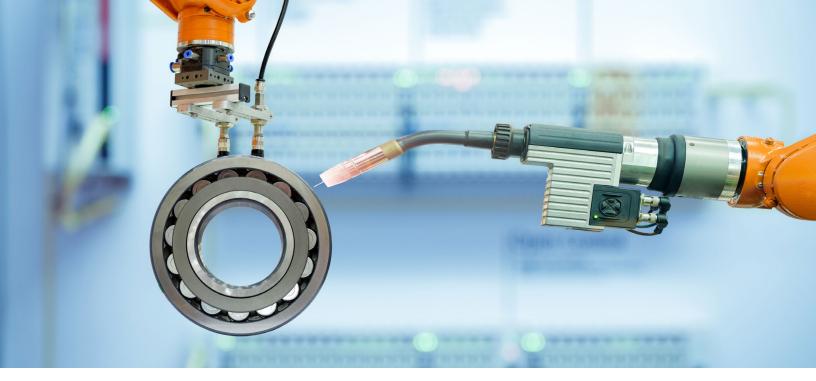


### **Table of Contents**

- 3. Introduction
- 4. Quantifying Quality
- 5. Raising the Bar
- 7. Giving You an Edge
- 9. Looking Ahead
- 13. Contact Us



### Industry 4.0 is upon us.

Powered by Internet of Things-reliant devices and web applications capable of processing unprecedented amounts of data, this is a revolution that will **touch every industry** and seismically shift the way we live, work, and interact with one another.

Sitting at ground zero of this revolution is the manufacturing industry. "Smart manufacturing," "advanced manufacturing," "industrial transformation," "The Factory of the Future," and a litany of other labels have been applied to the evolution of the way things are made. Regardless of what you choose to call this Fourth Industrial Revolution, it comes with new opportunities and challenges for manufacturers. Companies that thrive in this new era do so by leveraging digital industrial technologies to automate, integrate, and optimize manufacturing processes.

Solutions such as artificial intelligence and machine learning, virtual and augmented reality, and cloud computing already are **separating the leaders from the laggards**. Practicing companies are transforming operations within and across plants to efficiently develop new products, subsequently changing the way customers engage with their products and services.

Rather than pursuing continuous improvement (a hallmark of the past industrial era), companies embracing Industry 4.0 seek "step change," or the disruption of long-standing best practices, value drivers, and competitive advantages with digital tools and processes. Though the results of this new approach are still preliminary, they're already staggering.



### Quantifying Quality



According to a 2019 McKinsey & Company report, the emerging technologies driving Industry 4.0 allow labs and pharmaceutical companies to reach 80% paperless operations.



With fewer manual errors and data-enabled analysis of root causes, these companies can decrease investigation workloads by 90%.



Similarly, new technologies have helped companies achieve more than a 65% reduction in deviations and 90% faster closure times.

By itself, the prevention of major compliance issues can save companies millions of dollars. Plus, greater operational efficiency will help some dramatically reduce companywide expenses, savings that aren't dependent on a completely robotic workforce.

Despite the prevailing narrative, digitization isn't resulting in a mass exodus of industrial workers. Instead, the U.S. manufacturing sector has added 1.2 million new workers since 2011. While training this workforce to use Industry 4.0 technologies will be a top concern for all manufacturing companies moving forward, they're left with one question: In the midst of this massive change, how can manufacturers ensure quality at scale?

