



FEATURES

CDMOs & Pharma: How are Supply Practices Changing?



What are the most significant issues shaping the pharma customer–supplier relationship in 2022? Industry leaders weigh in on changing supply practices and project management in a post-pandemic world.

Pharma customers and suppliers: most significant issues for

2022 Bio/pharma companies and their suppliers have addressed challenges arising from the pandemic, but where does the industry go from here? To gain a perspective, *DCAT Value Chain Insights* asked senior executives of CDMOs and other industry experts of what they see as the most significant issues shaping the pharma customer–



Stuart E. Needleman,
Chief Commercial Officer and
Chief Patient Centricity Officer,
Piramal Pharma Solutions

“The three most significant issues we face today are supply chain, capacity, and the COVID-19 workforce,” says Stuart E. Needleman, Chief Commercial Officer and Chief Patient Centricity Officer, Piramal Pharma Solutions. “In looking at the supply chain, the industry faces long lead times coupled with ongoing security challenges. Developing multiple sources and verifying that those systems and processes are reliable is more important than ever. Capacity remains an issue because of how tight things are right now. The industry has to ask itself: ‘How far out do we have to work with our suppliers to ensure that our timelines can be met?’ Innovator companies need to order earlier and forecast better, be willing to take some risks, and accept the fact that they might have to buy in advance of when they really need it. Regarding the COVID-19 workforce, Omicron showed us that even as we hopefully move from pandemic to endemic status, the impact on the industry is still significant. Many suppliers are dealing with large numbers of sick employees, which causes delays. This is a fact of life that might not change anytime soon.”

Others agree. Hamilton Lenox, Senior Vice President of Business Development & Operations at LGM Pharma, identified what he sees as the three most significant issues shaping the pharma customer–supplier relationship in 2022: (1) the labor market; (2) supply-chain challenges/disruptions; and (3) price increases and inflation.



products and raw materials, longer lead times, disruptions in shipping and significant cost increases. These delays in key materials and cost increases will continue into 2022 and are an ongoing challenge for pharmaceutical companies and CDMOs.”



Hamilton Lenox,
Senior Vice President of Business
Development & Operations,
LGM Pharma

He expects that inflation/price increases will continue to be an issue in 2022. “Strong consumer demand, continuing supply chain challenges, and the emergence of new COVID-19 variants are prolonging sharply rising prices well into 2022,” says LGM Pharma’s Lenox. “Prices are rising at the fastest pace in nearly 40 years, and this translates into higher prices (and longer lead times) for drug substance and drug product services.”

Another contributor factor to upward pricing pressure are labor costs. “Recruiting and employee retention continue to be challenging, with strong competition for good candidates, and the tight labor market also is leading to higher salaries and benefits, further driving up costs,” explains LGM Pharma’s Lenox. “Also, in this type of labor market, many organizations are seeing increased turnover, which presents issues with continuity on projects and can lead to project delays or poor communication.”

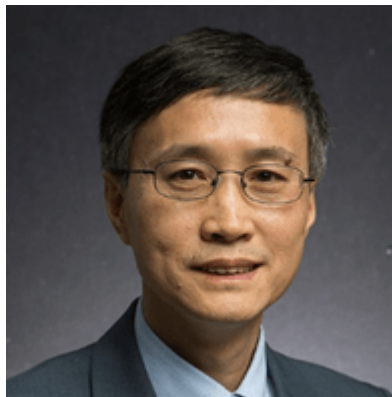


Scott Wagner,
Senior Vice President, Global
Operations,
Curia

Supply continuity and related factors were also cited by others as the most pressing issues for 2022 and that the ways to effectively address these issues will serve as the basis for competitive advantage. “The pandemic and other global events have combined with changes in buying patterns, which have disrupted the global supply chain,” says Scott Wagner, Senior Vice President, Global Operations, Curia. “Items that were once abundant have become scarce. And many industries are in expansion mode, which places even more demand on the same limited resources. Supply continuity has always been very important, but suppliers that can deliver reliably to their customers during this time have a great opportunity to secure preferred status with their customers for years to come.”

“The next issue I see is cost. Inflation is rising quickly across many sectors,” says Curia Wagner. “Suppliers that are able to contain their costs to limit cost increases to their customers will secure a unique advantage over their competition. The third issue I would highlight is quality. Quality is and always will be an important part of how the customer/supplier relationship develops.”

