



Expanding Expertise in Highly Potent APIs

At its Spanish Sites Near Barcelona, Siegfried Specializes in the Production of Complex Drug Products Containing Highly Potent APIs. This Competence Will Now Be Strengthened by a New Development Center.

After acquiring the two Catalan sites in Barberà del Vallès and El Masnou about two years ago, Siegfried is now significantly expanding its expertise in the production of complex Drug Products containing Highly Potent APIs (HPAPIs). In addition, the company has opened a new development center for oral solid dosage forms with active ingredients and HPAPIs as well as for ophthalmic sterile products. This not only strengthens Siegfried's position in the area of drug products, but also its global network and international competitiveness.

Drug products with highly-Potent APIs are a special species: these highly potent APIs are small, delicate and highly toxic. Handling them therefore requires an extraordinary expertise as it can be found in Siegfried's site in Barberà del Vallès in the northeast of Spain.

Carolina Bonifacio is the Head of Research and Development (R&D) in Barberà del Vallès and its neighboring site El Masnou. As an expert of this matter, she knows the requirements and challenges of HPAPIs: "These substances not only require particularly sensitive handling in the manufacturing process; the employees who work with them also need

special skills, knowledge and protection to handle them", says Bonifacio. "Therefore, for HPAPIs, a thought-out risk and hazard assessment is needed." That is the reason why in Barberà del Vallès these products are manufactured in a separate area in isolated facilities, with the actual production process largely automated.

But even beyond that, HPAPI production requires special requirements and skills: Investment in production equipment is high, manufacturing times are usually significantly longer and energy costs are higher than for conventional APIs. In contrast, production volumes are usually comparatively low. In addition,

the transition times from one product or batch to the next are quite long, while cleaning and waste management are complex.

Siegfried brings its entire expertise in this area to the plant just under half an hour north of the port city of Barcelona. The company claims a successful track record of supplying complex Drug Products containing HPAPIs to Europe, US, Japan and many other countries. It has a team that brings decades of experience with these products. And it has a wide range of technologies - from dry & wet granulation process (including roller compaction) over blending, capsule filling, tableting, coating and blistering to bottling.

Due to the increasing importance of HPAPIs and its special expertise, Siegfried is focusing on further strengthening this area and gaining additional customers. Indeed, Highly Potent APIs are a rapidly growing segment of the global pharmaceutical industry. Some market estimates project that the global HPAPI market could reach 26 billion dollars by 2023 and close to 10% annual growth in this area. "Already today, more than 25% of all drugs in development fall

into the HPAPI category," says R&D Head Bonifacio. Thereby the HPAPI market covers a wide range of product types across several therapeutic areas although oncology-focused medicines continue to lead in terms of innovative pipeline candidates.

New Development Center

In addition to their HPAPI expertise, the northern Spanish sites gain further importance with the opening of a new global development center for drug products in spring 2023. From then on, highly qualified specialists will work there closely with Siegfried's customers in modern, purpose-built laboratories to transform their innovations into commercial products. For both sites, this is a qualitative step forward —from pure production of a limited number of drugs to development activities as well. In addition, employees are developing individual approaches to solving customers' problems.

Bonifacio points to the state-of-the-art laboratories that have been built on an area of around 1,500 square meters, and that even now, at the start of the new department, around 40 employees are working in product development. This involves, for example, determining how best to formulate an active ingredient so that it exerts its desired effect in the right part of the human body. The manager points out that in the development center they also carry out process development, provide drugs for clinical trials and develop analytical methods to be able to provide evidence for certain ingredients.

Furthermore, the tasks include pilot productions, but also enabling scale-up, i.e. the transition to the regular high-volume manufacturing process. In the end, says Bonifacio, the decisive factor is that the production process is robust.

Investment of €15 Million

Siegfried has invested €15 million in the new development center. Furthermore, development activities and equipment were moved from the



Aerial view of Siegfried's site in Barberà del Vallès, Spain

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Siegfried's new development center in Barcelona, Spain.

company headquarters in Zofingen to Barcelona. The new facilities will be Siegfried's global research and development hub for its drug product sites, in addition to the development center for Biologics Fill & Finish in Hameln.

For CEO Wolfgang Wienand, this is an investment into the future, which will help to expand the competencies of the CDMO (contract development and manufacturing organization) and its service depth, as well as to win new customers: "The Center of Excellence for Drug Products development services at our Barcelona sites shows our strong commitment to invest in technologies and to development capacities for our customers."

Takeover in 2021

In Barberà del Vallès the lettering of the former owner Novartis is still slightly visible under the Siegfried logo, but the fresh wind that has been blowing through the plant with its approximately 550 employees since the takeover in early 2021 is clearly noticeable.

While the site, where solid oral dosage forms are produced in large quantities, served mainly its own internal production under the previous owner, under Siegfried they not only get additional competencies with HPAPIs and the new development center, they are also gaining new customers, each of whom has their own product requirements. This not only significantly expands the site's portfolio, but also demands a high degree

of flexibility and expertise from the employees.

These skills they demonstrate, for example, in the inhalation products manufacturing area. Laura Moreno, Production Unit Head, is responsible for this area. She points to a high-precision capsule-filling machine that connects to a complex process control system. Every time the product is changed, the employees must completely disassemble the individual parts, clean them and then reassemble everything. Almost like completely disassembling and reassembling a car. "In the beginning, it took us a week," Moreno says. "Today, we do it in less than 72 hours."

El Masnou: High-tech Near the Beach

Switch to El Masnou, a short drive from Barberà del Vallès and slightly elevated near the Mediterranean Sea. In the site's modern functional buildings, the focus of the nearly 400 employees here is on the production, filling, and packaging of aseptic ophthalmic products such as eye drops and eye ointments.

Access to the GMP (Good Manufacturing Practice) production of liquids and ointments is possible only in compliance with strong hygienic regulations. Also the manufacturing itself takes place under strict orders of absolute cleanliness: Materials are sterilized in autoclaves, 1,100-liter reactors produce fully automatically, the filling machine presses a cataract remedy into small containers, and in the packaging line, three ro-

bots connected in series, each with several arms, grab small vials from the assembly line at high speed and

place them with equal speed and precision into passing sorting systems.

Ready to Master the HPAPI Challenges of the Future

As the HPAPI market is growing faster than the overall API market, for CDMOs a commitment to continuous investment in equipment and technologies is crucial to ensure that the most advanced manufacturing and safety systems are in place. Furthermore, a comprehensive HPAPI programme requires extensive planning, the use of risk management tools, and a corporate culture focused on quality and safety. Siegfried brings all this to Barberà del Vallès and El Masnou. With the new development center, the company is now further strengthening the capabilities of its global network in the Highly Potent API business.

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