MasterControl™

Vital Signs of the Medical Device Industry

2021 Medical Device Industry Trends

Let's just say what we're all thinking: 2020 was rough. It threw pretty much every element of our lives into disarray, and we suddenly had to become experts at navigating a new way of working, schooling and socializing. It was disruptive, and it was challenging, but it was also transformative. While the past 12 months might have felt like 12 years, it's time to look forward to what the future holds. If 2020 was the year of disruption, 2021 will be the year of mastering change.

The medical device industry is no stranger to change, but in the face of a global pandemic's impact on business, many medical device manufacturers faced immense obstacles. The pressure to keep up with emerging technologies transformed a demand to shift entire production lines to meet medical device demand for critical equipment. The medical device industry emerged from 2020 a little beat up and bruised, but those that were able to adapt successfully will act as models for 2021 and beyond.

1

Market Demands Increase Pressure to Be Agile

The novel coronavirus and the disease it causes, COVID-19, put the medical technology industry at center stage with an unprecedented need for critical supplies and required a recalibration across the entire value chain to serve health care's most acute needs. As manufacturers adapted with agility to fulfill skyrocketing demand for products like ventilators and other medical equipment, the shift underscored the need for manufacturers to be nimble and scalable to accommodate a rapid shift in demand and changing environments. While some companies were able to adapt quickly, others found themselves struggling in the face of massive upheaval.

As the pandemic spread across the globe, the medical device companies that were able to pivot had already adopted digitization and could transition production lines quickly. While there is still an outstanding question surrounding the longevity of these gains, it has become clear that companies that embrace digitization are better able to adapt in the face of uncertainty.

One unforeseen impact of the pandemic was the postponement of elective procedures and the associated reprioritization of nonessential devices. 2021 will reveal how fluctuations in demand for noncritical procedures will impact the industry – from sourcing through production. A likely resurgence for both elective and delayed essential procedures in 2021 will further pressure medical device organizations to consider how digital tools can help them maintain flexibility in the next normal.

According to a McKinsey & Company report in 2020, "the flexibility and resilience that digital will add to operations as manufacturing ramps up again once the current crisis is over, will allow those organizations that transform successfully to gain a significant advantage over slower-moving competitors."[1]

Theoretical to practical: Enabling agility amid uncertainty

1. **Adopt Cloud Technologies:**
The cloud simplifies data management and access, and bandwidth increases on demand, minimizing delays in system processes and data requests. In addition to accommodating the need for expeditious data sharing and an evolving ecosystem, the cloud's scalable environment enables the deployment of data-intensive applications for more thorough, accurate and real-time data analytics.

2. **Prioritize Connected Platforms:**
Shifting from hardened integrations to modular interfaces enables agility and facilitates connected data intelligence. Multiple systems connected by application programming interface (API) or integration platform as a service (iPaaS) solutions offer a broader ecosystem of integration, eliminating errors and improving data integrity shared between your existing systems.

3. **Invest in Configurable Applications:**
Leverage flexible software that extends your digital edge beyond core systems. A configurable, purpose-built application can be fast to implement and deliver quantifiable benefits while empowering the workforce with the digital tools to streamline production and ensure quality throughout the entire product life cycle.

