Facing Strong Headwinds

In Light of the Covid-19 Pandemic the Pharma Industry has to Reinforce Supply Chains and Review Business Processes

So far, the pharmaceutical industry — including CMOs/CDMOs — has responded well to the outbreak of the Covid-19 pandemic. However, the Coronavirus crisis has uncovered some issues that were smoldering under the surface and need to be addressed by the industry and by politics alike. For instance, the pandemic puts pharmaceutical research and development strategies to the test and challenges manufacturing planning and supply chain management.

CHEManager asked executives and industry experts about how this pandemic may kick off changes in the pharma market. We wanted to know:

- After half a year of living and working under pandemic conditions, what in your opinion are the most important lessons learned so far, and how will the current pharma business model change in the post-Covid era?
- Read the insightful answers of the experts here.

A Paradigm Shift that Is Here to Stay

Sauri Gudlavalleti, Global Head of Integrated Product Development Organization (IPDO), Dr. Reddy's

The Covid-19 pandemic has been one of the worst crises to hit mankind, but has inspired tremendous resilience and innovation in all parts of the healthcare industry. Pharma R&D teams across the world have been working relentlessly to develop treatments, prophylactics and vaccines to combat the virus, and are experiencing a paradigm shift that is here to stay beyond the pandemic. The first and most significant realization is that pharmaceutical development, which is thought to be a long-drawn process, can create tremendous impact in the short term. The fervent pace of development over the last few months has shown that there is a tremendous scope for higher speed and efficiency in this space. Researchers have demonstrated this by simplifying development protocols, digitizing processes, using in-silico modelling and data analytics tools. The deployment of virtual collaboration tools helped integrating physical R&D activities across multiple global locations. Pharma researchers understood that it is critical to keep up and accelerate the development of all categories of medicines — not just those that are directly relevant to the crisis at hand. We have seen that several existing drugs can be repurposed (e.g. antivirals like Remdesivir and Favipiravir, IL6 inhibitors, corticosteroids, anti-parasitics are all being tested for Covid-19) and several other drugs become essential for supportive therapies (e.g. ventilation aids, anticoagulants etc.). On the chemistry and manufacturing side, disruptions in supply chains have highlighted the need for greater backward integration of key starting materials and simplification of manufacturing processes during development. Finally, this period has reminded us of the value of enhanced partnerships across pharmaceutical companies, academia, government and non-governmental agencies. Multiple organizations are collaborating to combine their respective strengths in discovery, development, manufacturing, clinical trials, regulatory management, and last-mile distribution to accelerate product availability to every corner of the world. All in all, this crisis has brought out a new sense of speed, urgency and purpose in the pharmaceutical industry, and with it, a series of shifts that are here to stay.

Effective Management Is Required

Mark Benger, Site Director, Cambrex Edinburgh

The six months spent working in pandemic conditions have seen the industry reflect on the next steps in the drug research and development pipeline, with companies having had to delay or even stop programs. This applies to the larger pharma companies, and also the smaller, virtual companies where funding may be an issue without clinical data to support next steps.
Delays have been caused by the interruption of vital supply chains and lockdown of areas where the drug substance may be under preparation, but also due to the delay in decision making because of remote working and working through video conferencing.
There have also been large operational changes for many staff working in drug development labs or in offices, such as the introduction of changed working practices, or shift patterns to minimize social interactions and distancing, which could lead to progressive mental and stress-related problems building up.
Breaking up teams when staff are asked to work from home or lone work could have long-term implications. Not everyone is comfortable working from home, and in drug development, problems are often solved best by teams in the same space. Although remote conferencing has improved, it does not replace the dynamic of a team meeting. Effective management is required to maintain the focus on key projects, and to ensure continuity of work within laboratories and plants to ensure staff safety. Even industry veterans with long drug development careers are dealing with new challenges in these times.
All of the measures that have been introduced to protect staff, such as wearing PPE, social distancing, mixing remote and on-site working, may become normal over time, so looking forward, safeguarding staff's mental well-being as well as physical health could well be the greater challenge for managers of drug development facilities.

