Strengthening Supply Chains

The COVID-19 pandemic exposed weaknesses in pharmaceutical supply chains. It's time to address these. Featuring input from Sanofi and Thermo Fisher Scientific.

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Strengthening Supply Chains Post-Pandemic

Ideal procurement systems should facilitate the launch, manufacture, and distribution of drugs while also insuring against logistical shocks – such as pandemics. But what should companies do to build supply chains that provide firm anchorage in a risky world? We spoke to Prateek Gadhoke, Global Head of Specialty Care Procurement at Sanofi, to ask what exactly makes a strong supply chain...

What is your background and experience in the industry?

After studying mechanical and biomedical engineering, I joined Bristol-Myers Squibb in an operations development program. I began in biologics technical operations roles and moved into global procurement within the biologics operating unit. I've been in procurement and biotechnology manufacturing ever since; my history includes Alnylam Pharmaceuticals, Novartis, and now Sanofi, where I am head of specialty care procurement. Sanofi Genzyme is the specialty care business unit of Sanofi. Throughout my career, I have focused on making procurement a trusted partner to manufacturing and supply chain. Designing long-term supplier partnerships are critical to support productivity, drug launches, and innovation in mature and new drug modalities.

How important are partnerships in procurement?

Biologics manufacturing benefits enormously from external innovation; in particular, supplier technology provides critical competitive advantage. By accessing innovative offerings and services from supplier-partners, R&D organizations and manufacturers can accelerate product launches and go-to-market more quickly.

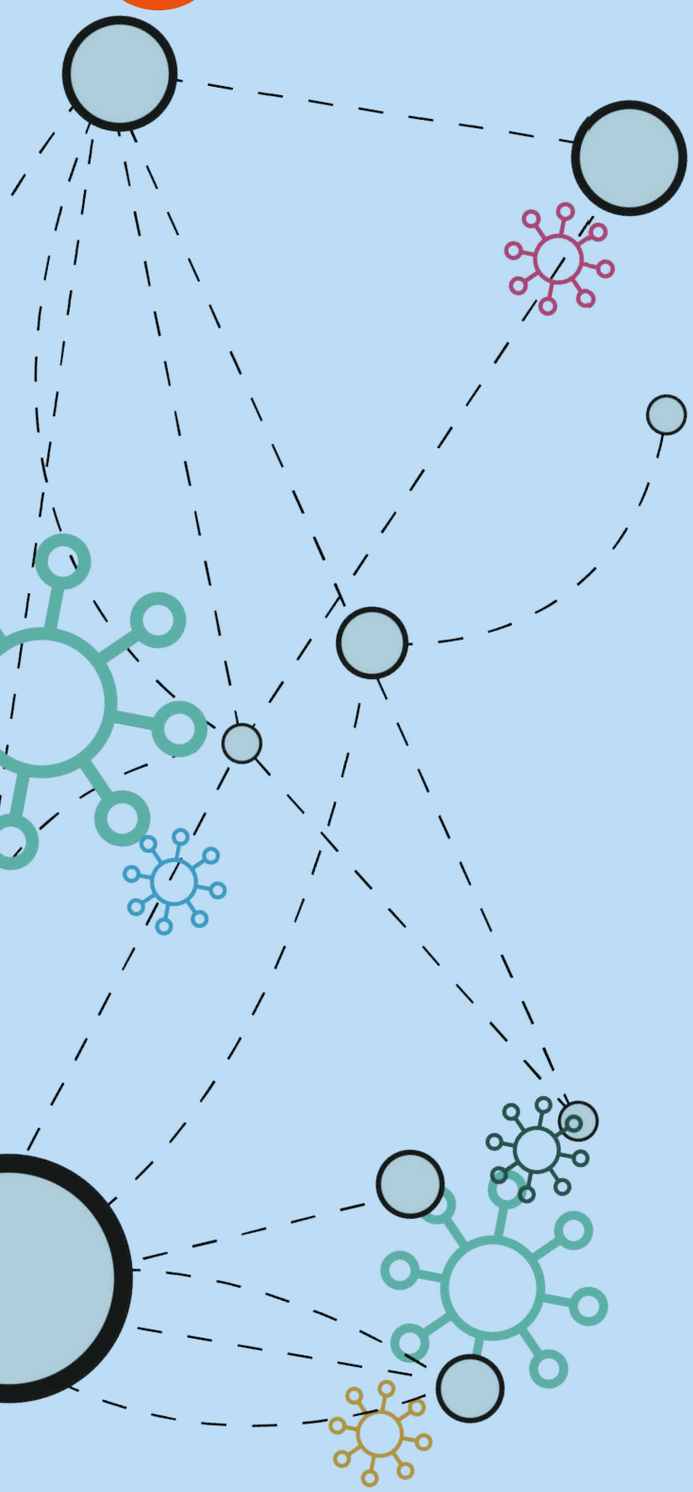
We work with Thermo Fisher Scientific as well as other key life sciences partners that support our value chain from research, drug development, commercial launch, and supply chain management. Corporate partnership spanning this value chain helps Sanofi to operate more quickly, efficiently, and effectively.

