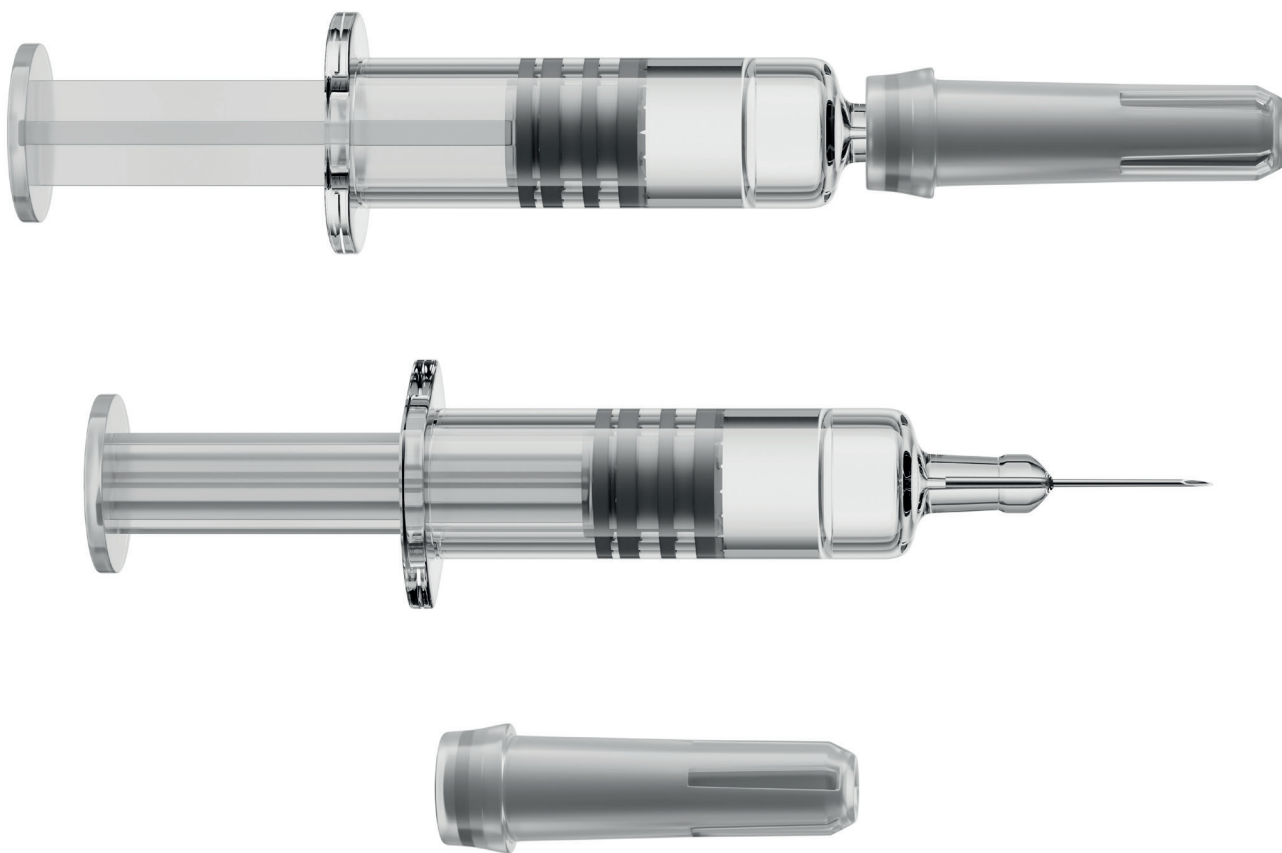


PREFILLED SYRINGES & INJECTION DEVICES



Aptar 
pharma

INTERVIEW

In this exclusive interview, Gabriel Zenker talks with ONdrugDelivery about Aptar Pharma's ambitions for the parenterals sector. Mr Zenker explains how Aptar, already a major player in the pulmonary, nasal and dermal markets, is undertaking a major expansion of its facilities, boosting the company's capacity, capabilities and technologies, to provide its extensive service and product offering to the exciting and growing injectables space.



GABRIEL ZENKER,
APTAR PHARMA

Gabriel Zenker is President of Aptar Pharma's Injectables Division. Mr Zenker has been in the pharma and injectables space since 2005, having served as EMEA Sales and Marketing Director at BD Pharmaceutical Systems and Vice-President Sales at Stevanato Group prior to joining Aptar Pharma.

Q The majority of ONdrugDelivery's readers are no doubt very familiar with Aptar Pharma, but for those who might not be, please could you provide a brief overview of the company – first in general terms and then going on to focus on the company's offering in the area of injectables and how it fits into the broader Aptar Pharma segment?

A To begin with, Aptar Pharma is a global leader in devices. We already have a strong presence in the inhalable, nasal, ophthalmic and dermal sectors, and we are currently undertaking a major expansion and transformation of our injectables division. Aptar Pharma is a company with a strong focus on data and services, with some of its prior and recent acquisitions

providing a strong demonstration of that focus, including working to provide more scientific and patient data in conjunction with our device capability. Building on that, the latest part of our expansion has been in the area of digital health, such as our recent acquisition of Voluntis, which adds digital to our device and data capabilities. We believe that there are clear points of intersection between the device and physical components on the one hand, and services and the digital aspects on the other. These are opportune sweet spots where Aptar can make a difference in the market and provide end-to-end solutions.

