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# How to Thrive in an Age of Disruption


**WHITE** PAPER

# DEALING WITH DISRUPTIONS

Global pandemics. Natural disasters. Political turmoil. Parts and labor shortages. As these events become more commonplace, it's evident that we are living through an unprecedented period of disruption. These disruptions can negatively impact not only our personal lives, but also the operations of manufacturers as they strive to introduce innovative, safe, and effective products to customers worldwide.

Manufacturers have had to adapt to an ever-changing market as the regulatory landscape continues to evolve and the introduction of Internet of Things (IoT), artificial intelligence (AI), augmented reality (AR), and other disruptive technologies continue to increase product complexity and customer expectations.

The COVID-19 pandemic has also significantly impacted manufacturers—causing raw material shortages, increased lead times for components, issues with logistics, and other sudden disruptions to their supply chains. One of the first major shocks was the shutdown of factories in Asia due to COVID outbreaks. It caused a global shortage of microchips, which are a key component of computers, smartphones, medical devices, and many consumer products. Ultimately, manufacturers were forced to scale down or delay the production of these products because of the shortage[1].

In addition to supply chain disruptions, many companies experienced communication and productivity issues due to their reliance on email, spreadsheets, document-based applications, on-premises software, and other disconnected systems. As more employees started to work remotely, these systems created silos, making it difficult for product teams and supply chain partners to collaborate efficiently and stay on the same page.

In the wake of the COVID-19 pandemic, manufacturers have experienced product shipment delays, quality issues, increased customer complaints, lost revenue, and the inability to gain first-mover advantages.

So how can companies better navigate future disruptions and continue to thrive?

In this white paper, we explore how the adoption of enterprise cloud-based solutions and other technologies enable product manufacturers to quickly adapt to change and make the necessary digital transformation to compete in today's global economy. We also provide some key steps that you can take to ensure your digital transformation success.

# GETTING AHEAD OF UNFORESEEN EVENTS

Despite the disruptions and challenges facing most manufacturers today, they still need to innovate rapidly and gain a competitive advantage. For many, the key to success will depend largely on whether they can complete a digital transformation to drive greater operational resilience, transparency, and agility.

## What Is Digital Transformation?

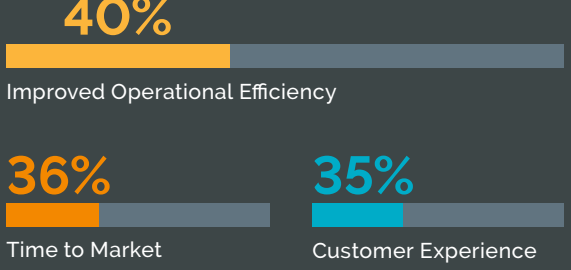
Digital transformation is a broad business strategy, applicable across all industries, to solve traditional business challenges and create new opportunities using technology. It requires acceptance of new ways of working and delivering value to customers.

By embracing new digital technologies, product teams can better communicate and gain greater visibility into supply chain execution activities to avoid unnecessary production delays, quality issues, and other factors that impede product launches. In turn, manufacturers can rapidly respond to and proactively address the next wave of disruptions that come their way.

**Benefits of Digital Transformation**

- Future-proofs your business by improving agility and resiliency to changes
- Increases visibility of changes up and down the supply chain
- Supports virtual collaboration and remote workforce models
- Boosts operational efficiency and productivity
- Provides more data-driven insights and allows for better decision-making
- Creates new business opportunities and revenue streams
- Improves customer satisfaction
- Drives a culture of innovation

**Top Reasons Why Executives Pursue Digital Transformation Initiatives**




Source: Digital Transformation Report by Corporate Leaders and PTC

## Adopting the Right Approach

Manufacturers often rely on manual processes, paper-based systems, spreadsheets, or other point software solutions to manage their product development processes—from product design and sourcing of materials to production and delivery to customers. And as companies grow, they end up with a patchwork of disconnected solutions. There are many reasons why these solutions appeal to companies. For example, apps like Google Docs and Google Sheets are inexpensive and serve as easy tools that supply chain partners can use. Companies also turn to traditional solutions that most employees are accustomed to using like Microsoft Word and Excel, and they attempt to make these solutions fit their growing requirements.