How is procurement evolving at Sanofi?

Sanofi's play-to-win strategy, implemented by our CEO Paul Hudson, required us to improve R&D productivity, increase value creation in manufacturing, and accelerate drug launches. And it necessitated a renewed focus on evolving procurement, supply management, and external partnering with our life sciences supply base. Our strategy also demanded the recruitment of a world-class leadership team in direct procurement, heavily drawing from outside talent. Why? Because Sanofi's innovative product portfolio, which includes new drug modalities from our various acquisitions and alliance partners, requires support from procurement professionals with not only the business acumen to make partnerships work, but also relevant scientific and operations experience to help bring innovative solutions to our business partners. For us, procurement is evolving from a traditional global, corporate-level role to become more effectively integrated with the business unit.

What are the biggest challenges in procurement right now?

COVID-19 mRNA vaccine demand has dominated life sciences supply chain and disrupted the manufacture of other vaccines and biotech therapies with overlapping materials requirements; affected supplies include raw materials and consumables. Single-use components used in disposable manufacturing systems have been severely impacted over the last 18 months. Given we don't currently have global standard designs in place for various single-use components, the Sanofi specialty care team focused our response during this supply crisis by creating a cross-functional control tower team including site operations, supply chain, procurement and manufacturing sciences personnel. This team is crucial to maintaining global prioritization with our key suppliers of SUT components.



Similar to Sanofi, many pharma companies customize components right down to the level of each product and each site, preventing manufacturers from using, say, the same bag for media and buffers, or the same bioreactor components in both specialty care sites and vaccine sites. This lack of standardization hinders efficiency.

Achieving global standardization, however, will be a huge challenge. It requires integration between technical, quality, and supply chain functions, and demands transparent supplier partnerships. It can only develop via incremental steps taken by manufacturers and suppliers working together. These relationships are essential if we are to develop global systems for qualification and standardization of designs and required documentation. Furthermore, partnerships can help manufacturers by identifying standardization shortfalls and revealing strategies for managing complexity. Manufacturers must, however, be willing to make the decision to start afresh and begin producing medicines using standardized systems.

Is integrated demand planning important?

Integrated demand planning would ensure that the manufacturer connects commercial demand planning, via sales and operations planning, with production planning and ultimately demand planning with key suppliers to effectively manage materials supply continuity. And, put simply, this enables production to meet patient demand. A critical aspect is manufacturing requirements planning (MRP), which helps estimate materials requirements based on each product bill of material. The advantage of integrated demand planning is that it enables companies to work closely with suppliers and CMOs by facilitating local demand planning and forecasting. Large manufacturers can link routine processes at local, regional and global levels, provide suppliers with accurate future demand estimations, and plan production more effectively. Given many suppliers and pharma companies are still operating on spreadsheets, it is even more crucial to have an integrated demand planning team and process to aggregate demand, thereby improving the efficiency of materials planning and forecasting.

The pandemic impact on the mRNA supply chain demonstrates that integrated demand planning is now critical – and I believe it will become increasingly important. Manufacturers that take this approach will have an advantage in the short-term and long-term during this COVID19 crisis period.

