Skyepharma’s David Lescuyer on Manufacturing & Supply Chain Reliability

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David Lescuyer, managing director of fully integrated French CDMO Skyepharma, outlines how the COVID-19 crisis could usher in a new era for the pharmaceutical industry, with a renewed pan-industry understanding of the importance of robust global supply chains.

COVID-19 has shed light on how fragile and fundamental supply chains can be and put manufacturing & supply chain reliability on centre stage. Could this be the beginning of a new industry paradigm?

COVID-19 will definitely bring about a paradigm shift. The supply chains of most pharmaceutical companies are currently extremely geographically dispersed and somewhat unstructured. A lot of efforts have been required for the pharma industry to keep supplying products.

Now, in order to increase the robustness of the global supply chain, CDMOs need to step up and play a larger role than ever before and need to work in a more integrated manner with pharma companies.

How has the COVID-19 crisis affected Skyepharma’s operations?

Skyepharma has not been overly impacted by the COVID-19 crisis as we have worked on improving our supply chain for the past four years. Our size and agility have been a strong advantage in minimizing the COVID impact. We have remained resilient to be able to deliver for our customers on time throughout this period, without any supply problems.

What is the potential impact of supply chain disruption and what role can CDMOs play in alleviating it?

The most important impact of supply chain disruption is not being able to deliver for our customers, thus not delivering the medicines that patients need. Therefore, this is an extremely important issue. CDMOs will continue to play a vital role in the global pharma supply chain by working hand-in-hand with their partners and suppliers and ensuring business continuity.

Skyepharma is continuously working with some of our partners on risk assessment of the global supply chain. This helps them reassure their shareholders that their product supply will not show any discontinuity.

Do you foresee pharma companies becoming more willing to pay a premium for the flawless delivery of their finished products?

Pharma companies expect a larger role within the supply chain for CDMOs. There needs to be a fair price attached to this service, especially considering its value in comparison to the potential risk of running out of stock. Price is not only related to the CDMO service but also to selecting reliable suppliers, which also has a price. The CDMOs who are able to help their partners throughout their whole supply chain will be differentiated, as not all CDMOs will be able to do so.

From 2016 to 2019 Skyepharma completed its transformation from a CMO to a fully-fledged CDMO. What have been the most important results of this?

Over the past three years, Skyepharma has transformed into a fully integrated, agile and expert CDMO. This has been achieved primarily through investment in new equipment, skilled resources

and a strong organizational culture, based on transparency, quality, and performance, which has allowed us to broaden our service offering.

The company has hired a full development team based on our site and now has a one-stop-shop platform for complex solid dosage forms from early stage development all the way to scale up, clinical batches, and technological transfer of manufacturing and packaging, including sterilisation and aggregation.

Moreover, we now also offer API sourcing and Vendor Management Inventory (VMI) services, helping our clients manage their stock so they can save money and reduce their supply chain organization size.

How has this significant investment been reflected in the company's commercial and financial results?

This investment has resulted in a double-digit growth in revenues since 2017 in line with our business plan. The next area of focus is growth for the next ten years, including a strong CAPEX plan to add new capabilities.

Skyepharma is now starting to realize the benefits of our investments in terms of new contracts in early-stage development of new chemical entities (NCEs) as well as existing chemical entities.

How has your client portfolio evolved?

Since 2016 the company has more than doubled its client base, with a focus on long-term strategic partnerships. With the extension of our manufacturing capacity, the firm has been able to welcome more manufacturing clients, along with new partnerships in development and commercialization.

Clients from across Europe, USA, Asia, and South America are being drawn to our ability to formulate and reach the quality attributes necessary for their products. These clients have also understood how Skyepharma can reduce time to market and the significance of our focus on 'right first time' using Quality by Design (QbD) projects.

This increase in volume of clients has been accompanied by our increased diversity. The company's client portfolio ranges from virtual pharma, small and mid-size to Big Pharma, and some

generics companies that are seeking help in developing and manufacturing complex generics.

What are the key concerns that commercial clients have when choosing a CDMO partner and what makes Skyepharma the partner of choice?

At their core, pharmaceutical companies' key concerns are around the robustness of their supply chains and finding a long-term reliable partner. Skyepharma understands this and working with us ensures that the clients' products are delivered on time and in full. Our solid track record of on time delivery of over 95 percent on the past four years – one of our main KPIs – demonstrates this.