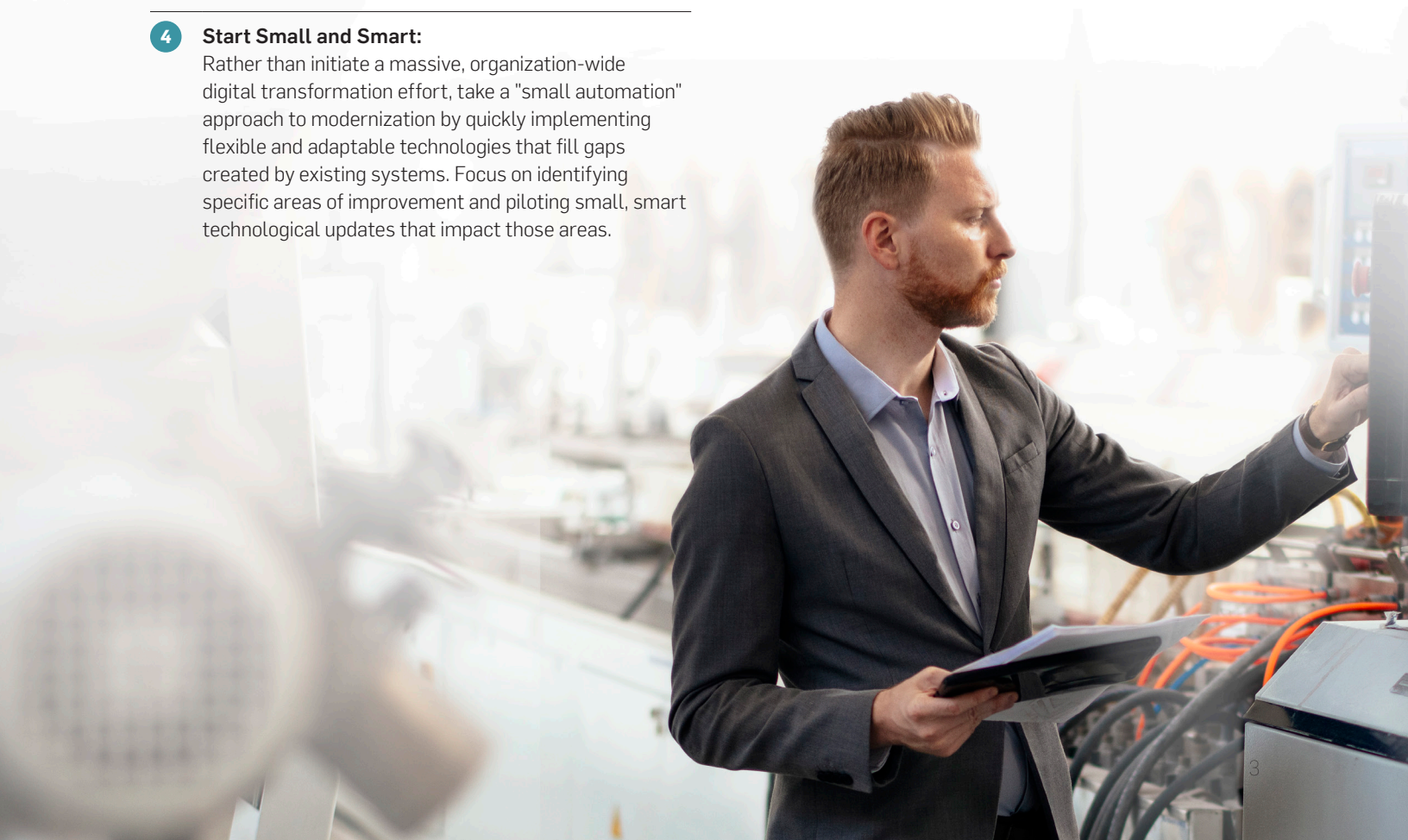
4. **Start Small and Smart:**
Rather than initiate a massive, organization-wide digital transformation effort, take a "small automation" approach to modernization by quickly implementing flexible and adaptable technologies that fill gaps created by existing systems. Focus on identifying specific areas of improvement and piloting small, smart technological updates that impact those areas.

> **"Organizations are facing challenges managing their business in this new virtual and remote reality. The demand for organizational effectiveness, visibility and control in a disrupted environment represents a watershed moment for the modernization and digital transformation in our industry."**

Source: Plastics Today, "Has COVID-19 Created a Tipping Point in the MedTech Industry?"[2]

> **"Activate the organization to operate with speed and agility, using data and analytics to inform decisions and assess critical impacts to operations."**

Source: Accenture, "Health's NewFUTURE for Technology"[3]



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Adapting to Consumer Expectations with a Renewed Focus on Quality

In 2020, how we ordered food, consumed entertainment and conducted business meetings seemed to change overnight. In areas of health care and medical technology, people have come to expect virtual health care appointments via telehealth and wearable technologies for remote monitoring. In short, the pandemic intensified existing digitization trends and highlighted consumer expectations of products and services – that they be delivered faster and served in a digital-first format.