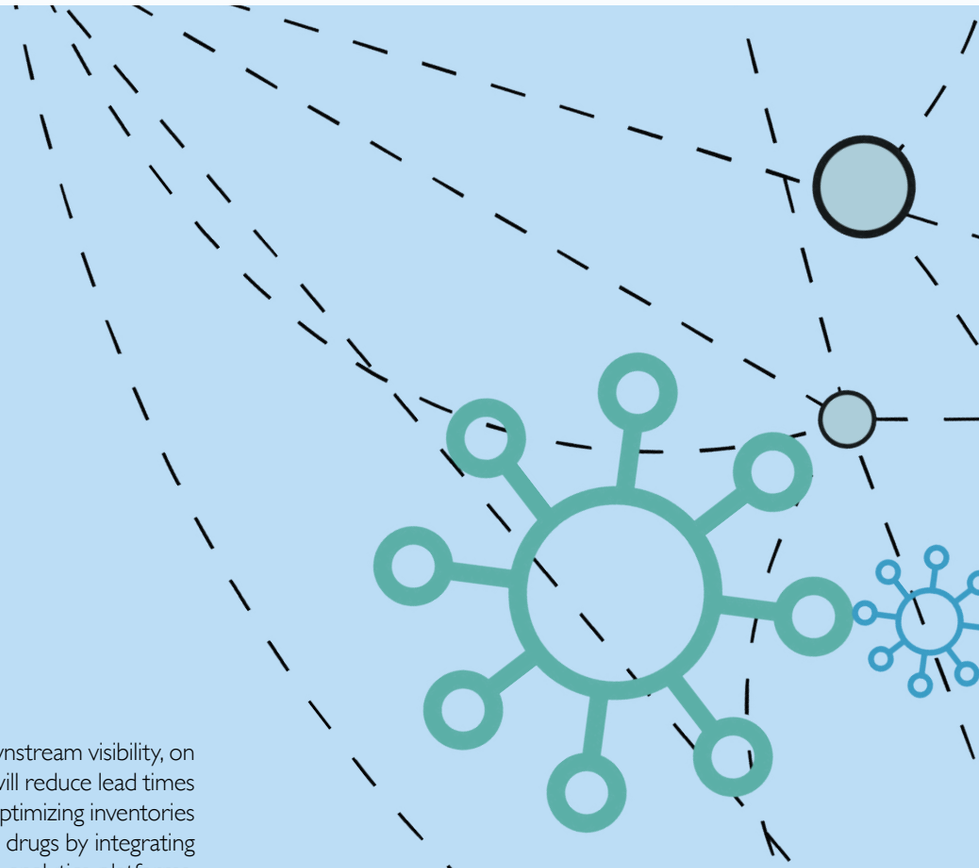
Has the pandemic encouraged closer collaboration?

Absolutely. It has forced us to focus to secure purchase orders well ahead of time, which ensures demand signalling and requires effective communication with core partners. Even before the pandemic, the progress of biotech innovation had led to a demand surge. The rate of collaboration will continue to increase as manufacturers increasingly appreciate that suppliers' specialized capabilities provide competitive advantage. Again, however, transparency is key if these partnerships are to work.

What are your top tips for successful procurement?

First, develop supply and demand planning in partnership with suppliers; to fully benefit from supplier capabilities, manufacturers should build transparent and effective relationships.

Second, insert robust risk management approaches into normal business procedures



including your budget cycle. For this, assess risk at the product/site level, based on the bill of material, and at different internal and external manufacturing sites. Good risk assessment at the product level includes cross-functional risk scoring with supply chain, procurement, quality, manufacturing sciences and regulatory inputs. This will help ensure the highest-impact risks are identified at the brand level.

Third, insist on implementing agreed mitigation strategies for high-risk materials/site combinations, and build them into the brand planning process. For risk and resilience strategies to be integrated with product planning processes at the corporate level, ensure commercial and operations divisions work in close partnership.

How important is digital technology for procurement?

Digital technologies are key enablers for procurement, supply chain planning, and the integration with commercial teams. Manufacturers that use digital tools and analytics can access critical, site-level information more quickly, and predict batch outcomes more accurately. Moreover, synergies between digital and single use technologies can help support modular manufacturing processes; manufacturers can switch products much more quickly than is possible with stainless steel facilities. But although digital is essential, it is not sufficient in itself; manufacturers also need appropriately trained people, not only in automation engineering but also data analytics for supply chain, procurement, and even more crucially quality control with the expansion of personal medicines. Finally, these new digital capabilities must be balanced by effective change control and cost management to enable the best outcomes for patients.

What is your vision for the supply chain of the future?

I envision an end-to-end supply chain permitting upstream and downstream visibility, on a per-product basis from raw materials to product distribution. It will reduce lead times and allow manufacturers to reach the market more quickly, while optimizing inventories and risk. Finally, it will support the launch of complex, personalized drugs by integrating R&D and commercial functions and leveraging advanced process analytics platforms. Overall, I think close collaboration across business units is becoming increasingly critical too; the time for silos is long past!

