive advantage.

*Intellect is a world leader in business applications, workflow management, and QMS software, with more than 18 years of experience helping companies improve quality, safety, and efficiency.*

**Speak with one of our experts in quality management today!**

