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The old business model of outsourcing to CMOs is changing and companies are moving more towards vertical integration, from development to production and even distribution

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Manuel Ramos Ortega, chairman of Labiana, a Spanish CDMO, highlights his strategy to create company stability and discusses the major trends in the manufacturing world of human medicines. Furthermore, he gives an overview of what differentiates Spain and Labiana in the competitive world of pharmaceutical production.

The company throughout its history has experienced ups and downs, though is now experiencing a good period. What has changed in recent times to turn the company around?

The original Labiana started in 1958 as an animal nutrition business, before transforming into an animal health company in the 1980s. This stayed constant until the late 90s, when we created the first vitamin injectables, while also having a focus on galenics.

The contract manufacturing arm of the company did not start until the 1990s when the large multinationals began diversifying their approach and selling their manufacturing facilities, which in turn established many Spanish CMOs. Labiana took advantage of this and has become the largest manufacturer in Spain, and one of the largest in Europe, for animal injectables. Furthermore, we invested a lot in R&D to develop our own products.

The old management at some point abandoned the human medicine R&D efforts, though we have started to recover this market and have invested a lot to do so. We now have our own API, using

Fosfomycin Trometamol, that falls under our brand Fosfomicina Labiana Pharma.

This year we made the decision to split our two sides of business: Labiana Life Sciences for animal health and Labiana Pharmaceuticals for human medicines. We see that animal health is shifting more towards the agri-model of business, not encompassing as many rigid rules as the pharmaceutical world.

What are the major trends you notice within the field of human medicine?

We are seeing that the old business model of outsourcing to CMOs is changing and companies are moving more towards vertical integration, from development to production and even distribution. This is due to the fact the margins at each level of the supply chain are becoming narrower and narrower, and it is hard to split the profit along each step.

The real question is, why are the profit margins so small? In human health, the biggest customer is the government. They have a position in which they must create a sustainable healthcare ecosystem, therefore, they are always looking at how to drive prices down, and because of their enormous market share, they have all the power in pricing negotiations. Having a vertically integrated approach allows a player to have control along each step and generate greater profit, and a reason many CMOs are turning to this business strategy.

I believe the market of CMOs is also experiencing a focus towards niche production as large companies look towards smaller batches. This will allow companies to develop their own dossier or products in parallel to CMO operations.

Where are your main clients coming from?

Our main customers come from large multinationals that are located outside of Spain. This depends generally on how negotiations are undertaken. If the company discusses the terms at a national level, it is quite simple. Though if we must go to HQ, the process is generally slower and quite complex.

We notice that competition of products into Europe is quite strong, with many low-cost countries becoming prominent players in the manufacturing world. Nevertheless,

historical nations, such as Switzerland and Italy, still are giants in this field. What is the differentiating factor Spain apart in the world of pharmaceutical production?

There is a big difference between manufacturing in Europe, within or outside of the EU. For companies inside the EU, such as Romania and Poland, they do offer competition to the Spanish manufacturers. Nevertheless, Spain has a longer history and more experience meeting the expectations of GMP and EMA regulations. Furthermore, if you look at the number of universities dedicated to pharmacy, Spain offers a high concentration; therefore, there are always a huge abundance of qualified and educated people.

Another contributing factor is the agencies that govern pharmaceuticals. Many countries promote local business to expand internationally while driving forward R&D projects. On this spectrum in Spain, I would say we sit around the middle, with the government more concentrated on companies meeting regulations, rather than facilitating large growth and R&D investments.

Finally, another advantage for Spain over its competition is the market itself. Other countries, like Malta or Slovakia, do not have a market size to justify such large production investments. Products made in Spain can stay here, rather than needing to be exported.

What about competition from outside Europe?

Markets, such as Brazil and Russia, are relatively closed markets, making it very challenging for foreign players to enter. On the other hand, the European ecosystem is quite open and really invites a competitive atmosphere. I believe that we should be more protective of our environment and make it more difficult for others to enter. Nevertheless, I do see the overall European mindset shifting to a stricter strategy when it comes to foreign entrants.

Though for some treatments I would be very cautious. For example, injectables coming from countries, such as India and China, I would not accept. Mainly because if there is a problem with these more complex medicines, you will then have to go to the source to resolve the issues. This will be a lot more complex than dealing with an EU nation. In this regard, again, governments are becoming stricter for more complex medicines.

Another factor which sets Spain apart if supply guarantees. For example, it is extremely challenging for a company from India to quickly meet the demands of customers. The issue is they are the ones offering the extremely low prices, yet they are unable to meet the real concern which is guaranteed drug supply. This is a problem that not only affects the suppliers but in the end the

patients.

What differentiates Labiana from the competition in the market?

We offer the highest level of flexibility to our customers. Customers are happy with this as if they require any changes during the production process, we are able to react quickly and efficiently. Furthermore, we have an incredibly short delivery time, especially in injectables, and are manufacturing many mid-size batches that other companies do not take on. Also, we are part of the development process of a product, acting more as a CDMO, rather than a CMO. This means we have a better knowledge of our customers medicines and can engage with them in ways to improve development and production processes.

Are their plans to increase capacity in the future?

The problem is there are many new regulations in the pharmaceutical market, and in recent times we have spent quite a lot to meet these standards that are due to be enforced in January. Nevertheless, we are looking to increase our injectables capacity and will be investing in solids manufacturing also by improving our production lines.

Where do you see the future of the company on the international market?

We have licensing in more than 40 countries for our products and we are now setting up a US partnership for our in-house medicines. Equally, we see a lot of potential in the middle east and Asia as in these regions the quality of product falling under EU and GMP is extremely well respected.

What do you see in the short to mid-term for Labiana?

We have made the decision to split the company into two parts for the long-term potential of Labiana. If we look towards private equity or public listing in the future, it will be easier if we have this split approach and can focus on each business individually.

In the animal business side, we have noticed many mergers and acquisitions on the top end of the market, leaving a large space for medium size players to exploit, and this is where we see

opportunities for Labiana. On the side of human medicines, we are looking for possible medium-size acquisitions, though we must be cautious as the pharmaceutical market shifts quite quickly, and this decision must be accurate to ensure the long-term success of Labiana.

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