The company has also continued to invest in additional capabilities on our work site. It is important for our clients to have a strong CDMO partner that is able to invest in its own facilities as it reflects a commitment to both ours and our partners' businesses.

Clients now expect CDMOs to have an impact on both time to market and safety. How has Skyepharma adapted its offer to cater to these two critical points?

Time to market is essential and Skyepharma is very well positioned to ensure efficiency on this point. Our company has always considered the 'technical transfer' timeline as a top priority and we manage to transfer products in six months. Potential troubleshooting is included in those six months and, thanks to our expertise, we can go fast and right first time.

For development stages, QbD tools which are customized and developed internally are used in order to speed up formulation development and achieve quality attributes for our partners' products in a very short time.

Additionally, we offer reformulation and life cycle management services to our clients. Our on-site experts work hand-in-hand with these clients to ensure we fully achieve what they are looking for in terms of time to market and costs.

Regulatory compliance is more important than ever in ensuring that pharma companies are able to access markets such as the USA and EU. How can Skyepharma help its partners to access these two important, but demanding, markets?

Regulatory compliance is a strong differentiator for Skyepharma and an area where it has a very good track record. The company has been authorized for the European as well as the US market since 1998 and a significant amount of production – 40 percent – goes to the US.

The firm also has a team of regulatory officers who help our clients on product transfer, clinical trials etc for the 30+ countries we work with globally. This is complemented by a very strong and clean regulatory track record in terms of authorities' inspections and clients' audits.

The EU's 2019 serialization regulation has been in place for a year now. What has been the impact on your clients' businesses?

Serialization and aggregation is something new in the pharma world, and Skyepharma started to invest in this area in early 2017 and now has a very strong platform. The company has partnered with Seavision and Tracelink from the beginning in order to offer a strong and versatile platform to help our clients get connected to all types of providers and authorities. Experts in this domain have also been hired in order to be able to help our clients get it right first time.

The taxonomy of the life sciences industry has evolved, driven by two key factors: the increasing participation of private equity investment and the higher success rates of biotechs in discovering new drugs. In most cases neither of these actors possesses or wishes to possess manufacturing facilities. What advice would you give to companies considering partnering with a CDMO like Skyepharma for manufacturing?

Discovering new drugs is challenging, but to succeed it is essential to consider the whole development pathway: from design of the final dosage form, to scale-up and manufacture in a safe GMP-approved environment, whilst maintaining the highest quality standards. Both private equity

and biotech firms are looking to reduce risk in their programmes and maximize the chance of success for their product candidates. This is how a trusted, quality CDMO partnership with Skyepharma can help.

The CDMO business is a growing segment within the pharma industry and competition between conglomerates and mid-caps is fierce. In which cases should clients look to large conglomerates and in which cases are mid-sized firms like Skyepharma the best option?

There is a high level of competition, with many players, and a lot of fragmentation. However, when you look at recent failures in the market, it is clear that being a large CMO conglomerate does not protect you from failure – some have had the wrong strategy, which focused on low prices only. Working on enhancing their differentiators is important for CDMOs to better help their partners in the supply chain. They need a clean quality and regulatory track record and a wide range of services, meaning that there is definitely room for mid-cap players in the CDMO space.

They need to have both a healthy business model and a robust operational platform.

The reason that larger pharma companies are knocking on our door is that Skyepharma is able to offer services, products, and technologies that other companies cannot.

Moreover, we are very focused on client experience. Our clients understand that they are paying for a service and that our role is to help them, not take control; something that is not always the case when working with larger CDMOs.

Having a personalized, human touch is important in terms of building trust. When you sign a contract with a partner, the signature itself is just a milestone but it’s the performance across the life of the contract and beyond that really matters Skyepharma is looking for long-term partnerships. It is very important that trust is there from the beginning so that problems can be solved quickly and efficiently, working hand-in-hand with the client.

Our number one value is “Team is Number 1” and we apply it also when working with our partners.

In terms of location, what are the benefits of manufacturing in France and in Lyon in particular?

Lyon is perfectly located within the heart of European pharmaceutical innovation, within easy reach of the airport and next to some significant pharma clusters including Northern Italy, Switzerland, and Southwest Germany. The Lyon region has a strong interest in the ease of transport between the various countries around it and the network of suppliers nearby which is great for customer experience and project delivery.

It is also a scientific hub that allows us to attract a lot of skilled talent.

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