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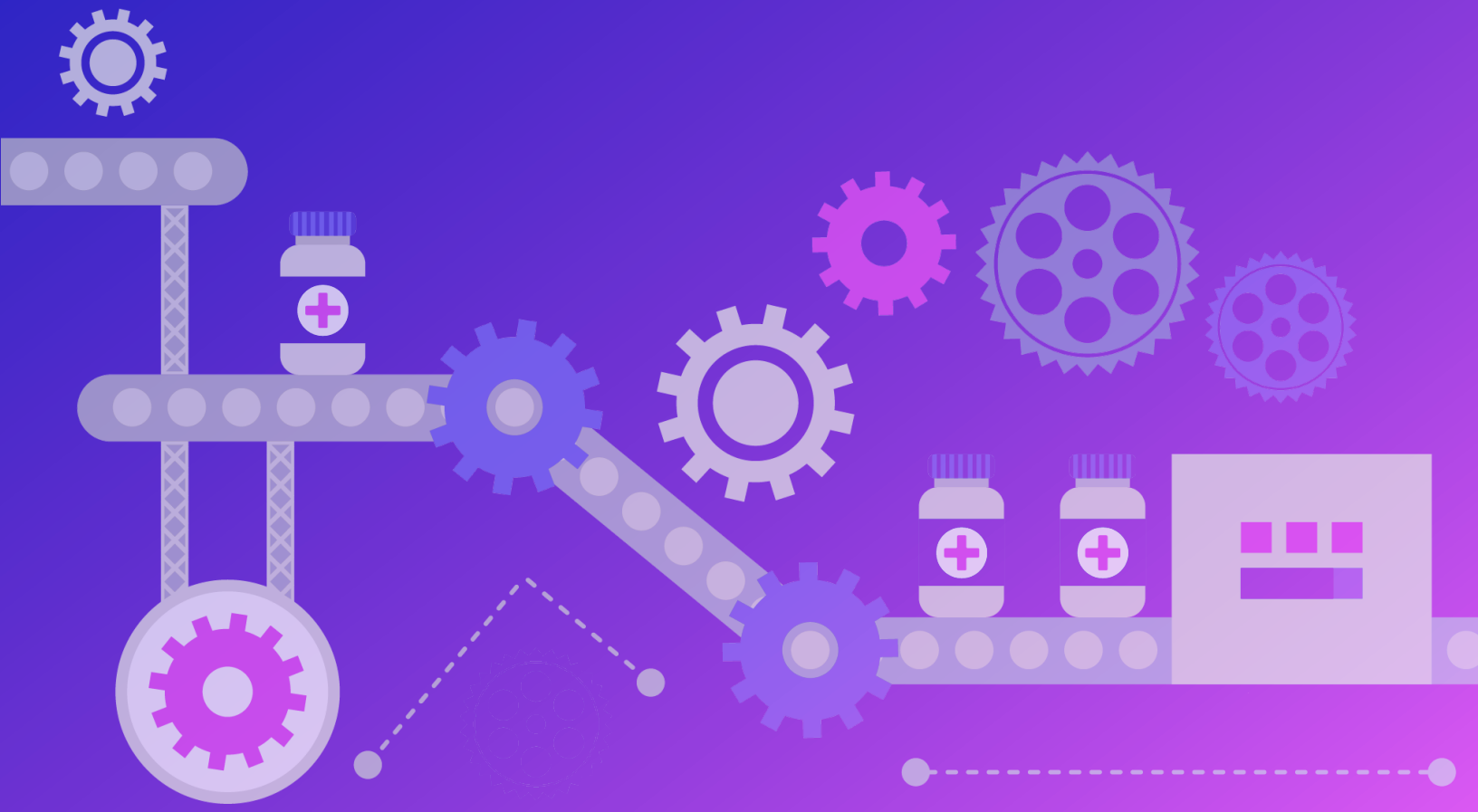
Good Distribution Practices for Life Science Manufacturers



