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22.02.2019

Tags: France, CDMO, Skyepharma, Manufacturing

David Lescuyer, managing director of Skyepharma, a specialized CDMO, reflects on the past three years of the company as it transitioned from a drug delivery platform to a fully-fledged service provider leveraging agile solutions across the value chain. Lescuyer also shares his insights on the service sector and the most relevant trends impacting CDMO players.

Please begin by introducing yourself and Skyepharma.

Skyepharma is a member of the Vectura Group of companies, a British pharmaceutical company focused on drug delivery and formulation of inhalation devices. As part of Vectura, Skyepharma is the oral solutions business unit, specialized in complex solid dosage forms.

It is important to note that three years ago, Skyepharma embarked on a transformation journey from solely being a drug delivery platform to a fully integrated, expert and agile CDMO. We leverage a strong technological platform, professional expertise, and state of the art equipment to provide our clients with an end-to-end service offering. We have invested very much in machinery, but not only. We have also made evolutions on our organization and corporate culture and instilled lean management practices across the company. In Skyepharma, we have nurtured a strong culture based on respect, trust, performance, transparency, and team values not only internally but with our clients as well. The goal over these three years was about to establish an integrated

organization where discussion and exchange are encouraged in daily operations. Since then, we have increased our team size by 20 professionals, including three PhDs, two pharmacists and many engineers.

What have been the challenges of instilling this team culture and customer-centric approach?

The first step we had to take was clarifying our positioning internally and deliver the vision of transitioning into a CDMO to our team. Later on, we also had to convey our new capabilities to our existing clients and future prospects. These efforts were very successful, and we have quickly been able to build trustworthy partnerships and extensive collaborations with existing clients and many new clients as well. This has been reflected in the double-digit growth we reached for the past two years and we anticipate this trend to continue for 2019 as well.

Skyepharma has adopted a strong development offering to help our clients with activities such as formulation, lifecycle management, early-stage development, scale-up, commercial production, packaging and more services such as regulatory expertise, supply chain improvement projects… We are able to provide seamless and adapted solutions as our clients' projects grow and their needs evolve.

What are the production capabilities of Skyepharma?

Our site near Lyon is 65,000 sqm with an advanced 22,000 sqm manufacturing facility. Our high-tech equipment includes two integrated granulation lines of 600 litres and 1,200 litres, wet granulation and fluid bed drying, a micro fluidization line with high-pressure homogenizer equipment, and more. Our facility has eight compression suites able to manufacture single, 2-layer, 3-layer tablets, press-coated tablets, hard capsules…

Moreover, Skyepharma leverages three of our own patented technologies; Geomatrix®, Geoclock®, and Soctec® which deliver a strong differentiation compared to our competitors. These platforms allow us to build controlled release formulations to adapt to patient dosing schedules or adjust API intake. These technologies allow us to better manage side effects, something our clients highly value. As a part of the pharmaceutical supply chain, we focus on creating value for our clients to assist them in better meeting patients' needs.

What comparative advantage is Skyepharma able to leverage within the CDMO sector?

Although there are notable large players in the CDMO sector, we still see many small to mid-size CMOs/CROs growing and there is still room for expansion in this area. The CDMO space is very fragmented and it was imperative that Skyepharma continues to differentiate itself in order to stay ahead of the competition on the complex solid forms segment.

As I mentioned, the first capability Skyepharma has lies in our ability to produce complex oral solid forms ranging from capsules, granules, tablets, and more. Through our technological know-how, we can support our partners from the earliest stages of their development using innovative compression simulators and quality by design processes which we have developed in-house and used many times to support our partners. These competencies help us reduce time to market, which is what clients look for the most. One example would be the Skyepharma technology transfer process. This can be carried out in six months with API savings thanks to our innovative compression simulator and our efficient “quality by design” procedure, instead of ten months on average.

An equally important facet in our transformation has been the creation of a customer service department, focused on better anticipating our clients’ needs. Clients want to be heard, they want to be able to ask for advice, share ideas… and they are seeking a long-term partner to reflect with them on their projects. At Skyepharma, our vision and mission are: “solving healthcare industry complexity”. Our dedicated and result oriented team provides product development, manufacturing, and packaging services to the healthcare industry through state-of-the-art facilities, scientific expertise, and open transparent relationships.