The COVID-19 pandemic was the catalyst that led to supply chain disruptions globally. With a heavy reliance on just-in-time (JIT) and lean manufacturing models, coupled with the use of siloed point solutions, the perfect storm emerged to create issues getting raw materials, components, resources, and finished products to consumers. As workforces became more isolated, so too did the entire new product launch process.

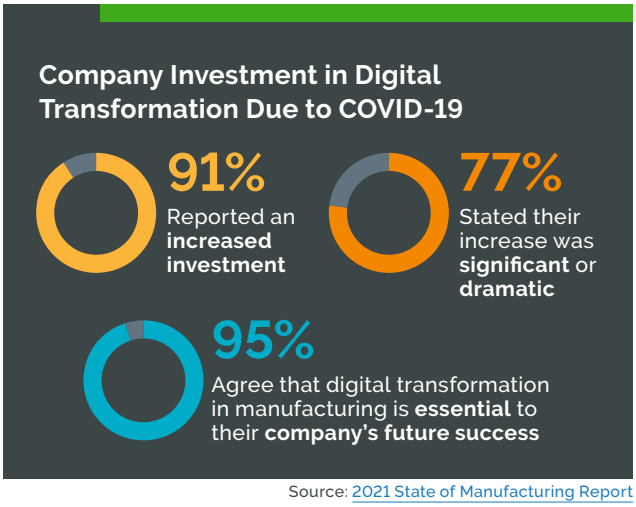
To keep the lines of communication open and maintain productivity while shifting to a remote workforce, some companies quickly adopted cloud-based applications such as Zoom, Asana, Microsoft Teams, and other chat apps. Although these apps helped teams collaborate and share information—they still created silos. And because these methods of communication were not connected to the complete product record—they made it nearly impossible to identify the latest product design or track the continual changes that occurred daily, if not hourly, between internal teams and supply chain partners during new product development and introduction (NPDI).

So, what is a more suitable approach for product manufacturers looking to lessen the impact of pandemics, natural disasters, regional conflicts, and other supply chain disruptions?

> When it comes to digital transformation and product development, it's not just a matter of working in the Cloud or with digital technology—it's a matter of *connecting* the right product information, people, and processes in the Cloud.

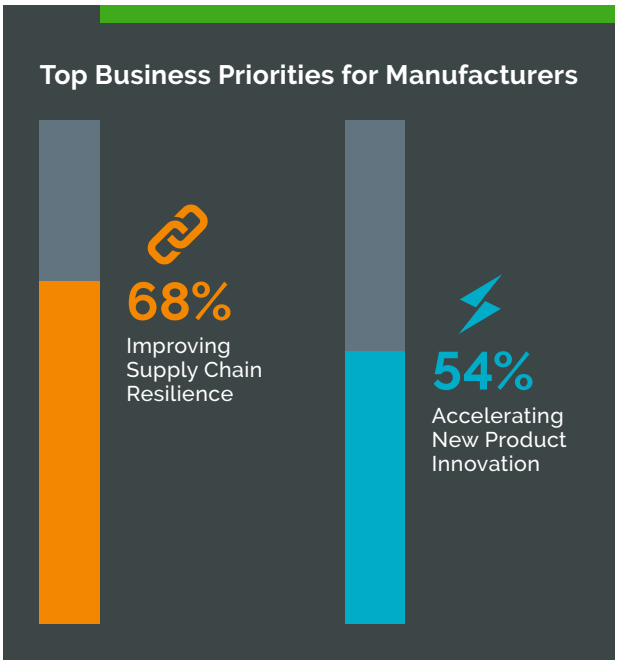
## A Shift Toward Digital Manufacturing

According to a recent State of Manufacturing survey, most companies reported an increased investment in digital solutions across both operations and production. This was due to the long-term effects of the pandemic on their business and the overall need to enhance supply chain resiliency and accelerate product innovation.




Source: 2021 State of Manufacturing Report

Companies are now looking beyond the COVID crisis and implementing more long-term digital approaches that can help them improve collaboration across dispersed teams and supply chains and adapt to the "new normal" of remote work processes.