Yet as consumers continued to drive demand for innovative products, with innovation comes challenges – and quality must be at the forefront.

The past year introduced a new level of complexity to an already complex landscape, accelerating the need to modernize clinical trials, improve regulatory affairs management and digitize quality processes. With the introduction of brand-new competitors in the market, thanks in part to Emergency Use Authorizations (EUAs), the pressure to compete while continuing to focus on high-quality product development remains at an all-time high.

And, if a global pandemic and pressure from new competitors entering the space weren't enough, the industry broke a two-year record in 2020, surpassing more than 300 medical device recalls early in the year. While medical device recalls decreased to 242 events in the third quarter of 2020, the quarterly average for 2020 remains higher than 2019, putting the industry on track to experience about 1,100 recalls by year-end compared with 884 recalls in 2019.[4] These numbers don't include the unofficial recalls of personal protective equipment (PPE), which can sometimes be handled at the state and local level.

For successful medical device companies, quality will remain one of the most highly competitive assets in their arsenal. To ensure quality while gaining a competitive edge, management needs to implement tools that align people, processes and policies. The right solution must be aligned with the mindset of digital leaders seeking data insights that will promote continuous improvement.

Theoretical to practical: Taking a data-centric approach to quality

1. **Extend Quality's Reach:**
   Take quality beyond the quality department. Quality must be consistent and pervasive throughout the broader ecosystem. A robust electronic quality management platform that connects with other core systems and data sources breaks down siloes and allows organizations to expand quality's scope and effectively assess supplier implications on product quality.

2. **Adopt a Data-Centric Quality Mindset:**
   Move beyond just digitizing document-centric processes and focus on a holistic approach that allows quality professionals to access, analyze and apply insights from structured and unstructured data within the same system across the product life cycle.

3. **Explore Advanced Data Analytics to Identify Bottlenecks in Quality:**
   Pilot programs involving advanced analytics, artificial intelligence (AI) and machine learning (ML) applications have shown promising results in reducing the reoccurrence of quality errors and the time it takes to complete an investigation and in increasing customer satisfaction.[5]

> **"Whether scaling up, down, or maintaining production, most manufacturers have had to ask themselves tough questions about how best to utilize their investments and facilities, both now and in the long term. Not only is there interest in switching to domestic suppliers, but there's also interest in the strategy of moving manufacturing sites onshore. Taking a more measured approach can help ensure the quality from development through the entire product lifecycle."**

Source: Medical Product Outsourcing, "Quality Assurance When Supply Chain Disruptions Arise"[6]

3

Connecting Operations Without Endangering Employees

COVID-19 has accelerated new ways of working, chief among them a shift to digital interactions and workforce agility. Recent data show that we have vaulted five years forward in consumer and business digital adoption in a matter of around eight weeks during the global pandemic.[7] According to Forrester, 18 million U.S. workers will work from home in the wake of the pandemic.[8] By 2024, 50% of factory work is expected to be done remotely, according to Gartner research.[9] Yet critical gaps remain where paper-based processes hinder visibility and efficiency on the shop floor, where pen and paper are used to track vital manufacturing steps and spreadsheets are used to maintain data.

The pandemic has exposed weaknesses in manufacturing, such as managing a remote workforce, and has created a sense of urgency around accelerating efforts to digitize and connect areas of operations that are offline and disconnected. While engineering and manufacturing personnel must be on the shop floor, individuals in operational support roles interacting with different sites worldwide can work from anywhere. Beyond basic videoconferencing applications in the office and tablets on the shop floor, more advanced solutions, such as fully electronic device history records (DHRs), are also helping maintain safe distancing as manufacturing operations continue.