How significant are the international activities of Skyepharma?

Skyepharma exports products around the world to markets such as US, Europe, Brazil, and Asia, including Korea, for example. At the moment, we have experienced an expansion of our partners’ network in Europe, as more companies are knocking on our door to establish long term and broader collaborations. Looking back at the Skyepharma legacy portfolio, we did not have any French clients up until two and a half years ago. Today, we have two clients in France and even more business leads in the country. In the last three years, we have primarily seen a rise in activity coming from France, Switzerland, Italy, Germany, and the US.

Excitedly, Skyepharma is seeing an increase in players from the US who are interested in our ability to develop complex dosage forms. As a matter of fact, approximately 40 percent of the products produced in our facility are exported to the US.

What trends do you see evolving within the CDMO sector?

We try to observe similarities between the pharmaceutical industry and the electronic and automotive industries. In these areas, there has been a divestment of activities outside of sales and marketing to contract service providers. A similar trend can be seen in the pharma sector, as Big Pharma is increasingly outsourcing activities such as research, development, manufacturing, and even regulatory. Having a focus on operational activities, CDMOs have the ability to leverage their processes and create greater efficiencies in this space. Therefore, we expect to see a further increase in the competition and capabilities of the CDMO sector as pharmaceutical players collaborate more and more with top service providers.

Another key development impacting the pharmaceutical and CDMO players is the implementation of new EU drug regulations, following the US ones. In accordance with the Falsified Medicines Directive, all drugs were to be serialized in the EU by February 9, 2019. This is still a very recent movement, but a crucial topic in the discussions of all pharmaceutical stakeholders.

What impact will serialization have on the industry and Skyepharma?

In the face of serialization, the CDMO space is confronted with both opportunity and challenge. There will be a natural selection of players, between those who are prepared to meet the regulatory requirements and those which are not. Keeping up with the constantly increasing regulatory requirements allow us to offer up-to-date services to our partners. We have had for instance pharmaceutical companies approach us as they were unable to serialize or aggregate their products with their previous CMO partner. For Skyepharma, serialization and aggregation are very favourable entry doors to expand our client network and create new business activities, such as supply chain improvement projects.

Our French site is FDA certified and has been since 1998. This is an important feature for Skyepharma, and we are prioritizing quality and regulatory evolution to ensure that we are able to meet modern demands. Serialization and aggregation are examples of key developments within the European context that Skyepharma anticipated ahead of time. Since our transformation period

began three years ago, we have invested in these areas and are pleased to say that we recently distributed our first package of medication that was fully serialized and aggregated for the US market.

How is Skyepharma taking advantage of the growing CDMO sector and reinforcing its position in the market?

The CDMO space is dynamic with a CAGR over the past four years of 4 to ten percent, depending on the galenic forms considered. The development of the sector is very positive for Skyepharma's growth pattern as we establish collaborations with new actors. We have begun to see a differentiation between CMOs that are not transforming into CDMOs, and CDMOs that are anticipating the next steps. At Skyepharma, we are trying to envision what will be the future business model of the sector.

As a drug delivery platform with tremendous development capabilities, we are focused on what additional value we can bring to our partnerships. We are also able to offer solutions for PK studies, lifecycle management strategy, regulatory strategy, and consulting for lean management practices. We have developed a site integration methodology that brings value to Skyepharma and its partners.

What makes France a competitive market to base Skyepharma's operations?

Seen from the outside, France is a challenging market. However, I have worked in many countries, including the US, and I can speak to the many competitive advantages that France offers. The workforce in the country is very well trained and there is a high level of expertise. Process development is remarkably efficient thanks to the free and quality education that is accessible in France. Furthermore, our team here is exceedingly dedicated and motivated and with the formation of a consistent company vision, we have been able to reduce our overall absenteeism ratio from ten to one percent in three years.

Geographically speaking, France, and especially Lyon, are ideally centralized locations. From the airport, our facilities are easily accessible which is a convince that is well appreciated by our clients. Lyon's proximity to the European Health Valley allows us to open ourselves to our partners and be actively transparent in our operations, another value Skyepharma holds highly.

Any final message on behalf of Skyepharma?

We are uniquely positioned as a developer and producer of complex solid dosage forms with a distinct drug delivery platform and an agile proficiency to work alongside our partners and solve healthcare complexity.

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