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In addition to supply chain and related issues, others point to additional industry dynamics, such as increased supplier consolidation and greater emphasis on environmental improvement initiatives as key issues for 2022. “As the pharmaceutical industry evolves, we are seeing outsourcing activities increase, which in many cases is also leading to further consolidation of the supplier base as innovators try to optimize and streamline their business processes and core activities,” says Xiaoyong Fu, Ph.D., Chief Technology Officer and Head of the API Business at WuXi STA. “Three of the most significant issues we see are all interlinked: (1) increased supply risk monitoring and supply-chain security, (2) the growing importance of online collaboration, transparency, and information sharing; and (3) incorporation of environmental improvement initiatives throughout the supplier base.”

Supply practices for improving supply-chain resiliency and

transparency Given these challenges, how have supply practices and the ways of doing business between bio/pharma customers and their suppliers changed or may be expected to change?

“Supply chain has been a huge issue and it’s changed the way we all do business,” says Piramal’s Needleman. “Dual sourcing is the minimum; multiple sources of supply are preferred. Geography matters too. You cannot rely on any single geographic region; you need the supply chain to be spread out across multiple regions. Maintaining extra stock of raw materials is obvious, but somewhat less obvious is the need to maintain extra supplies of consumables such as bags and filters. The rule of thumb has become: ‘Need one? Buy two.’”

LGM Pharma’s Lenox further elaborates. “The pandemic highlighted the importance of adopting a multi-source strategy and maintaining a geographically diverse supply chain, for companies and their suppliers,” he says. “By qualifying multiple facilities, as well as choosing facilities in different regions, countries, etc., a company can help ensure continuity of supply if an unforeseen issue occurs in the country of origin. Further, many organizations have recognized that Just-in-Time planning is not a workable strategy when facing the current multitude of supply-chain challenges. Many have adopted different approaches, such as increasing safety stocks, adding secondary and tertiary suppliers for all key raw materials and components, and others



Ashley Hetrick,
Principal,
Vantage Partners

In addition to adjusting supply practices and inventory build, more collaborative planning has and will continue to be important. “Some companies have focused primarily on increasing safety stock, and on increasing dual source and multi-source arrangements,” says Ashley Hetrick, Principal, Vantage Partners, a management consultancy with specific expertise in supplier relationship management for the bio/pharma industry. “Others have focused more on deepening collaboration with key suppliers, increasing transparency, and working to enhance joint forecasting and increase supply-chain agility. We expect a focus on resiliency and agility to continue 2022 and beyond. The challenge will be how to do so without significantly increasing costs—which we believe will require a focus on customer-supplier collaboration and partnership.”

That deeper collaboration also projects to produce better results. Hetrick says according to Vantage Partners research, customers that put a high priority on creating a foundation of mutual trust, understanding, and respect with suppliers also report realizing 24% more of the value from their supply contracts compared to those companies that place a low priority on building and maintaining collaborative relationships.

Supplier qualification: remote customer audits: here to stay or no? Due to pandemic-related health and safety protocols, restrictions on travel, and/or lockdowns in certain locations, suppliers and pharma companies had to shift from the traditional



“Undoubtedly, they will continue, and they potentially could expand once the industry has adjusted to the change and experienced successful virtual audits,” says Piramal’s Needleman. “The savings in cost, time, and travel is too great for it to be otherwise. Digital communications have made virtual audits simple and effective. We use virtual, real-time video that delivers the experience of a live audit, and we support it with the corresponding paperwork. The protocols on both ends, customers and suppliers, are making remote audits the norm.”

Others agree. “I’m confident that remote and virtual oversight will remain a feature of 2022,” says Curia’s Wagner. “Even after the pandemic, I expect customers to continue leveraging remote audits on a risk-based approach. New technologies make sharing of documents and performing the audit from a distance possible. I believe video conferencing and virtual collaboration have been the biggest gamechangers in making remote audits more effective. There is no equivalent to an in-person audit, but remote audits should have a place in every company’s risk and compliance strategy.”