#### That's where Quality 4.0 comes in.

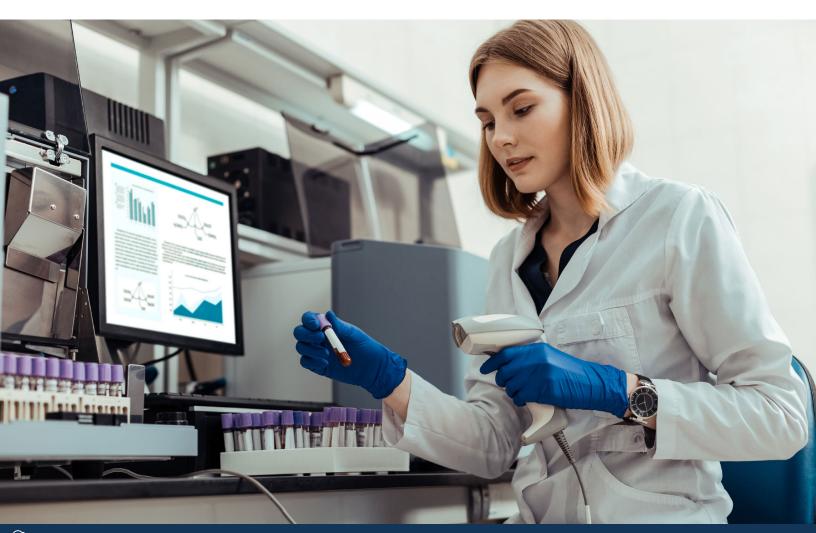
### Raising the Bar

The same characteristics that drive Industry 4.0 — digitization, connectivity, advanced analytics, and reporting — power Quality 4.0. Automated tools already optimize product quality by minimizing manual error, preventing compliance issues and variability, and enabling more efficient decision-making.

By leveraging these technologies and embracing digital transformation, companies can improve business agility and streamline business processes, each of which leads to more revenue and fewer expenses.



For example, the aforementioned McKinsey report found that pharmaceutical companies that are equipped with mature, efficient lab environments see their productivity increase by 30% to 40% when automation enters the mix.





Intellect's Quality 4.0 solution — titled Smart Quality Automation — gives companies ownership over the entire quality management process. The solution lets businesses control how software automates a process and empowers them to determine automation's place in their organization.

With Intellect's eQMS software, manufacturers no longer have to outsource compliance and quality management to a third-party vendor. The platform implements a process-based approach that's grounded in five dimensions of product and service quality: conformance, feature, performance, reliability, and responsiveness.

Each clearly outlines an enterprise user's policies, authorities, and responsibilities within a global quality management system. This transparent process shows customers, suppliers, and employees how committed a company is to meeting consumer standards and regulatory mandates.



### Giving You an Edge

As the manufacturing landscape has evolved, Intellect's eQMS platform has moved right along with it. Our experience has shown us that an out-of-the-box quality management tool doesn't exist — nor should it.

Every company within every industry has its own standard operating procedures that software should be tailored around. Our platform is completely customizable to support every user's unique processes. With a drag-and-drop interface that empowers citizen developers and minimizes user onboarding times, Intellect's platform allows you to implement a sophisticated yet intuitive workflow.

When quality is the goal, the idea is to get things right the first time — but systems can fail. Quality professionals identify critical points of failure before a breakdown occurs and make the necessary corrections to prevent failures from happening. Our highly configurable platform can change with you as you optimize your processes to eliminate errors.

Similarly, customization is vital in any industry governed by a complex and evolving set of regulatory standards. When standards or regulations change, you

must be able to modify your software so your digital and automated processes can adapt accordingly. Thanks to new, more nuanced data and more advanced analytic capabilities, manufacturers can be more proactive and rely less on postmortem inspections and retroactive evaluations. Businesses are able to predict when and where problems might occur or maintenance might be required, removing the need for expensive repairs.

In industries like auto manufacturing, where products are expensive and safety implications are considerable, predictive technologies have long been essential to operations. Now, businesses producing durable manufactured goods in other sectors are increasingly reliant on those same tools to remain competitive.

Intellect's dynamic reporting system allows you to maximize the value of your data so you can speed up the identification and resolution of quality problems. The result is reduced expenses associated with warranties and regulatory fines and less damage to your brand reputation.

In a hypercompetitive business environment, customer loyalty is precious and can be nurtured through an unwavering commitment to quality. With a new generation eQMS that allows you to minimize production defects and prevent recalls, you can be sure you'll keep that loyalty.