Excellent Program Management Is Vital

Kay Schmidt, Senior Vice President, Technical Operations, Catalent

Early on, as the virus spread internationally, we took advice from someone with experience of the deadly Ebola outbreaks: "Take action fast, because otherwise the pandemic will outrun you." Organizations have needed to be both engaged and focused to make agile decisions on what's important. As suppliers of life-changing medicines, pharma companies needed to continue operations and keep employees safe. At Catalent these measures included remote working, shift re-alignments, unidirectional corridors, cohort work assignments, and line layout changes.

Excellent program management is vital as we have integrated capabilities across our global network. To meet program demands, we have worked on more tasks in parallel and, with constant communication with and the trust of our partners, taken measured risks to compress timelines. The need for transparent and technically-sound risk management and mitigation is critical. For example, to support clinical trials we have worked with partners to turn repurposed API into patient doses in just days, and we have worked 'at risk' to supply patients even before formally signing contracts.

The pharma industry will undoubtedly make more use of connected technologies to speed processes and reduce in-person contact; for example, we have already implemented virtual tours and remote viewing, negating the need for some visits, and further use of e-signatures where possible.

The industry was already transitioning from the 'blockbuster' era to a future of treating orphan conditions and more personalized medicines. The increased flexibility and agility these new 'small batch' programs require has helped Catalent deliver solutions for the pandemic. Focusing on providing the appropriate and efficient infrastructure and equipment to meet multiple customer needs, and the introduction of, for example, more flex suites and micro environments, has meant Catalent has been able to initiate programs quickly to supply more than 50 antivirals, vaccines, diagnostics and treatments for Covid-19.

A Real Leap in Efficiency and Productivity

Jan Kengelbach, CEO, Aenova Group

At Aenova we had two simple objectives to navigate through the global Covid-19 pandemic: First, to protect the health and safety of our colleagues and their families, and second, to fulfill our role as a critical supplier of essential medications including those to mitigate the symptoms of Covid-19 to patients and healthcare customers around the world. Our countermeasures were strict and achieved the desired success. And, of course, they still apply.

Let me sum up in three points: First, CDMOs depend on a large and complex global supply chain and given that raw materials are often by definition in the dossiers single-sourced, the supply of certain APIs or their transport routes may be negatively affected. The pandemic has highlighted were supply chains are at greater risk of being disrupted. Our strategic procurement team has done a fantastic job in proactively addressing these, but the identification and approval of alternative resources is absolutely fundamental for our business.

Secondly, our operations and service levels depend on the 4,500 people who contribute to making products for our customers. Safety and hygiene measures have always been part of our daily operations, but through Covid-19 we were able to make them even better in this respect, we are proud that our absenteeism rate during the pandemic has been lower than ever before.

Thirdly, we have also learned that the Covid-19 pandemic accelerates digitization and virtual work. This even goes so far that customer meetings and negotiations of new contracts, onboarding of new colleagues, customer and regulatory audits and even due diligences can be performed digitally now plus administrative staff can work from home. All this leads to a real leap in efficiency and productivity.

Collaboration Is more Important than Ever

Dago Caceres, Global Strategic Marketing Leader, DuPont Nutrition & Biosciences

The pandemic has demonstrated that all members of the pharma community — from regulatory agencies to suppliers — can join forces and leverage their respective areas of expertise to develop safe, efficacious and cost-effective products, and deliver them swiftly to market. At DuPont, we've learned that the development time of novel APIs, of biologic or synthetic origin, can be further optimized and streamlined to bring crucial solutions — such as vaccines for prevention or medicines for treatment — to market faster. Now more than ever, pharmaceutical companies need to collaborate with their partners and stakeholders to facilitate the development of new medicines.

We've always known that business continuity is critical, but 2020 is a great reminder of its importance. The pandemic has shown that the pharmaceutical supply chain is a global, complex and interconnected web that needs to be assessed holistically, as it's only as strong as its weakest link. Each member of the chain plays a vital role in ensuring that products can be produced and made available to patients and consumers, even under the most challenging of circumstances. We'll likely see more companies focus on inventory build strategies to secure product in the event of unplanned shutdowns due to lack of resources. Additionally, we expect to see more suppliers expand the "flexibilization" of assets/materials on the systems side, to produce the same products in different assets and in various regions. This has always been a priority for DuPont, but it will become even more crucial as the industry visualizes what may lie ahead.

