Interview: Bernhard Wittmann – Managing Director, Sigmapharm and MoNo, Austria



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Bernhard Wittmann, managing director of Sigmapharm and MoNo, discusses the company's product portfolio and the diverse tailored services for their partners. Furthermore, he provides an in-depth look into MoNo's new 20 million EUR (24 million USD) CMO production plant that will be completed in 2019. The ten-fold increase in capacity will expand the company's capabilities as well as open up new opportunities for future endeavours and expansion.

As managing director, could you please introduce Sigmapharm and MoNo to our international readers?

Sigmapharm is a domestic player that was founded in Vienna in 1949 by Prof. Dr. Pichler and Dr. Punzengruber. At that time company was focused on the production of own products, including chemical synthesis for active pharmaceutical ingredients (API's), as there was a shortage due to the circumstances of World War II. Initially present solely in the Austrian Rx market, our company has diversified over the decades and now our products, both Rx and OTC, are sold internationally. At the beginning of the century there was a push to commence contract manufacturing operations (CMO) and in 2000 the manufacturing department was spun-off into the independent company MoNo. This has opened up the possibilities to perform CMO for partners outside and in Austria as well as for Sigmapharm products.

Our core competence are products for Ear-Nose-Throat applications (ENT). MoNo manufactures non-sterile liquid products such as high viscosity, watery and oily solutions. Furthermore, we undertake aseptic production of sterile liquid products, without parenteral administration, such as eye drops and non-preservative containing throat and nasal treatments.

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Do you also develop your own products?

Most of the products that we distribute are developed in-house. Based on decades of experience in aseptic processing and product manufacturing Sigmapharm and MoNo are offering services in development, production, CMO, regulatory activities, pharmacovigilance, wholesaling operations and sales as a comprehensive service package; all from a single source.

We keep up to with changing regulations in each key area of healthcare and we are active in the relevant Austrian association; the Association of the Austrian Pharmaceutical Industry (PHARMIG), the Austrian Self Care Association (IGEPHA) and the Interest Representation of the Medical Device companies (Austromed) but as well as international associations, namely DIA and ISPE.

Sigmapharm has a long history in distribution. How would you describe the current distribution landscape in Austria?

There are many distribution companies in Austria although the backbone of the sector is represented by five key players. In Austria, wholesaling is not specifically just distribution of the full range of pharmaceutical products, but also presenting a specific product portfolio in pharmacies and hospitals. Our business model is very effective as we not only sell our own products, but are equally partners, allowing us to gain a stronger foothold in the market. This is especially important as the education of pharmacists and consumers is important for our OTC treatments.

Sigmapharm’s own products and the treatments manufactured by Mono as CMO, are found in over 50 countries. We have partners in key markets, such as Germany and Switzerland, as well as in smaller healthcare nations, for example Latvia and Croatia. As a small company, we are proud of our large scope, the quality of our services and our well-established position in the market.

What are the competitive advantages of Sigmapharm?

Sigmapharm and MoNo can offer a one-stop-shop package in the fields of Rx, OTC and medical devices, covering everything from pharmacovigilance, pre-wholesaling, analytics or regulatory affairs in addition to manufacturing, storage and logistics. Short communication lines enable highly

customized solutions and effective risk-based quality management that supports all processes.

What services will be developed in the future?

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Times are moving within the Austrian healthcare landscape and we are facing some major changes regarding our business structure. Changes in the European Medical Device Regulation and the new EU-Anti Counterfeiting Directive forces investments to keep up with international industry standards.

The company is investing about 20 million EUR (24 million USD) in a new production plant in the south of Vienna (Burgenland, Austria). This plant shows our intention to meet the challenge of the future and to stay a strong partner in CMO in our key areas.

What capabilities does this new state-of-the-art plant open up?

When the plant opens in 2019, it will offer a tenfold increase of our CMO capacity and we will expand our product portfolio for nasal and throat sprays, eyedrops and non-injectable vial products. The manufacturing area is equipped for production of glass and plastic containers. For eye-drops classic dropper systems will be available as well as new dispensers for non-preserved solutions. In addition to manufacturing and filling of batch sizes between 30L and 1000L, a GMP compliant filling area for small batches such as pilot batches, stability batches and clinical trial medication will be available.

The plant will enable flexible state-of-the-art manufacturing focused on small production amounts in our niche capabilities. This year in June we presented our new plant to our partners and customers and the interest has been encouraging. It will be a pleasure for us to bring our partners new projects to life at our new production site.

What determines success in your eyes for the new plant?

As an independent organisation, our future is not only determined by profit maximisation but by long term business-relations based on high reliable quality and satisfaction of our partners and customers. Commercial success is of course necessary and will enable a stable growth of Sigmapharm and Mono. The new site will offer enough space to expand and to increase our capacity.

The local stakeholders and community have welcomed us and they have assisted us along each step of the journey. We are now one of a handful of companies with a manufacturing plant there,

collectively forming our own production cluster.

The company has undergone lots of changes over the last decade. What lies ahead for Sigmapharm and MoNo?

MoNo will be offering an increased volume of services and higher production capacity with the opening the new plant. Sigmapharm will expand its portfolio through product development and constantly search for business partners, both domestically and internationally.

Constant development is an important motivation for myself and my team and has pushed me every day since I started here 15 years ago. Sigmapharm and MoNo will be part of the Austrian healthcare landscape in long-term. We must now ensure that our operations keep up with the ever-changing regulations in the pharmaceutical industry. Furthermore, we must make sure that the healthcare market is aware of Sigmapharm and MoNo as a competent and comprehensive service provider for medicinal products and medical devices as well as related services.

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