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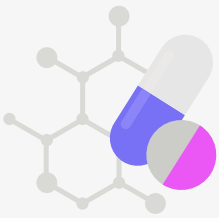
Introduction

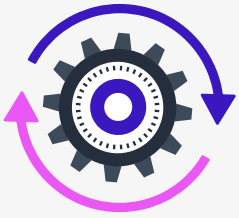
2020 was the year of life science supply chain breakdowns, elevating the importance of good distribution practices (GDP). The inherent gaps in quality measures that rose to the surface during the COVID-19 pandemic are now being leveraged by manufacturers as lessons learned to pave a more resilient path forward.

There is no going back to the old ways of doing business in the life sciences supply chain. Change is here to stay as witnessed by trends that have emerged. Those manufacturers that are able and willing to evolve their quality processes will have a competitive edge post-pandemic and beyond.

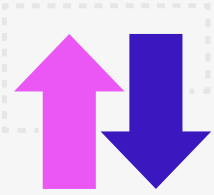
In this paper we examine:



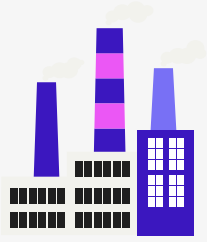
The impact of the COVID-19 on life sciences supply chain



3 elements of the "new normal" reshaping the industry



3 applicable lessons to achieve meaningful and sustainable change



The digital divide between manufacturers in their quality operations

“The COVID-19 pandemic is not just a short-term crisis. It has long-lasting implications for how people work and how supply chains function. There is a pressing need for businesses to build long-term resilience in their value chains for managing future challenges.”

- Supply chain disruption, Accenture[1]

Hidden Vulnerabilities Exposed

COVID-19 threatened manufacturer compliance with good distribution practices (GDP) in the life sciences supply chain, both upstream with raw materials/component suppliers and downstream with the delivery of drugs and devices into the hands of clinicians and patients. Manufacturers struggled to maintain the quality of their supply chain operations as they faced roadblocks in every direction.

While no one could have predicted the COVID-19 pandemic, there were warning signs that the life sciences supply chain was at risk before the virus outbreak.

A 2019 Accenture survey of pharmaceutical and medical device manufacturers found 44% of their manufacturing volume was externalized, 60% struggle to get real-time inventory or manufacturing visibility, and close to 40 percent lacked control over product quality.

Furthermore, 58% said a lack of process and technology standardization was leading to operational complexity.[2]

In October 2019, just a few months before SARS-CoV-2 emerged, Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) raised the reg flag on the pharmaceutical sector's dependence on foreign sourcing for critical components, materials and finished products. Her statement: "the use of foreign-sourced materials creates vulnerabilities in the U.S. drug supply" was an eerie prediction of what was soon to come.[3]

The Digital Divide

"As the peak and panic associated with the current crisis subsides, R&D leaders will be faced with a crucial choice: attempt to return to some version of pre crisis 'business as usual' or embrace the change and fundamentally reimagine the drug and device development paradigm."

- COVID-19 implications for life sciences R&D: Recovery and the next normal, McKinsey & Company[4]