Source: 2021 State of Manufacturing Report

Enterprise product development solutions that are born in the Cloud address the challenges that today's dispersed teams face. More specifically, cloud-native product lifecycle management (PLM) and quality management system (QMS) solutions provide a single source of truth for internal and external teams to collaborate 24/7 via a web browser anywhere around the world. These types of enterprise solutions offer complete visibility into customer requirements, product design changes, quality issues, regulatory compliance mandates, and other processes that are critical to manage throughout NPDI.

Cloud-native (multi-tenant) PLM and QMS solutions that are sold under a software-as-a-service (SaaS) subscription model eliminate costly IT resources and upfront expenditures for hardware, software, virtual private networks (VPNs), and other infrastructure. Furthermore, cloud-native SaaS solutions are designed for fast deployment—speeding time to value (TTV) for companies looking to make the transition from traditional software systems. Once the software system is deployed, continuous enhancements are provided by the vendor, eliminating the traditional costs associated with upgrades and ongoing maintenance. These cloud-based solutions also reduce the IT infrastructure and security obstacles associated with on-premises and single-tenant SaaS platforms.

For manufacturing companies and global supply chains, Cloud PLM and QMS solutions are critical to drive a successful digital transformation strategy.

# 7 STEPS TO FUEL DIGITAL TRANSFORMATION SUCCESS

Making the transition to digital may seem overwhelming, especially if you're working with multiple legacy systems (e.g., on-premises software, document-based solutions) that maintain high volumes of product data.

Cloud-based product lifecycle management (PLM) and quality management system (QMS) solutions offer a straightforward and fast approach for manufacturers to move their new product development and introduction (NPDI) processes into the digital realm.

As you contemplate making the transition, it's important to not overcomplicate things. You need a simple, clear strategy to overcome any resistance or roadblocks.

To advance your digital transformation, we recommend following these seven steps:

## 1. Evaluate, or audit, your current product development and launch processes.

Conduct a cross-functional assessment of your current systems and processes. Identify the areas that may need to be changed.

Solicit feedback from impacted product teams to gain a complete picture of all areas that are affected. This will also help your employees feel included and heard from the outset.

Some questions to ask:

- Do we have problems/gaps collaborating today?
- Are we reliant on tribal knowledge vs. transparent systems?
- Is there an opportunity to improve customer satisfaction/reduce customer complaints?
- Are there areas where the company lacks insight and visibility?
- Can we easily identify problems before they become roadblocks?
  - Is there an opportunity to improve efficiency?
  - What processes need to be streamlined?
  - Are there areas where we can reduce costs?

Completing this assessment will help you set realistic goals and objectives for your digital transformation journey and the adoption of a Cloud PLM or QMS solution.

## 2. Identify business goals and objectives.

Set goals and objectives based on your evaluation. Establish realistic short-term and long-term goals. Be sure to consider other competing projects and whether having a phased approach to reach your goals will be most effective.

## 3. Build your project team.

Your team should include key stakeholders from across the organization, including:

- Engineering
- Procurement
- Manufacturing
- Operations (manufacturing supply chain teams)
- Quality and regulatory affairs
- Customer support
- Executive sponsor that is responsible for getting products to market

## 4. Choose the software solution and vendor that best aligns with your business needs.

Choosing the right software or technology involves many steps—from capturing requirements and evaluating vendors to building a financial case. To gather insights, read our comprehensive software buyer's guide.

## 5. Empower employees to drive continuous improvement.

- Encourage and reward new ideas, accountability, and transparency
- Provide access to all teams from engineering to quality to manufacturing so that everyone can contribute and address opportunities to improve product and customer satisfaction
- Give management the tools and ability to measure performance and make adjustments to eliminate delays, errors, and unnecessary processes

## 6. Regularly assess the business processes.

Evaluate the actual performance of your software against the targeted business objectives.

Key metrics to measure:

- Product development cycle time
- Time to market
- Reduction of scrap/rework
- Reduced costs (development, manufacturing, field support)
- Operational efficiencies (faster review cycles and fewer production errors)
- Customer satisfaction

## 7. Optimize processes based on metrics and findings.

You can't improve processes, designs, or products unless you know how well they are performing. Every team from engineering through manufacturing and customer service should be measuring outcomes. Adjusting designs or processes will yield continuous product improvements to maintain a competitive edge.