We've learned that digitizing our production capabilities, investing in improved technology and bolstering data infrastructure can produce even better products. We've invested in better planning and reporting tools, as well as in-depth digital and analytics, to enable faster decision-making, more efficient solutions and better understanding of variability in our processes — and we're already seeing outstanding results. Moving forward, we'll likely see increased digitization efforts across the industry, as well as virtual technical support throughout the supply chain and enhanced tools for remote communication and verification. This will allow us to keep our fingers on the pulse of the supply chain, without even being there.

Agile Companies Have Benefited from the Crisis

Andreas Bonhoff, CEO, TTP Group

In 2020, the pandemic will present us with a completely new situation: the process chains and flow of goods from outside Europe have been halted.

The trend in the pharmaceutical industry is: Find solutions to increase innovation, investment, value creation and jobs in the EU. Therefore, in the medium term, increased investment should flow into production in Europe. Investments in domestic production can be expected in particular in the area of pharmaceutical API.

Since the core of TTP Group is in Europe, we do not expect Covid to cause any persistent downturn. We are focusing on organic growth — particularly in times when pandemics may not remain isolated cases. And this is where we see our greatest market opportunities in the next two years as a specialized engineering service provider.

We are currently seeing that the pharmaceutical industry is doing generally well. We have responded to this trend with a broad range of services. Our local presence with competent employees directly in the customer's environment is of great benefit to us in these times. So, it is possible for us to be there for our customers during the whole Covid time and we are able to serve every customer requirement within the scope of the respective hygiene regulations.

Still, due to the higher coordination effort, the effects were mainly felt internally: deployment plans had to be optimized; home office infrastructure and networking capabilities had to be ensured.

Agile companies have thus benefited from the crisis. We have seen that modern companies are capable of implementing changes in just a few weeks.

Through the merger of TTP-Pharmaplan-Triplan, we already initiated a transformation process a year ago, which enables us to use cross-industry optimization processes.

The development of digitalization was definitely driven by Covid, which will also be of benefit to us after the crisis. The new situation has forced us all to deal with the new technical tools and to use them now in our day-to-day work.

Thanks to digital networking via a cross-group platform with over 900 experts, we are now bundling outstanding knowledge competence, across sectors and countries. This year was therefore also marked by an uninterrupted increase in the number of employees, which we were able to achieve with the help of digital tools, even during the Corona crisis.

Safeguarding the Reliable Supply of Essential Therapeutics

Wolfram Schulze, Vice President Information Systems, Organization & Digital Transformation and Head of Infection Prevention Task Force, Rentschler Biopharma

Cooperation in times of Covid-19 is key to weathering the crisis. In these unprecedented times, we at Rentschler Biopharma are deeply committed to safeguarding the reliable delivery of essential, sometimes lifesaving, therapeutics for our clients and their patients. At the same time, we are strongly dedicated to ensuring the safety of our employees and our partners.

We understand the change initiated by Covid-19 as an opportunity for further development and optimization of existing processes along the entire biopharmaceutical value chain – together with partners and clients.

A continuous optimization of operational fitness regarding processes, business continuity and digital maturity has always been an integral part of our company's strategy, even before the outbreak of the Covid-19 pandemic. We had previously started an initiative to focus on establishing second sources for raw materials and to balance global and local vendors to become more resilient against disruptions in global supply chains. Leveraging and further growing our strategic partner ecosystem will furthermore ensure the reliable delivery of premium services to our clients. The Rentschler Digital Agenda and its initiatives will complement and further enhance our existing services with digital capabilities, which become more and more important in our fast-paced and interconnected partner ecosystems.

In short, the Covid-19 pandemic helped us to verify that the direction set forth by the Rentschler Strategy 2025 is now even more valid than ever and allowed us to re-prioritize related strategic implementation projects.