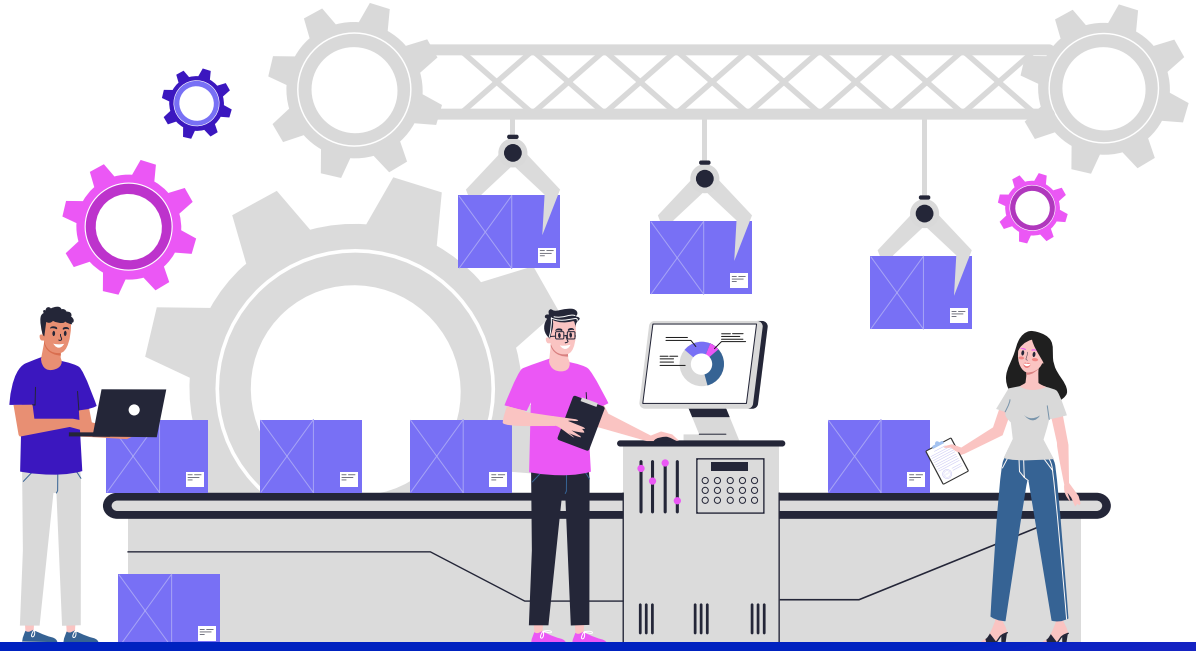
While all life science manufacturers were impacted by the collapsing supply chain in 2020 to a certain extent, some were equipped to handle it better than others. When access to raw materials and components in China came to a halt and business interactions overnight switched from in-person to remote, these changes revealed the significant divide between life science manufacturers that had clung to the old ways of doing business and those that had evolved their quality operations.

Companies dependent on manual, paper-based processes or homegrown information technology (IT) solutions for quality management quickly realized they did not have the capabilities to function in this new environment. In essence, a wall was erected overnight between employees working remotely and their quality operations. They had no way to access documentation, perform training, or conduct inspections and audits.

Life science manufacturers with outdated, on-premise quality management systems (QMS) found they were unable to identify reliable, high-quality, alternative suppliers, let alone switch to new suppliers midstream to fill production gaps. Even when a manufacturer could identify an alternate supplier of materials or contract manufacturer of finished product, onboarding them in a remote work environment proved a significant challenge without a digital QMS.

On the other hand, life science manufacturers with centralized, electronic and automated QMS solutions had the capabilities and flexibility to adapt to these unforeseen circumstances - replacing the need for physical presence and processes with digital tools.

When offices shut down, travel restrictions enforced and face-to-face meetings ceased to occur, those companies with digital QMS platforms could move forward with their operations and support compliance with GDP. The continuity of workflows enabled by cloud-based solutions allowed team members to collaborate with each other and suppliers to keep the supply chain moving forward.



"Manufacturers must take a hard look at existing operating models – where and how work gets done (and for what reason), challenging legacy ways of working, and building in more transparency and intelligence across core workforce dimensions."

– Supply chain disruption, Accenture[5]

3 Elements of the "New Normal"

The global pandemic shook the very foundations of the life science supply chain. Yes it forced change. Many of the processes that were adopted are here to stay. Here are three trends that reflect our new reality.