By using digitization to develop new or enhanced ways of operating their businesses, manufacturers will experience reductions in machine downtime, improvements in labor productivity, increased throughput and decreased quality costs.[10]

In this new normal, manufacturers will focus on ensuring workforce safety and productivity on the shop floor while enabling roles that don't have to be on the shop floor to stay connected and actively engaged in manufacturing processes remotely.

Theoretical to practical: Ensuring operational continuity and employee safety

1. **Employ Virtual Collaboration Tools:**
   Digital work instructions, automated controls and virtual training can help improve performance while mitigating risk. Digital tools and process automation can enable real-time collaboration between onsite and remote personnel, connecting workers and supporting the virtual workplace for nonproduction departments.

2. **Digitize DHR Processes:**
   Digitizing DHR processes with an electronic system eliminates the need to carry paperwork to different departments, so a manufacturer can easily build, review and approve a DHR and quickly release product from anywhere in the world.

3. **Empower Personnel with Data:**
   Digital solutions can provide real-time visibility into work on the shop floor with anytime-anywhere access to the most current data. With greater access to digitized shop floor data that is more accurate and complete, personnel in manufacturing operations and in quality assurance can make more informed, data-driven decisions.

> **“There is a shift under way, due to the huge impact of COVID-19 on digitization — the perception of what digital can do and how new business models can leverage that.”**

Source: McKinsey & Company, "Medtech innovation in the time of COVID-19: Resilience and growth during a crisis"

> **“Companies can deploy digital solutions beyond the four walls of a manufacturing plant, reaching across the end-to-end value chain to address planning (and replanning) challenges related to disruptions at suppliers or production plants, operational challenges in managing workplace health risks, and delivery challenges posed at transportation modes or in warehouses.”**

Source: McKinsey & Company, "Industry 4.0: Reimagining manufacturing operations after COVID-19"[11]

4

Increased Regulatory Pressure to Modernize Systems

The 21st Century Cures Act, signed into law in December 2016, gave the U.S. Food and Drug Administration (FDA) the tools to begin modernizing regulatory programs. Since the Cures Act passed, the FDA has made several updates to help accelerate the development, assessment, review and surveillance of medical devices.

Among the significant updates is the agency's Technology Modernization Action Plan (TMAP), a three-pronged action plan aimed at modernizing the use of technology to advance the agency's public health mission. The plan, which describes near-term actions the agency is taking to update its use of computer hardware, software, data and analytics, places significant emphasis on the notion of moving to a more digital environment via the cloud.[12] In addition to getting behind developing technologies, the FDA's transformation is designed to encourage the entire life sciences industry to follow the agency's lead in modernization and match the pace of innovation.

Meanwhile, many device companies face the European Union's Medical Device Regulation (MDR)/In Vitro Diagnostic Regulation (IVDR) – and the changes to processes, data gathering, and documentation that come with it – making it all the more crucial that medtech companies continue modernizing.

The pandemic only accelerated pressure to modernize systems and processes involved in quality and regulatory management. This includes the need for digitization, remote or hybrid audits, changes to submissions and approval processes and more, leading many companies to reimagine and reevaluate their digital infrastructure altogether. As the FDA and other health agencies take steps to modernize, medtech manufacturers that embrace and adapt will evolve technologically and enhance their compliance activities' effectiveness, ensure quality and accelerate time to market.

> "The FDA is blazing the path by building a national system for collecting real-time data and clinical proof on everything from gadgets used in spinal fixes to ligament closure procedures. The discoveries may well define the connection among patients and medical devices throughout the coming years."

Source: Medical Product Outsourcing, "Top 10 Trends in the Medical Device and Equipment Industry"[14]

> "By streamlining regulatory processes and removing or reducing unnecessary burdens associated with FDA regulatory activities, patients can have earlier and continued access to beneficial products."