# DIGITAL TRANSFORMATION SPURS AGILE PRODUCT DEVELOPMENT

As companies make the move to digital systems, they are starting to recognize how cloud-based solutions keep virtual teams connected and primed to mitigate disruptions that threaten to compromise product launches.

To eliminate collaboration gaps and confusion, cloud-based systems, like PLM and QMS, bring the essential product development and quality management processes into a single platform. From the bills of materials (BOMs) and engineering change processes to quality records, design files, requirements, and employee training plans—everything is connected, providing product teams, design partners, and suppliers real-time access to avoid communication gaps. This helps companies become more agile in their approach to product development.

## Cloud PLM and QMS Solutions Speed Product Launches

When it comes to delivering innovative products, the first critical step is creating and controlling the product record. Once the product design and full product definition is controlled, you can start to link key processes and people to the underlying product record—ensuring that the right product gets built and shipped without mistakes or delays.

> “To help better quantify the business value of digital transformation, we've been working with hundreds of our customers worldwide. The cumulative impact that we've seen runs into billions of dollars as companies use digital strategies across the product lifecycle to increase revenues, improve operating margins, and increase asset efficiencies. The benefits are found up and down the supply chain and across engineering, manufacturing, and service.
>
> —Lucas Fernandez, Senior Director of Quality and Regulatory
>
> somalogic

### Bringing the Product Together

By aggregating the product parts, documents, and software into a centralized system—product teams and supply chain partners can easily create, share, change, and approve product designs. Product teams also gain better visibility into any changes that impact production. Automated processes and revision controls can be applied to parts, BOMs, and documents to ensure the latest product information is used by everyone involved in getting the product commercialized.

### Streamlining Product Development

By leveraging the centralized product record, manufacturers can effectively manage and track product requirements, design changes, and team deliverables to resolve issues more quickly and meet their new product development milestones. An effective solution should drive controlled engineering change management processes with automated reviews. It should also enable teams to better capture requirements and address issues to drive continual improvement and innovation.

### Enhancing Supply Chain Collaboration

Effective communication between original equipment manufacturers (OEMs), design partners, suppliers, and contract manufacturers is essential to optimize design for manufacturability (DFM) and ensure commercialization success. The ability to access current product information and collaborate in real time from any location will ensure that all impacted teams are always on the same page. Cloud solutions can foster frequent, proactive communication to help circumvent manufacturing design issues, material shortages, and other supply chain shocks, that often lead to product launch delays.


Source: McKinsey & Company

### Ensuring Quality and Regulatory Compliance

If a product doesn't meet today's strict quality, safety, and regulatory compliance mandates, it will not realize commercialization success. Life sciences, aerospace, and other highly regulated companies must adhere to an ever-changing myriad of laws, standards, and regulations to sell their products globally.

Delivering safe and effective products is the goal of all product manufacturers. However, the nature of compliance varies across industries and countries. Consider the following compliance requirements:

- ***Life Sciences and Medical Device Compliance:*** Companies that are subject to FDA (U.S. Food and Drug Administration), ISO (International Organization for Standardization), EU MDR (European Union Medical Device Regulation), and other key industry regulations can mitigate compliance risks by ensuring policy, process, and system adherence. For example, the FDA and EU MDR require life sciences companies to establish and maintain a quality system to ensure that medical devices meet all safety and performance requirements.
- ***Environmental Compliance:*** All electronics manufacturers must limit or restrict the use of toxic materials in products. This involves managing components and material compliance evidence for RoHS (Restriction of Hazardous Substances), REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), WEEE (Waste Electrical and Electronic Equipment), and/or conflict minerals regulations.
- ***Export Controls:*** These vary by country. However, aerospace and defense companies that do business with the U.S. government or military are subject to International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR). ITAR- and EAR-related product data must be controlled, and, if exported, done so only with proper export licenses.

### Improving Business Insights

By managing the core product design and enabling fluid collaboration with a quality and compliance mindset—manufacturers can begin to leverage the power of the Cloud with analytics that allow the tracking of performance and quality trends. This helps companies adopt and embrace continuous improvement as products go from early concepts to fully commercialized products.