We must also recognize another important trend: the primary driver in procurement is no longer cost – it is resilience. Ideal supply chains therefore will embrace alternative sources for key materials and services. This approach to de-risking will involve regionalization, such that manufacturers employ partners in non-standard locations. And regional supply chain models have advantages for fragile biologics: outsourced analytical testing can occur close to manufacturing facilities, which reduces lead times. De-risking by geographic diversification is facilitated by partnering with major life sciences suppliers, such as Thermo Fisher Scientific, that have capacity beyond the standard US and European supply chains.

The impact of COVID-19 has significantly disrupted supply chains, causing a broad range of problems from logistics to supplies of even basic raw materials, such as wood and glass. Building resilience into procurement systems is essential; Sanofi has ensured continuity of supplies for its processes, and ultimately continued to meet patients' needs by collaborating with partners like Thermo Fisher Scientific and other major life sciences partners. I believe that all biologics manufacturers should consider strengthening their supply chains via advancing supplier partnerships.

Building Resilience in the Supply Chain

How to keep logistical wheels spinning in the face of adversity or change

The COVID-19 pandemic continues to have far-reaching consequences on our daily lives, forcing us to re-think many aspects of our routines that were previously taken for granted. As one key example, we've seen how, quite suddenly, a forced change in our lifestyle broke supply chains of domestic products. Scale this up to a global industrial level, and supply chains across the world, in all sectors, found themselves fighting a rear-guard battle to keep the wheels spinning and maintain supplies to customers.

Here, we catch up with Christine Callahan, Vice President of the Global Supply Chain for Life Sciences and Bioproduction at Thermo Fisher Scientific, about how suppliers and customers need to reimagine their business models and relationships to succeed in these challenging times.

How has the last 18 months affected the management of global supply chains at Thermo Fisher Scientific?

COVID-19 has challenged the logistics of supply in every industry. Transportation, import and export procedures, and the general handling of goods has become increasingly complex. New factors continually emerged, and legislation has slowed things down. Access to raw materials was strained, staff levels at factories became critical, and operational processes – even down to planning access to the canteen – were immersed in protocol! Companies have had to become resilient fast.

One challenge directly resulting from the changing working conditions of the pandemic has been recruiting the right blend of talents across the various functional aspects of the group. Putting the right people in place is key to the success of any business. Like any other company, we suffered from the stresses of staff shortages, changes in shift patterns, cleaning protocols, demands from home life, and so on.

However, despite the challenges, the COVID-19 pandemic has provoked a deep re-think of supply chain management – and we, at ThermoFisher Scientific are heavily invested in finding the right solutions for our customers. Hard challenges emerged very quickly from the health crisis, but that can be viewed as an exciting time too in some ways. The last year has been rich in experiences, and though there has been a lot of urgent actions to ensure commitments were kept, we have had to react, adapt, and proactively change – from increasing our infrastructure and capabilities, through to finding better ways to work with our customers.

Are there any challenges specific to the bioscience industry?

Pre-COVID-19, the bioscience industry generally was not overly focused on the supply chain. The industry is driven by the opportunity to have a meaningful impact on patients' health and lives. This viewpoint is fantastic, but despite the supply chain being very much part of the story, it's an aspect that only seems to stand out when it breaks. The bioscience industry has grown from smaller companies, who often become attached to particular suppliers and are generally nimble enough to navigate around supply chain interruptions of a smaller scale. As these companies have grown, however, they may not have evolved their perspectives on the supply chain or adjusted supply chains to meet the needs of the growing company. Of course, the massive impact of COVID-19 on supply chains has now brought these weaknesses to the forefront.

Demand planning in this sector also has always had its challenges. Determining what the customer really requires can often be a struggle, and certainly demand planning is for the short term only. This reflects the inherent risk in the industry and the nature of uncertainty obscuring robust forward predictions.

How has Thermo Fisher Scientific responded to the crisis?

The immediate answer is in building out capabilities. We have many factories across Life Sciences and BioProduction and are investing to scale up even further to support the continued growth in these industries. However, there is also much more that needs to be done to solve the problems faced by the industry. COVID-19 has been a catalyst – I could even say it has sparked a revolution – one that has

forced us to think deeply about how we work and re-imagine processes from top to bottom.

