Interview: Giulio Volpe â?? Managing Director, Lundbeck Pharmaceuticals Italy

17.12.2015

Tags:

Pharma, Pharmaceuticals, Italy, Lundbeck, API, Giulio Volpe, Production, Manufacturing, Regulatory Reform, Regulations, Interview, Insight

Giulio Volpe, Managing Director of Lundbeckâ??s Italian APIâ??s production plant, discusses what is leading multinational companies to relocate their production to Italy, the value the Italian plant can offer the Lundbeck group and the future of API production in Italy.

Could you start off with a brief overview of the history of this facility, and the manner in which your operations changed when Lundbeck acquired you?

The company was founded in 1928 as a small pharmaceutical company and in 1961 was moved to the industrial zone of Padova in the current location. In 1980 it was decided to reposition the company into a chemical-pharmaceutical company producing APIs. I came on board in 1985 with as mission to facilitate this shift. The manufacturing of APIs became our sole focus from then on, with exports mainly to the US and Europe.

In 2000 we were bought by Lundbeck, and the site began producing intermediates and APIs for the group. We also had R&D activity dedicated to the life-cycle management of Lundbeckâ??s products, developing second and third generation processes for existing Lundbeck APIs.

In 2004, in light of the decreasing needs of Lundbeck we obtained permission to re-enter the market with the ability to offer production, process research, quality-control, regulatory, and marketing services to third parties. Those were challenging years, as we had lost our previous clients and were

regaining their trust. That was also the time when China and India were rising in this field and were attracting a lot of business in API manufacturing, so it was not easy to develop a new business from scratch in that environment. Nevertheless, we were able to build up a product portfolio consisting today of 25 APIs and some intermediates.

Lundbeck has manufacturing facilities in Denmark, France, Italy and China. Where does Lundbeck Italy fit in this supply chain?

Our role is two-fold. Firstly, we have a long history in the development of various processes on an industrial scale and secondly we deal with the management of regulatory affairs. This is useful to the group because the experience gained in producing and registering many different products for different customers is also beneficial when producing for the mother company. LUPI has been challenged in all aspects of API production by being involved in the production of several different products for many different customers over the last decades. So what we can offer to Lundbeck is our significant experience in the multi-step production of a wide range of molecules. Besides this, our regulatory management capabilities are also useful for the filing of CMC sections in different countries, especially in the US, EU, Japan, Korea, and Australia. Finally, our analytical research capability during the process research phase which allows us to list potential impurities and detect the actual ones early in the development phase is an expertise which is highly valued. Regulators ask for a robust process for a product with a reproducible analytical profile, and this requires the skills and process consistency which we can offer.

When we spoke to Gianmario Baccalini, the President of Aschimfarma, he also identified a relentless commitment to quality as the distinguishing factor for API manufacturers in Italy, leading the country to export 90% of its API production. How are you exporting your products to countries outside of Europe?

The majority of our production goes to the US, the EU and Japan; however, we are also exporting to India and other developing countries. Many of the APIs we export to India in fact are also produced locally, but it is the â??Made in Italyâ?? brand and the associated high quality standards that nevertheless allows us to compete with those local Indian producers. Often we will see Indian companies importing the APIs from Europe, formulating the product locally and selling the finished product to the US market. This desire for a European source is a big shift which has only really gained momentum over the last few years, and it has assisted in the relocation of production contracts and even facilities to Europe.

Of course it does take time to select new partners, audits must be performed and trust needs to be built up, so we do not expect a massive relocation to happen overnight; however, there has definitely been a trend to move back to Europe, and it is gathering momentum. In that area, Italy has an advantage in its long tradition of pharmaceutical quality. AIFA has always been one of the strictest regulatory agencies in Europe, and as a result we have had many more requirements to assure product quality over the years compared to those imposed by other European agencies. Now this is starting to change, and regulations are becoming stricter in other countries as well. As a result, though it was perceived as a disadvantage to us for many years, this environment has meant that we are better able to adapt and perform under strict conditions. Today, I would say it has given us a competitive advantage over other countries, and it has made Italy one of the preferred destinations for companies relocating to Europe.

Have these exports led the â??Made in Italyâ?? brand to gain a wider recognition among international companies, especially in the US?

Yes, it is the reason that US companies are looking to us for their manufacturing. We have a long tradition in process innovation, not just in pharmaceuticals but in other sectors as well, allowing us to add value through processes innovation. Looking at multinationals, we see that they keep the basic innovation in-house, and when it is time for production they have usually outsourced this years ago. Today though they are looking to innovate in their production processes as well, and that is leading them to Italy.

Consistency is key here as well, if you can produce high quality products over a long period of time, you build up trust. This starts with contracts for smaller, low-potential products which are also â??used â?? to test you as a reliable producer. If you can demonstrate your consistent performance over the course of many years, you will eventually be given more important projects. However, if you fail once, you are out of the game, so a meticulous attention to detail is a pre-requisite for success.

How do you work to form partnerships and attract customers, especially US-based ones?

It is very important to have a high level of customized service for your customer. Each client will have very specific needs and priorities, and it is vital that you understand and support, and often anticipate those needs. This means tailoring your production, but also your services to each new potential partner, for example in terms of project management or, sometimes, for less complex, but certainly not less important, issues like those related to shipping, aiding in the quick navigation of customs regulations and helping with the registration at the local agency. Time is especially crucial for US customers, if they send a request or an update you need to respond quickly and accurately. Delayed or, even worse, inaccurate answers are not an option. Sometimes a partial response will work but only if it precipitates a more complex and thorough one. A poor response is perceived as not having the whole situation fully under control or, worse, having something to hide.

Lundbeck has a long tradition of working with local communities, and this facility is no exception. How do you maintain your relationship with the rest of Padova?

We invite educational institutions to tour the plant, this is especially interesting for the local university as we are in a university town with more than 60.000 university students. Chemical and bio-chemical students get invited, as well as primary school students in order to promote science among the younger generation. It is a way we can give something back to the local community . Usually chemical plants are located far from cities while we are much closer. We feel that we have a responsibility to the city, and to fulfill that we also organize open-door sessions for the local population in order to showcase the plant and demonstrate our safety and environmental protection measures.

Do you think there is a future for Italian API production, exporting the â??Made in Italyâ?? brand around the world?

Yes, I think so. In proportion to the rest of Europe, Italy has a much larger number of production sites dedicated to the manufacturing of APIs. This has historical origins due to the fact that until 1978 in Italy there was a prohibition of patenting medicines and the processes designed to produce them, boosting the establishing of a large number of APIs producer in the country. So while this harmed basic research, it did help our API production and process research in general. When patent-law was introduced, including for pharmaceuticals, in 1978 those companies had already set up operations here and while they reoriented themselves towards new markets they generally remained in the country. As a result, during the sixties and seventies we were the largest API producers in the world. This wide experience and excellence in process-development capabilities combined with a well rooted culture of quality has created a very positive environment for the production of APIs in the country, and that is why we see continued potential for our segment to prosper, especially with the

renewed global focus on quality.

Click here to read more articles and interviews from Italy, and to download the latest free pharma report on the country.

See more interviews