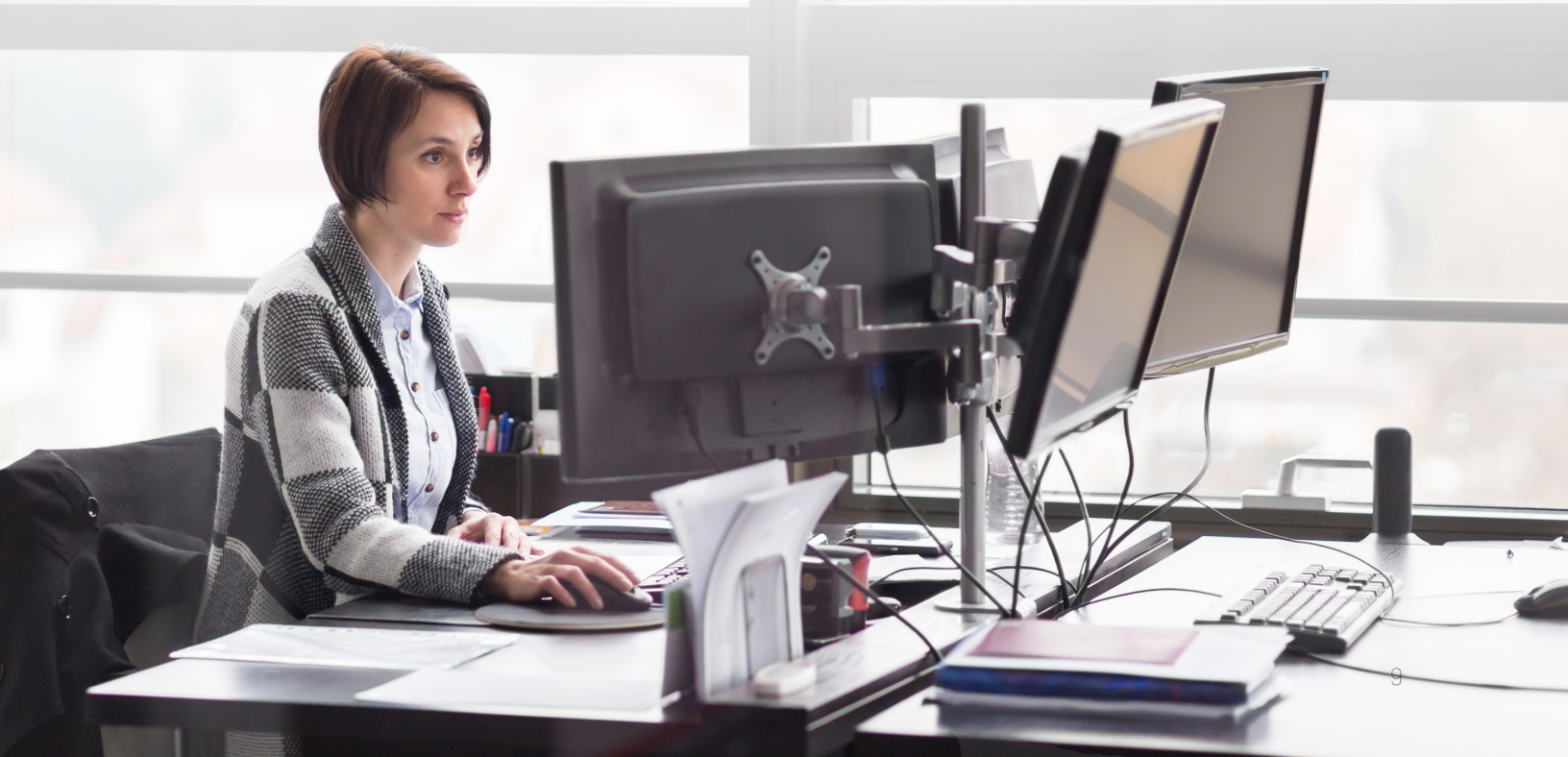
Source: FDA, "The Least Burdensome Provisions: Concept and Principles"

Theoretical to practical: Taking digital transformation cues from the FDA

1. **Build Quality Directly into Production:** As the FDA moves to revamp its own use of technology, medtech manufacturers that do the same will be able to reduce the time and cost required to produce safe and effective devices. Digitizing the DHR process can eliminate data entry errors and proactively track production data that affect quality in real time rather than during quality review.