United We Withstand the Corona Crisis

Thomas W. Büttner, Managing Director, Gemini PharmChem

In May 2020, at the height of the coronavirus crisis, Gemini PharmChem successfully launched commercial production of anthracycline anti-cancer active pharmaceutical ingredients (APIs) at its production facility in Mannheim.

This was a concerted push on behalf of Gemini's employees, shareholders, suppliers and other stakeholders. We are incredibly thankful for the efforts of the entire team to advance the company's strategic goals during these times of unprecedented challenge.

Gemini's production, now ongoing, is beginning to alleviate a worldwide product shortage in the anthracycline product category and helping doctors provide patients with the therapies needed to fight a range of cancers.

Gemini, a subsidiary of Synbias Pharma, plans to strengthen its product portfolio by launching the production of additional anti-cancer APIs later this year and is exploring other strategic initiatives to grow its production business. With this in mind, the group expects to increase its team in 2020 to meets its growing production needs and will continue to invest in its facility in Mannheim.

Collaborations and Partnerships Leveraged the Industry's Collective Knowledge

David Ginivan, Vice President Corporate Communications, Vectura

It has been remarkable to see how our industry has come together. Collaborations dominated the news headlines and the pharma industry was lauded for mobilizing quickly to try to help contain and treat the fast-spreading Coronavirus.

Collaborations and partnerships leveraged the industry's collective knowledge to expedite development and approval of new vaccines and therapies. These include compounds formerly tested on other viral pathogens, such as Ebola and HIV, and the repurposing of existing medicines to help in the fight against Covid-19.

It usually takes over a decade to develop a safe, effective anti-viral therapy. But, when it came to Covid-19, we didn't have that kind of time. One way to speed the process was to look at old drugs to work against this new disease threat.

One of those drugs was low-dose dexamethasone, an anti-inflammatory steroid which has been in use since the early 1960s. Scientists found that dexamethasone helped hospitalized patients who needed oxygen or were on a ventilator. It appeared to dampen the immune response, giving the lungs a better chance to recover. A breakthrough with a repurposed drug during the crisis.

Repurposing and repositioning projects offer the prospect of a faster route to patients than a discovery project for a new molecule; and, if the drug is already on the market, most necessary safety trials will have been completed.

As a result of the Covid-19 crisis, a key reminder for medical scientists and the industry is that, before embarking on new expensive discovery projects, we should look at what is in our medical arsenal as the solution might already be in our hands. In some ways, this crisis has laid out a blueprint for scientists to research the properties of existing and marketed molecules as one of the options to solve and treat emerging new diseases.

Business Continuity Planning, Agility and Flexibility are Crucial

Leon Wyszkowski, President, Commercial Operations, Pharma Services, Thermo Fisher Scientific

As the world leader in serving science, Thermo Fisher Scientific has been involved in virtually every aspect of the ongoing fight against Covid-19, including more than 200 projects in vaccines, antivirals and treatments over the past several months. Over this time, there are several important learnings for pharma services businesses to keep mind: 1. Robust business continuity planning is crucial. The plan should be flexible and agile — since you will need to adapt. Importantly, you can't wait for a major event to happen — it needs to be in place and tested well before you need it. 2. Create simplicity and agility in the supply chain. It is more important than ever to work closely with supplier partners and monitor and reassess your supply chain. It is equally critical to validate alternative sources of supply and expedited transportation modes wherever possible to ensure critical inventories for both Covid and vital non-Covid medicines. 3. Ensure redundancy in supply chain. The pandemic has underscored the need for redundant capacity across the network to eliminate single points of failure. Second sources either within a single network or leveraging multiple supply organizations will be a priority in the future. 4. Continue to invest. While the Covid-19 pandemic continues to create uncertainty, continue to invest in your business. For pharma services, this means growth in capabilities, capacity and supply to ensure that critical medicines are never delayed in reaching patients. 5. Innovate and leverage digital. The adoption of digital technologies are critical to ensure business continuity and connectivity with colleagues and customers in new, virtual ways. For example, virtual and augmented reality technology can provide virtual site visits and inspections for regulatory agencies and customers alike, without the need for them to physically travel. These solutions create new opportunities for agility, flexibility and cost reduction at sites.