Our expansion of operational sites was designed to achieve several things. We wanted redundancy in our systems to soak up the strain during a pandemic – or any other resource risk to a customer's supply chain. However, we were mindful to approach our expansion globally, so that customers can source their supplies from a number of different Thermo Fisher Scientific sites across the world, reducing supply timelines and potentially easing the complexities of transportation across countries and import/export procedures. COVID-19 significantly impacted upon lead times, and our new network of flexible capacity should mitigate some of those issues.

How have customer relationships changed?

We want to forge more profound relationships with our customers, such that we become integrated into their operations, like a new department of the customer's business. We want to begin this process early – and at a high level. Furthermore, we aim to foster transparent, fully collaborative relationships. We have a wealth of oversight that allows us to see trends and make good predictions of supply availability. For example, we can see variations in the marketplace early that may be invaluable to our customers. By working openly together, we can build better predictions for demand and, importantly, longer-term predictions that we can commit to meeting through our increased footprint and openness to buying-in greater stock.

Being involved in the planning stages with our customers also allows us to help with designs, promoting the use of more standardized components and improving the ease of supply. The greater standardization of components is something that would benefit the supply chain industry overall – but it requires acceptance by the customer first.

Importantly, we want our customers to think of us as their primary and secondary source for supply. Our flexible network of capacity provides this resiliency.

What can companies do to minimize risk in the supply chains?

Before COVID-19, the industry showed a single-source preference. Customers were, therefore, "backing a single horse." My top piece of advice: collaborate with your customers and your suppliers. Transparency and partnership has never been more important. Work together to build in optionality at the manufacturing network level and the component level. Review supply chain risks and create options in your supply base and by reviewing specifications. There is a lot of over specification inherent in the industry. Designing in wider tolerances and driving standardization will give greater options to the choice of components; therefore safeguarding successful maintenance of long-term supply. If you are thoughtful about your specifications, you can still protect your branding, intellectual property and comply with quality requirements, but give plenty of options for sourcing.

I believe that companies must change their approach sooner, be proactive, and learn from these difficult times. We need to look further ahead and use two or three year timelines. I would urge customers to let us help you with your predictions, so that we become part of your process and business.

How can companies future-proof supply chains against another pandemic?

Most companies give a nod to disaster planning, but perhaps now we need to re-evaluate these plans more often. We need more scenario-based alternatives to remain flexible enough to cope with the impact imposed by a pandemic.

I champion transparency and collaboration. If we can have open discussions early on and at a meaningful level company-to-company – and commit to a longer-term relationship, it means that we can set up bespoke lines of supply that we can better protect. I believe this change in mindset and outlook will benefit both suppliers and their customers. Moreover, the approach works equally well regardless of company size.

What kept you resilient throughout the pandemic?

The pandemic has been a truly difficult time for people and businesses everywhere. For me, the most meaningful part of my job is knowing that, every day, my team and Thermo Fisher Scientific as a whole are improving and saving lives. This simple thought inspires me and provides more than enough energy to keep me moving forward.

Mapping Out Material Resilience

A short guide to strengthening raw material supply chains

Since our earliest origins, we humans have come face to face with disasters and catastrophes; famines, floods, earthquakes, wildfires, wars, outbreaks of infectious disease – they've all brought the notion of resilience to the fore. Strategies exist to help us build resilience – broadly defined as the ability to bounce back from adversity or trauma. But how is the concept of resilience reflected in the biopharmaceutical industrial setting? Here, Luis (Lucho) Bianchi Pintos, Vice President of Procurement, BioProduction at Thermo Fisher Scientific, discusses what resilience looks like when sourcing – or providing – raw materials during a pandemic.

How is the industry being challenged by change?

Both the sourcing and supply of raw materials for many industries has been fundamentally challenged over the last few years – driven by the pandemic but also other trends. But the industry has not stood still; I have seen significant changes taking place to respond to these critical demands. Thermo Fisher Scientific works in the life science sector and we acutely understand the vital importance of maintaining our operations in the supply chains of medicines, medical devices, and medical research in times such as these. We work in a sector where technical specifications are highly regulated and offer little flexibility. In this world, it is of paramount importance that we have the right material resilience in place – and this remains the case even during a global crisis, such as a pandemic.

What does raw material resilience mean?