# **Quality Questions**

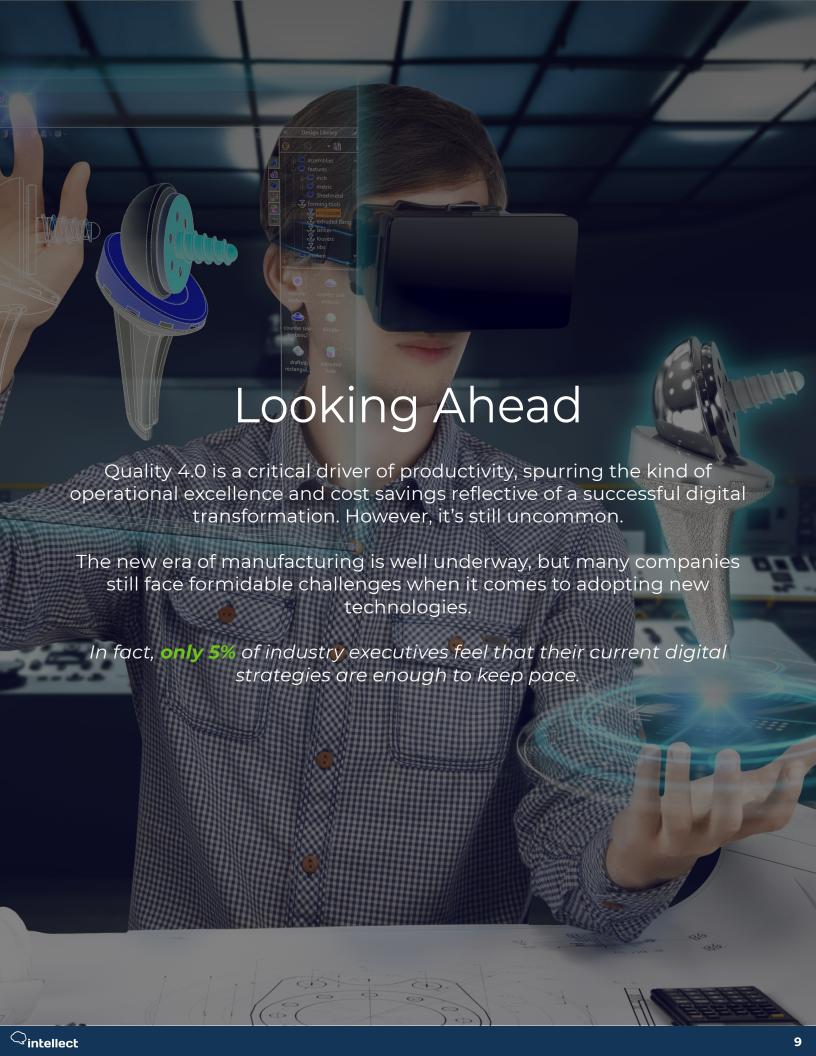
Quality 4.0 is a concept that focuses on the increased prominence of automation and secure data exchange in the quality control processes of modern manufacturers.

Companies embracing Quality 4.0 leverage emerging technologies and digital-first processes to anticipate supply chain disruptions and enhance a good's overall quality, cost, and speed to market.

If you're unsure whether Smart Quality Automation would benefit your organization, ask yourself the following questions:

- **1.** Are our products becoming smaller and in need of increased precision?
- 2. Is the product's life cycle shrinking, mandating reduced delivery times and quicker responses to engineering changes?
- **3.** Do we increasingly engage in short-cycle manufacturing, continuous-flow manufacturing, or demand-flow manufacturing? Are we facing supply chain pressures created by just-in-time manufacturing?
- **4.** Is automation helping our competitors become more productive and efficient?
- **5.** Are OEMs imposing more stringent quality standards or demanding greater supply chain transparency? Are they mandating that we adopt automated technologies that improve quality, productivity, and overall supply chain efficiency?

If you answered "yes" to any of these questions, a quality management platform may help you overcome the challenges directly in front of you. If you answered "yes" to all of them, you needed Smart Quality Automation yesterday.