While in-person audits, as conditions permit, will remain the standard in the industry, others concur that remote audits will play a role in the future. “We expect remote audits will continue throughout 2022, and most likely far beyond this year and the current challenges related to COVID,” says LGM Pharma’s Lenox. “Visiting multiple manufacturers in diverse geographic regions can be expensive and time consuming and remote audits have provided some relief to these challenges. Remote audits also have promoted improved pre-audit communication, with auditors required to share detailed agendas in advance, thus allowing manufacturers to be better prepared at the time of the audit. Manufacturers are using data rooms to pre-load documentation (based on auditors’ agendas) and using video conferencing software such as Zoom to give facility tours as part of an audit. While in person audits remain the gold standard when auditing a new potential supplier, remote audits are allowing small- and medium-size companies access to an expanded group of international suppliers at reduced cost, and it has simplified the requalification process larger organizations use for their existing suppliers.”

Others also point to the continued use of remote audits in some form. “We encountered varying levels of client engagement with the concept of remote audits,” says WuXi STA’s Fu. “With clients where we already had a very high level of engagement and audit experience, we were often able to support remote audits in a framework that met their performance and compliance requirements. Newer clients are slower to adopt virtual



time tools such as smart glasses (3D) to provide an artificial ‘person in plant’ experience and communicate these observations back to the audit team. While both parties consider these remote audits a necessary tool in the current environment, we believe that most companies and regulatory authorities will welcome the return of onsite auditing when safety permits.”

Evolving approaches in project management *DCAT Value Chain Insights* also wanted to gain a perspective on how project management has evolved since the pandemic in areas such as the type and frequency of communication.

“Transparency and increased communication are a necessity for good relationships between pharmaceutical companies and suppliers, but they become both more challenging and critical when the entire industry struggles with a variety of unknowns (raw material shortages/delays, increasing prices, labor shortages, COVID lockdowns/quarantines, etc.) such as we’re currently facing,” says LGM Pharma’s Lenox. “We are seeing many suppliers proactively focusing on increased transparency and improved communication with clients throughout the entire project. Clients and suppliers are working more as true partners, with stronger project management team and systems in place that provide detailed scopes of work, consistent and regular communication, and high levels of transparency in order to mitigate risks and meet timelines.”

Others agree that increased communication and deeper project management have and will continue to be important. “For pharma, it’s meant more communication, more use of video, embracing [Microsoft] Teams and other platforms to stay connected,” says Piramal’s Needleman. “There’s been a significant increase in the frequency of communication too, not just in the status of a project but also the health status of supplier teams. Pre-existing relationships that have been built over time are key and need to be taken even deeper. We’ve invested heavily in new IT tools that are specific to project management, including standardized training. One thing is clear: the project management role needs to be elevated within one’s organization.”

Curia’s Wagner points to ways in which the company is deepening its project management. “We have seen an increase in customer needs and requirements throughout the pandemic. Customers have aggressive schedules they need to meet, which drives our need for excellence in execution. It is in this environment that we have



Committee meetings to ensure we remain aligned with the customer's executive team as we collaborate to meet their aggressive timelines."

WuXi STA's Fu points to the value of real-time data sharing and other digital tools to further strengthen project management. "The need for regular and accurate communication is critical, with information efficiently disseminated across both organizations," says WuXi STA's Fu. "The ability to provide real-time data sharing is most compelling when projects are at the production stage, with activities advancing 24 hours per day and 7 days per week. We have established an online meeting platform across our entire teams such as analytical, quality, or process development. Some information, such as analytical results or viewing a critical production activity through new technologies such as smart (3D) glasses and virtual reality (VR) programs, can be shared virtually and reviewed immediately shortening the time between receiving results and approvals to progress to the next stages. These days the expectation from our customers is to deliver faster than before. More timely communication to quickly respond to changes and access to a critical mass of workforce to support projects without delay has become increasingly important in the overall timeline expectations for many projects."

Other industry experts concur that digital technology will become a greater part of project management in the future. "In 2022 and beyond, we expect that in-person collaboration will resume, but the future will be hybrid," says Vantage Partners' Hetrick. "Many interactions that used to occur in-person will now occur virtually. Customers and key suppliers will continue to learn how best to blend virtual and physical engagement. We see use of VR [virtual reality] and AR [artificial reality] technologies increasing in manufacturing plants. The semiconductor industry specifically is more advanced in use of these technologies than bio/pharma, but we expect bio/pharma companies to close the gap in the coming years. The pandemic accelerated evolution in site-less clinical trials and use of real-world evidence, and we expect this trend to continue, with sponsors and CROs/CDMOs collaborating to improve the speed and efficiency of clinical development."

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