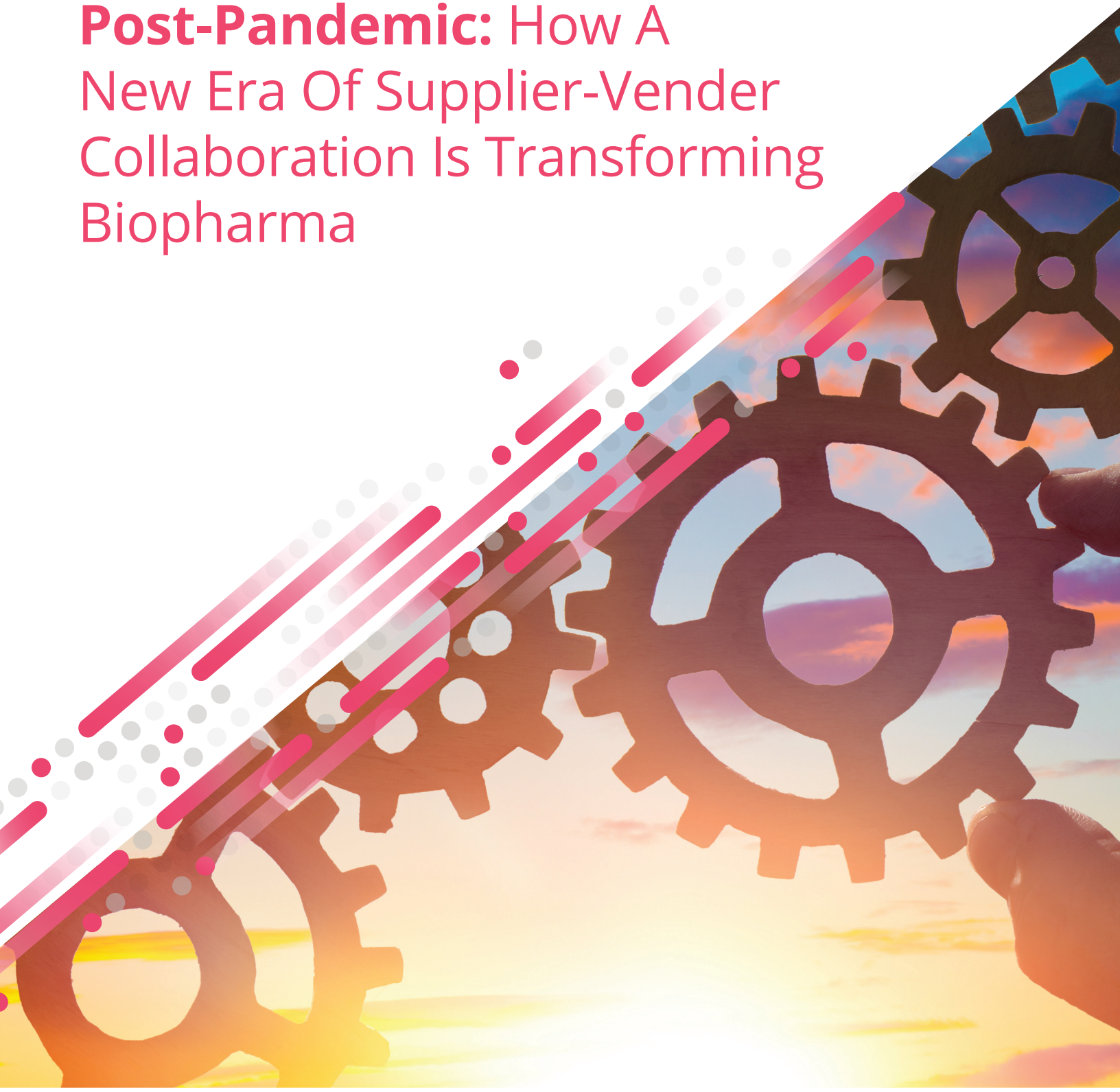
CITELINE

Post-Pandemic: How A New Era Of Supplier-Vender Collaboration Is Transforming Biopharma



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Post-Pandemic: How A New Era Of Supplier-Vender Collaboration Is Transforming Biopharma

The biopharma industry finds itself at a crossroads in 2023. COVID-19 showed the old approaches cannot comfortably cope with disruption, but the industry is yet to settle on a new model. One thing is certain: collaboration between vendors and customers will be critical to shaping all aspects of the future, from building more resilient supply chains to unlocking the potential of novel modalities.