Resiliency can be defined in many ways, and there is more than one way to build it within a company, but the fundamental challenge for businesses is "change." Change does not come easy in our industry. At a product level, the industry is usually steered away from change due to regulatory requirements. This in turn leads to a very narrow procurement process for raw materials – to the point where some organizations opt for a single source supply. With the pandemic pressurizing supply chains, you might think an obvious and easy fix would be to simply widen the sourcing of materials; however, to make that happen, an organization must restructure its thinking and operating practices – and that requires commitment.

The species that survive the longest are those that adapt the fastest, according to Darwin. And the pandemic presented a testing challenge, both at home and at work. For businesses, speed with which they adapt will almost certainly impact on their chances of survival. Pharma is not always used to change – but change we must.

Where do companies start the process of strengthening raw materials resilience?

Maintaining supply chains is very much about managing risk. Companies must identify risk, acknowledge its presence, and understand how it manifests across whole processes – a fine balancing act! It can be impossible to chase risk through multiple tiers of suppliers, but companies cannot just stop at their most immediate supplier. In some cases, companies might have to go deeper and collaborate even more closely with their partners to explore the tiers below. In my opinion, it's important to ask questions. Who holds inventory or stock? Who can source alternative supplies? Do we build extra capacity? Do we have room to flex our specification requirements? When are the answers to these questions critical? A supply relationship is a mix of co-dependencies and it's crucial to build in redundancies at strategic points.

There is also work to be done internally. Internal protocols, processes, and decision making must adapt – and I believe that raw material resilience must feature higher on agendas within an organization. Transparency throughout the whole process is key – whether internally or between the company and its suppliers. We must work together to ensure that products will still make it to patients. COVID-19 acted as a catalyst, exposing the weaknesses of organizations both internally and externally. To address these weaknesses, commitment, upper management drive, and extra cross-functional resources must all come together in a time when everyone is focused on fire-fighting strained supply chains that cause day-to-day urgency.

What other considerations are key to building resilience?

Once you have addressed your internal constraints, mapped out your risk profile, and identified strategic weaknesses, you can then turn to strengthening those weaknesses. You will need to chase alternatives – alternative materials, alternative suppliers, and even alternative geographical locations. You also need to predict less obvious risks, such as site disruptions, and build in adequate redundancy.

Supply chains have historically been built to be efficient, narrow, and focused on driving down costs. But these features make them particularly inflexible and, therefore, breakable. We must move away from rigidity while accounting for risk. For instance, sourcing supplies from different countries at first appears a sensible solution – and though this approach does have several benefits, it can also be subject to geopolitical issues, macro-economic pressures, and even environmental challenges, which create risk and the potential for disruption. Therefore, choosing alternative suppliers in a way that balances these risks is important.

Are you proud of Thermo Fisher Scientific's response to the challenges of a pandemic?

Yes. And I am amazed by what we have been able to accomplish given the size of the challenge – and in such little time! Thermo Fisher Scientific is a busy, fast-moving company with a strong belief in its mission to enable customers to make the world a healthier, safer, cleaner place for everyone. I feel everyone within the company rallied behind that as the pandemic closed in. Our customers had a crucial role to play in fighting COVID-19 – and that meant that our role in supporting them was crucial too. There is still a lot of work to be done, but we found that our suppliers rallied behind the call and prioritized efforts to secure and maintain a supply chain for essential healthcare products. We raised commitment throughout the company to address these issues head on and resourced multifunctional internal teams to identify, map, and tackle them with the support of our external suppliers. We continue to drive this support as far down the supply chain as we need to, helping at times our tier one suppliers with their own supply chain, reinforcing our ability to adapt.

Will resilience be a differentiator in the industry moving forward?

Absolutely. The pandemic has forced companies to acknowledge several weaknesses, but resilience in the supply of raw materials is an aspect that needs to be addressed urgently. From this point on, companies will need to have contingency plans that are tested, robust and in plain sight to give their commercial partners the necessary level of confidence. Having a secure, dependable supply chain policy will be a key differentiator of companies as we move out of the grip of this pandemic.

Our industry is highly regulated, and products have little tolerance in their composition. We must work together with full transparency to continue to deliver lifesaving biotherapeutics to patients. To do this, industry must build in alternative materials or supplies. With commercialized products already on the market, this is a big challenge. However, with products in development and particularly those at the research stage, manufacturers should instil a discipline to test supply chain resilience – and have a range of approved raw materials in their composition to enable multiple sourcing within the final product specification.

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