> "Having the ability to integrate our Cloud PLM system with an electronic component database has provided us greater visibility into imminent component shortages. We're able to quickly source substitute parts from suppliers and keep up with our production schedules."
>
> —Cindy Lalowski, PLM Manager, AEye

### Connecting Upstream and Downstream Processes

As product designs move from early research and design in engineering, this information needs to be passed from engineering design systems to PLM or QMS systems that help aggregate all of the mechanical, software, and electrical systems into a single place. Later, when the product is tested and prepared for production, PLM and QMS solutions must pass the latest product information to enterprise resource planning (ERP), electronic component databases, and other downstream systems. This enables manufacturers to better manage the complete NPDI process by streamlining the handoffs between engineering, quality, and production teams to speed time to market (TTM).

## Extending Product Development Capabilities Through Smart Technologies

As global innovators look for ways to streamline NPDI, they also seek to take advantage of advances in smart, connected technologies. These technologies provide new opportunities for manufacturers to improve operational efficiency and transparency across the supply chain. The benefits extend beyond the factory floor and into functions like product design and supply chain management. More importantly, these technologies are improving how we live, work, and play. Consumers' appetite for smart solutions that improve their quality of life is increasing exponentially every year.

***Internet of Things (IoT):*** The use of IoT and sensors enables manufacturers to collect real-time data on product performance, as well as the entire production process. These real-time insights help companies optimize productivity and respond more quickly to customer demands.

***Artificial Intelligence (AI) and Machine Learning:*** The emergence of big data and IoT makes it possible for manufacturers to apply AI and machine learning to various aspects of product development. Generative design, predictive maintenance, defect detection, and supply chain logistics optimization are just a few applications where these technologies are making a significant impact.

***Robotics:*** Powered by AI and machine learning, industrial robots help increase operational efficiency by performing fully automated, repetitive tasks as well as analytics-based activities on the factory floor.

***Augmented and Virtual Reality (AR/VR):*** Immersive technologies like AR and VR help factory workers connect their physical surroundings with real-time visual information to perform complex tasks with greater precision and speed.

***LiDAR (Light Detection and Ranging):*** To address the increasing labor shortage, manufacturers are adopting LiDAR technology to automate their warehouse operations with driverless vehicles that can unload and stack inventory and pick items to fulfill customer orders.

Innovation with smart product development is advancing rapidly due to these technological breakthroughs. Regardless of industry, companies are looking to make their products smarter and more interactive. Designing and producing smarter products requires greater reliance on more sophisticated designs that leverage software, sensors, and electronics. With this added complexity, companies must find more effective ways to manage the design across dispersed teams and throughout the entire product lifecycle. Today, we are at the crossroad of product development and digital transformation and taking the right path will enable tomorrow's leaders to thrive while leaving laggards in their wake.

# PROVEN TRANSFORMATION WITH CLOUD PRODUCT DEVELOPMENT

Arena's cloud product development solutions have fueled success for over 1,300 life sciences, aerospace, and high-tech electronics manufacturers. Prior to using Arena PLM and QMS, many of these companies were accustomed to working with manual or siloed systems which created confusion and errors from design to manufacturing. Here are just a few examples highlighting how companies overcame obstacles and achieved commercialization success with the adoption of Arena's cloud-based product development solutions.

## Instant 24/7 Product Development Collaboration With Global Teams

Globally recognized for delivering intelligent and connected energy systems for over a thousand solar power plants worldwide, Nextracker, a Flex Company, is one of the fastest-growing cleantech companies in solar today. Its breakthrough technology enables plant owners to harvest the sun more efficiently, at lower costs, and with more flexibility.

Prior to Arena, the company did not have a single source of truth system to track and manage its engineering design and development processes. Product information was tracked manually in workbooks, spreadsheets, and personal file folders, requiring too much reliance on tribal knowledge.

Rapid growth, coupled with the need to collaborate with a global team, meant that Nextracker needed to modify its product development processes. After implementing Arena's cloud-based PLM solution, Nextracker was able to *cut review and approval times by nearly 60%, eliminate time-zone delays with global partners, and accelerate product introductions by 25%*.