2. **Shift from Document-Centric to Data-Centric:** The FDA's interest in a data-centric approach to quality management should encourage a departure from housing product-related data in paper records and standalone spreadsheets. Instead, leverage digital platforms to connect data sources and collect and analyze data. Fully digitizing data facilitates efficiencies and open communication lines that allow quality and manufacturing to align their goals and objectives.

3. **Simplify Regulatory Processes:** The FDA recommends "streamlining regulatory processes and removing or reducing unnecessary burdens associated with FDA regulatory activities."[13] Digitizing quality systems and regulatory processes can help medtech manufacturers reduce redundancies in regulatory submissions, reduce the burden of medical device reporting and streamline quality processes to improve efficiency throughout the entire product life cycle.



Conclusion

As the medtech ecosystem and medical device regulations continue to evolve in conjunction with the continued pressure to meet demand while adhering to quality expectations, medical device companies must embrace digital transformation and shifts in mindset to remain competitive. Digital technologies and industry challenges will continue to evolve and impact the way medical devices are regulated and manufactured.

MasterControl's business excellence solutions serve as the foundation of quality and compliance for hundreds of medical device companies worldwide. Providing much more than enterprise quality management system (EQMS) automation, MasterControl allows companies to efficiently manage change within manufacturing operations with a fast and flexible system that provides real-time data and analytics to keep your business ahead of the competition and on the cutting edge of digital transformation.

Manufacturing

MasterControl Manufacturing Excellence:
Fast, flexible production management and execution for process and discrete manufacturing that connects your shop floor workers and delivers right-first-time results without the cost and complexity of a traditional MES.

Quality

MasterControl Quality Excellence:
Smart, dynamic enterprise, plant and supplier quality management that allows organizations to manage product quality, compliance and risk intelligently.

Insights

MasterControl Insights:
Modern data architecture and advanced analytics that allow manufacturers to turn product quality and operational data into a competitive advantage.

Sources

1. "Preparing for the next normal via digital manufacturing's scaling potential," by Enno de Boer, Søren Fritzen, Rehana Khanam and Frédéric Lefort, McKinsey & Company, April 2020.
2. "Has COVID-19 Created a Tipping Point in the MedTech Industry?" by Chris Parsons, Plastics Today, May 2020.
3. "Health's NewFUTURE for Technology," Accenture, June 2020.
4. "Recall Insights Report, Edition 3, 2020," Stericycle Expert Solutions, November 2020.
5. "Advance Quality Performance Through Data-Driven Insight," Gartner, June 2017.
6. "Quality Assurance When Supply Chain Disruptions Arise," by Sandi Schaible and Peter Steen, Medical Product Outsourcing, November 2020.
7. "The COVID-19 recovery will be digital: A plan for the first 90 days," by Aamer Baig, Bryce Hall, Paul Jenkins, Eric Lamarre and Brian McCarthy, McKinsey & Company, May 2020.
8. "Predictions 2021: Accelerating Out of the Crisis," Forrester, October 2020.
9. "Factory Innovation Post-COVID-19: Five best practices for manufacturing operations leaders," Gartner, 2020.
10. "Medtech innovation in the time of COVID-19: Resilience and growth during a crisis," McKinsey & Company, October 2020.
11. "Industry 4.0: Reimagining manufacturing operations after COVID-19," by Mayank Agrawal, Karel Eloot, Matteo Mancini and Alpesh Patel, McKinsey & Company, July 2020.
12. "FDA's Technology Modernization Action Plan," U.S. Food & Drug Administration, September 2019.
13. "The Least Burdensome Provisions: Concept and Principles," U.S. Food & Drug Administration, February 2019.
14. "Top 10 Trends in the Medical Device and Equipment Industry," by Praveenkumar Yadav, Medical Product Outsourcing, September 2019.