Elimination of manual processes

Manufacturers, their supply chain partners and regulatory agencies will no longer accept paper documentation and paper-based processes. The pandemic forced a move to electronic means of interaction, all parties have seen the benefits and it is here to stay. Among 14 business-critical applications for life science companies, two-thirds are already deployed in the cloud, with an expected increase to near 90% by 2022.[6]

Transition from reactive to proactive quality management

Just before the pandemic, an estimated 40% of quality resources were spent on reactive activities, such as non-conformity resolution, corrective actions and complaint handling.[7] Moving forward, life science manufacturers will be more proactive in their operations and need technology to support this. A holistic, cloud-based QMS offers the real-time environment and on-demand access to analytics required to identify and address emerging quality issues before they escalate.

Greater stakeholder collaboration in the supply chain

The pandemic has shown that all stakeholders in the life sciences supply chain (manufacturers, suppliers, distributors, etc.) must work more collaboratively to address vulnerabilities and build greater resiliency. This requires the adoption of collaborative technology platforms that unite all parties (e.g., employees, suppliers, business partners) in the pursuit of improved quality.

“Manufacturers, regulators, and other healthcare stakeholders have made substantial changes to how they conduct clinical trials, manufacturing, patient engagement, and other undertakings. Looking ahead, they should consider which changes to keep and which ones to roll back.”

- Reimagining how life sciences work will be done in the next normal, McKinsey & Company[8]

3 Applicable Lessons

While some life science manufacturers over the years heeded the warning signs of supply chain vulnerabilities and its impact on GDP and quality, it took a pandemic to truly move the dial. Here are applicable lessons learned that are driving meaningful and sustainable change.

1

Keep quality as the priority

Although the FDA expedited some permits and relaxed some requirements where it was needed, compliance and quality management requirements did not change during the pandemic. Adherence to strict regulations and guidance continues to be an integral part of doing business in the life sciences industry.[9] Manufacturers that successfully navigated the pandemic are those that made quality a priority, investing in their people, processes and technologies to strengthen supply chain resiliency.

2

Establish a strong and reliable alternate supplier base

Manufacturers must be able to quickly switch suppliers when disruptions hit their supply chains. They need to build a knowledge base of available suppliers that can meet their needs with reliability, efficacy and efficiency. Identifying alternative or backup suppliers is the top supply chain strategy for life sciences chief financial officers (CFO) in 2021, with 61% of CFOs naming it as a priority.[10]

3

Stop talking and start doing when it comes to digital transformation

As an industry, life sciences has long talked about digital transformation of quality management processes to support GDP but the pandemic proved that it has a long way to go. The time to move on this is now. Life science organizations require the ability react quickly, pivot when necessary, and utilize new technologies that ensure minimal disruptions. Among science CFOs surveyed, 63% say digital transformation is a top business strategy for 2021.[11]

“The potential of advanced digital capabilities should be considered (by the MedTech industry) to provide visibility, augment operations, drive scenario modeling to build greater resilience and agility in supply chains and operations.”

- COVID-19: Leading with agility and responsible innovation in MedTech, Accenture.[12]

Conclusion

2020 was the year that ripped off the band-aids holding together gaps in the life science supply chain. The pandemic swiftly revealed long-standing vulnerabilities in GDP and quality management processes, forcing industry-wide action.

Manufacturers that had already embraced digital QMS had the advantage when COVID-19 hit, with the capabilities and flexibilities to navigate complexities and challenges to their supply chains. For those that have not yet embraced digitization of processes and data, the pandemic has been an alarming wake-up call.

There is industry-wide recognition that changes to quality and supply chain management ushered in by COVID-19 are here to stay, from the diversification of suppliers to remote work environments.

To strengthen the resiliency of their operations and remain competitive in the "new normal" all manufacturers – from the pharma and MedTech giants to small and mid-sized life science organizations – must adapt to these and other emerging trends.

Digital solutions exist to meet the needs of all companies, regardless of size or stage. Don't risk being left behind or unprepared when the next unforeseen disaster hits the industry.

It is time to embrace change and it can be done quickly, easily and cost effectively with ready to use QMS solutions.

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