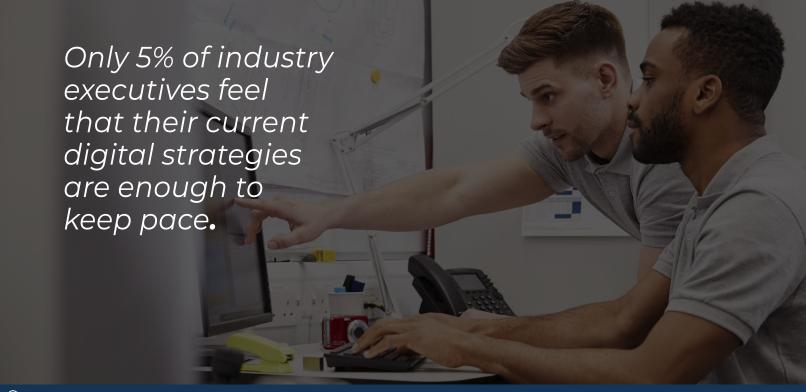
# If your company falls into that **other 95%,** here are three tactics you can employ to bolster your own strategy:

#### 1. Determine what you need.

Clearly articulate your business objectives and a timeline for meeting them. Once you're clear on your goals, identify potential barriers such as lengthy cycle times, drawn-out or frequent investigations, siloed data, or poor product quality. Smart Quality Automation can help mitigate these challenges, provided you're willing to change where change is needed.

Most executives understandably focus on the company balance sheet, and automated quality control can certainly deliver incremental revenue and cost savings. However, attaining Quality 4.0 requires ongoing investment and a commitment to long-term sustainability derived from step-change improvement in industrial operations and enterprise performance.

The rewards of enhanced quality may not become apparent immediately in all areas. Risk reduction associated with product recalls, lawsuits, and lost customers is harder to quantify than simple cost reduction. However, you can be sure these intangible benefits will make the future easier for your organization.





## 2. Create a five-year plan for meeting those needs with technology.

Industry 4.0 represents a once-in-a-generation economic shift that could impact the world well into the next century. Regardless of where you are now in terms of technological adoption, your focus should be on where you want to be. It bears repeating that attaining all of the benefits of Quality 4.0 is a relatively long-term objective, and your plan should include both your company's current and projected needs for the next several years.

As you think about the future, make it a point to stay well-informed of new developments related to international standards and regulations. When it's time to choose QMS software, insist on configurable technology solutions that give you the flexibility to adapt to new regulatory requirements, major market developments, and your own evolving business process needs.



### 3. Get your team ready to go.

Employees across your entire organization will be affected by digital transformation. Understanding employee perspectives will allow you to more easily explain how Smart Quality Automation will influence their day-to-day responsibilities.

Among management, quality is typically seen as a cost center. Your quality analysts and business analysts use similar tools and methods to improve efficiency, but the focus of business analysts tends to lean toward direct costs. Be clear about what you hope to gain over the long term through automation and digitization so your employees can shift their focus accordingly. Digital transformation isn't accomplished by merely replacing outdated technology; it must be accompanied by a transformation in your organization's collective mentality.

This new mindset will alter how you engage with both internal and external stakeholders. You'll likely experience a significant change in the way customer service is handled, so prepare your workforce accordingly. When you achieve Quality 4.0, you'll notice a marked reduction in complaints from end customers and OEMs, but any complaints that you do receive should be escalated to nonconformances and CAPAs so you can identify and eliminate the root cause.

When you rely on an automated system, errors can be rectified quickly. A failure to address them, however, can lead to more consequential operational disruption. Even in the technologically enhanced, data-driven factory of the future, people are still your greatest asset. Your software and digital processes are only as good as the people using them, so prioritize employee education and incentivize workers to adopt new processes.

Smart Quality Automation can give you a significant competitive advantage in the new era of manufacturing. In Industry 4.0, your organization will be judged based on the quality of your products and processes. As manufacturers continue to evolve, quality standards will rise and be dictated by customers, regulators, OEMs, and your competitors. Intellect can help you ensure that your business is setting the standard, no matter what sector you operate within.

To learn more about our eQMS solution and how we can help you meet your needs, speak with one of our experts in quality management today.