COVID-19 made the case for change clear. Most companies had preparedness and business continuity plans in place when the pandemic began but still faced problems as the virus disrupted global trade.

"Whatever preparations the industry made in the past didn't fully work, because otherwise we would not have seen the issues everybody has faced," Eva Schaefer, Director Supply Robustness at MilliporeSigma*, said. "Moving forward, it's important that together we look at new approaches and ideas in order to adapt quickly in an agile environment to better manage disruptions and support business continuity across the industry."

As another crisis is inevitable, the industry needs to use this period to improve preparedness. Some people see holding increased inventory as the answer to the problem. Yet, while that may be part of the solution, extra inventory will only delay disruption for a few months. Worse still, as the years pass, memories of COVID-19 fade, and management teams change, companies may identify excess inventory as an inefficiency and eliminate their buffers by the time the next crisis hits.

There are new, innovative ideas about how to prepare. The question is whether the industry will adopt them or revert to old habits now the acute phase of the pandemic has passed. If suppliers and customers engage in open-minded discussions, they have a chance to ensure that next time is different.

Making Supply Chains More Resilient

Rethinking internal decision-making processes is one way to make supply chains more resilient. Teams need to be asking: How can we be agile in our internal processes? If something changes, how can we move quickly to find a solution? How can we prioritize sooner? How can we have fast decision making in a complex environment? The answers to those questions will vary from team to team but, in many cases, digitalization will play a role.

Overarching planning is another route to a more resilient supply chain. Regionalization has become a priority since governments restricted cross-border trade in the pandemic — and has additional benefits related to sustainability and energy cost — but having a global network will remain important for supply stability. Global networks can ensure continuity when regional supply is disrupted.

The need to balance day-to-day routine regional production and an active global network that can step in as needed will challenge industry planning processes. Companies will have to find ways to keep global sites qualified and validated and to source from them on an occasional, ad-hoc basis. Setting up different suppliers and maintaining validations locally will require considerable effort.

Lessons learned during the pandemic are reshaping demand planning too. COVID-19 drove demand for products to either soar or collapse, causing companies to ask how planning can become more robust and provide more visibility. While seeing the need to optimize long-range planning, the industry is yet to decide on how to change. Some companies focus on purchase orders, others do more scenario planning. 2023 is the year to sit down and collectively decide on how to move forward.

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MilliporeSigma is a leading voice in the conversation. During the pandemic, its employees went the extra mile and leaders rolled out continuous improvement and efficiency projects to meet the changing needs of customers. Now, the same people are working with customers to define the post-pandemic future.

Digitalization, automation, and artificial intelligence are central to their vision for the future. Pharma faces challenges due to the fast adoption of digital tools and needs to adapt to reap the benefits. Companies that embrace the existing tools, and find the right people to use them, will be rewarded with scenario modeling that improves preparations for the next crisis and early-warning systems that enable fast responses to supply signals.

Optimizing Production Of Novel Modalities

The need for a new, more collaborative approach extends to the development and production of novel modalities, an umbrella term that covers new types of medicines including adeno-associated virus (AAV) and lentivirus gene therapies and mRNA therapies and vaccines.

Novel modalities open up new ways to treat disease, enabling developers to address unmet needs, but also pose new challenges. Decades of work on monoclonal antibodies and plasma proteins have shaped biomanufacturing and bioprocessing technologies. Novel modalities have different characteristics and, in many cases, require a different approach.