> "Arena PLM has changed the way to design and get products to market. It is the well-oiled machine that complex, global product companies need to run their business. We have a much faster and transparent process that allows for better visibility to identify where obstacles lie and helps us become even more efficient."
>
> —Ratana Lee, Senior Manager, NPI Master Archivist for Nextracker

## Achieving Commercialization and Compliance Success

Accuryn Medical is a predictive health company pioneering the next generation of medical devices with smart sensors and artificial intelligence. The company developed the Accuryn Monitoring System, which enables the remote monitoring of urine output, intra-abdominal pressure, and

core body temperature to help guide clinicians in treating critically ill patients. The system's remote monitoring capabilities are also helping frontline workers combat the spread of COVID-19.

> "We have all the phases of design and development managed in Arena QMS. This includes secure access for our suppliers, which are located globally, allowing them to be notified immediately of any change and ensure their system is up to date."
>
> –Sanjay Banerjee, COO, Accuryn Medical

Prior to adopting a cloud-based QMS solution, Accuryn's product and quality information was managed using paper-based processes, where bills of materials (BOMs) were documented on paper and then uploaded to a manufacturing system. Engineering change orders (ECOs) were also reviewed manually with limited supplier communication.

"We didn't have a system that was robust enough for new product introduction and compliance processes. We had FDA clearance, but our product was not commercialized yet and our current manual processes would not scale or hold up to the scrutiny of audits," stated Sanjay Banerjee, COO for Accuryn Medical.

Since implementing Arena QMS, Accuryn has seen significant improvements across product design and quality, including the *improvement of product nonconformance by nearly 20% and a decrease in complaint resolution cycle time by 25%*.

## Delivering Innovative Technologies to the Defense Industry

With its mission to provide the most modular cyber-electronics systems in the world, Spectranetix has pioneered hardware and software solutions for defense primes, military groups, government agencies, and commercial industries.

Initially, Spectranetix relied on engineering tools, spreadsheets, and emails to conduct early concept and prototype design work. To support its rapid growth and shift to product commercialization in the highly regulated defense sector, the company needed a secure, controlled process for managing product development, undergoing customer risk-based assessment audits, and demonstrating thorough configuration management practices.

After adopting Arena PLM for AWS GovCloud, Spectranetix was able to effectively manage product development and change processes. The company was also able to run nonconformance material report (NCMR) and corrective and preventive action (CAPA) processes and conduct supply chain management with better traceability.

> "We've developed strong working models of processes that now include remote teams—Arena supports all this with ease in a secure platform. Since going live with Arena, the benefits have been countless."
>
> —Don Perkins, Director of Hardware Engineering and Operations, Spectranetix

## Enhancing Quality and Compliance Processes With a Global, Unified System

Filtronic is a leading designer and manufacturer of high-performance radio frequency (RF) devices and subsystems for telecommunication infrastructure, aerospace and defense, and critical communications.

Prior to Arena, Filtronic relied on a database platform which kept their design, manufacturing, and quality documents siloed. This made it difficult to track compliance and issues with parts. Furthermore, they were not able to implement changes quickly enough to enable collaboration across multiple teams and time zones.

After adopting Arena PLM, Filtronic's teams gained complete visibility of critical product processes and were able to easily track requirements, revisions, quality, and compliance. They were also able to easily track issues with parts and take the necessary corrective actions to ensure customer satisfaction.

> "We selected Arena to bring our global teams closer together. It's a very visible system that benefits all of our projects and is now an integral part of our business processes."
>
> —Richard Rushton, Quality Environmental Health and Safety Manager, Filtronic

# THRIVE ANYTIME

This unprecedented age of disruption has tested the resiliency of manufacturers across the globe. More importantly, it has highlighted the need for a robust, digitally enabled system that can support transparency and agility across the supply chain.

Cloud-based product development solutions provide a single source of truth for dispersed teams to access, control, and collaborate on the most current product information. When faced with unforeseen disruptions, product teams and supply chain partners have better visibility into material shortages, production delays, and other issues that can create setbacks in new product development and introduction (NPDI). Ultimately, embracing cloud solutions enables all teams to be more proactive at putting the necessary countermeasures in place to overcome any disruption and thrive anytime.

References

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