For example, the impurity profile is different — and therefore the purification process must be different. With monoclonal antibodies, viruses are an impurity. With AAVs, viruses are the product. Techniques and technologies used to purify monoclonals will not work with

AAVs. Similarly, viral vectors are much larger than traditional proteins and that creates filtration challenges and a need for new technologies.

Stability is different, too, with lentiviruses and mRNA breaking down relatively quickly if not formulated properly. For now, novel modalities are often produced at smaller scales, with some notable exceptions, and the market dynamics are different. Small biotechs are often leading the way in novel modalities.

The challenges are magnified by uncertainty. Regulators are still clarifying the requirements for activities such as purification for some modalities. Faced with the challenges, customers and suppliers are working in close collaboration, just as they are doing to shape the future of supply chain and demand planning. By collaborating, suppliers can develop consumables and equipment that address the specific processing challenges of novel modalities and ensure they provide the right tools to end users.

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Collaborating For Mutual Benefit

MilliporeSigma is supporting the search for new ways of working with its global network of eight M Lab™ Collaboration Centers. The technical experts at these sites work side by side with customers to address problems and establish how to optimize their manufacturing process. These non-GMP facilities allow collaborative experimentation and the trialing of new technology and approaches, without the burden of regulatory paperwork and SOPs.

"The advantage of us working and collaborating directly with our customers, and vice versa, is that we can ensure that we're manufacturing and creating the right products to directly meet the unique needs of novel modalities," Tom Elich, Manager, MSAT Purification Process Engineering at MilliporeSigma, said.

The power of the model is illustrated by a project at the M Lab™ Collaboration Center in Burlington, Massachusetts. The project explored several steps within a purification process focused on plasmid DNA, an enabling tool for novel modality processes including the transfection of viral vectors and transcription of mRNA. Many novel modality production processes start with purified plasmid DNA that encodes genetic material.

MilliporeSigma worked with the customer to identify an optimal purification strategy for its plasmid DNA. In doing so, the team looked at several unit operations, such as clarification, chromatography, and tangential flow filtration, and posed itself a series of questions: How would we size those devices? What devices would we select? What recommendations would we make for the scale up of a plasmid DNA process?

As is typical with these types of projects, both sides gained knowledge. The customer learned how to improve its plasmid DNA purification process, and MilliporeSigma gained a deeper understanding of its products and how to support manufacturers of novel modalities.

Digitalizing For Closer Cooperation

The pandemic intensified MilliporeSigma's collaborations and advanced understanding of novel modalities. While the crisis showed there was still a lot to learn about some novel modalities and exposed inefficiencies on the supply side, it also revealed the advantages

of new approaches. Vaccines based on mRNA and viral vectors advanced faster than traditional modalities and helped to bring the pandemic under control.

As MilliporeSigma supported programs, speed of implementation and speed of knowledge transfer were critical, a fact that played to the strengths of the direct interaction enabled by its network of labs. Because travel and in-person interaction were limited, the company built a digital infrastructure that enabled it to engage customers, show them how to use a product, and optimize processes virtually. The digital infrastructure is helpful when troubleshooting because it provides timely, remote access to technical capabilities and engineers.

The experience has resulted in a stronger MilliporeSigma. Digital infrastructure that proved itself in the crucible of pandemic R&D is now enabling vendors and customers to work hand in hand to accelerate the progress of life-changing medicines. Details of the post-pandemic future are still up for debate, but the direction of travel is clear. A new era of collaboration is underway.

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About MilliporeSigma

Together, we impact life and health with science. We offer one of the broadest portfolios in the industry for scientists, best-in-class products for pharmaceutical development and manufacturing, and a fully integrated service organization to support CDMO and contract testing across traditional and novel modalities. Our vision is a world where our innovative products, services, and digital offerings help create solutions for people globally and a sustainable future for generations to come.

To learn more, please visit www.sigmaaldrich.com/US/en

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Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.

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