The injectables space has been a key area of investment for Aptar over the past few years. We've invested approximately US\$180 million (£151 million) into our

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operations, resulting in a significant expansion of an existing plant in Granville (France) and leading towards building an additional plant next to the existing one (Figure 1), to further increase our elastomer component production capacity with a special focus on our film-coated PremiumCoat® solutions. This investment is also aimed at expanding Aptar Pharma's injectables operation in North America. Our facility in Congers (NY, US) will be a part of that, and we'll be developing our PremiumCoat® production capabilities and capacity to better serve the market locally.

Furthermore, this transformation of Aptar Pharma's injectables operations have gone beyond just increasing capacity, with investment in new technologies, sustainability and our people. We're very committed to healthcare, very committed to pharma and our ambition is to shape the future of injectables together with our customers.

Q Looking towards the coming months and years, what are the major trends, significant innovations and key drivers for growth likely to be in the parenteral delivery space?

A First of all, I think there's been a very strong impact from covid-19. Looking at the situation now, I believe that covid-19 is becoming endemic and that there's a continuing market need and growth related to it. Beyond covid-19, some of the more high-value vaccines and treatments will require very specific solutions from the parenteral packaging sector to ensure that these sensitive doses are protected, remain efficient and are safe for patients.

I think the world overall was really impressed by how quickly the pharma industry was able to develop successful vaccines and manage the pandemic.



Figure 1: Aptar Pharma's new Granville production facility.

Furthermore, I think that investment in new drug technologies will continue and that we're going to see it with both large pharma companies and newer, smaller biotech start-ups. We are likely to see technologies such as mRNA (messenger RNA) picking up more traction and looking to address a wider range of diseases.

We're definitely seeing growth as we move past the pandemic, and we need to be ready. There are some definite learnings post-covid-19, a key one being security of supply. We've learned that having just one supplier can be risky and that having surge capacity available can prove critical for pandemic response.

However, capacity is not the only lever available – manufacturers must also consider more innovative manufacturing and supply models to be able to adapt and respond to emergency situations more quickly. This, of course, is coupled with the need to have the right technologies to deliver new and existing drugs in a safe and appropriate way. Though new trends are taking shape, we cannot know what the next healthcare challenge will be and we must be ready for the unexpected.

We must be proactive, we must be more open and we must make sure we have the right technologies ready to be delivered. We have to make sure we have the right supply chain and the right supplier base to really play our role, no matter what comes next.

Q What is Aptar Pharma's vision for itself within the injectables market?

A We've been investing in our capacity and capabilities, bringing in new manufacturing technologies that can raise the bar from a quality perspective. In parallel, we have been investing in the organisational, technical and commercial capabilities we need to be able to deploy this. It's our goal to be a first-choice

"It's our goal to be a first-choice solution provider for pharma, with our solutions able to deliver performances in line with, or even superior to, the gold standards currently on the market."



Figure 2: The expansion of Aptar Pharma's manufacturing capabilities will provide increased production of its PremiumCoat® product line and support the development of the North American market.

solution provider for pharma, with our solutions able to deliver performances in line with, or even superior to, the gold standards currently on the market. We believe that we can be a trusted partner to lead our partners towards success. It's in our DNA to try harder – to make each of our relationships with our customers a commercial success.

Our size and organisation is instrumental to providing the flexibility and proximity our customers need. This remains at the centre of our expansion programme with additional capacity and capabilities being built outside of Europe and closer to our customers.

Q Can you provide more details on what this expansion would involve and how these elements will strengthen the company's position in each area of its injectables offering?

A Our transformation started in France, with the upgrading of our two facilities in Normandy – Brécey and Granville. As part of our \$180 million expansion plan, we have built an extension to our original factory, adding 30% to its capacity, which has been operational since 2021. We are also building a new factory right next to the historical plant.

A key focus of the expansion is to increase our rubber mixing capacity, while also implementing state-of-the-art manufacturing lines. This benefits our PremiumFill® and PremiumCoat® product lines and enables the deployment of surge capacity for all our components if needed.

We're also expanding in North America, with the implementation of moulding and trimming capabilities in our Congers facility, adding to the overall capacity for serving the American market. This puts us in a very strong position from a capacity perspective.

In addition to the trust of our customers, our expansion plan has been recognised by the French government and, as part of its Program of Investments for the Future, we received partial funding of €13 million for the building and expansion of our European facilities. This is further evidence that Aptar is a company worth investing in for shaping the future of injectables and to serve the healthcare industry.

Q So would you say that this expansion isn't just about volume, but also about upgrading Aptar's capabilities and technology?

A I agree, that's an important point to make – it's not just about volume. The digitalisation of our processes is a key pillar of our expansion that is essential for increasing the reliability and control of our processes.

In parallel to digitalisation, we are also implementing state-of-the-art robotisation as a way to increase the reproducibility of our processes while minimising the risk of contamination. With the same objective, we are increasing our cleanroom footprint to ensure that our operations meet the strictest cleanliness requirements.

We have taken the opportunity to upgrade our processes and technologies to

ensure that we meet the quality requirements of our customers. As a major player for injectable delivery, our operations must be aligned with the expectations of the market and we must anticipate the ever-increasing stringency of regulatory authorities.

Our expertise does not stop with rubber and closure component manufacturing for injectables. As part of improving the journey for our customers, we have service capabilities to support the drug development journey for our customers by providing additional data for derisking the choice of closure component and performing the analysis required for the regulatory validation of drug products.

Our history and proven track record ideally position us for offering this type of service, which may be essential for customers who do not necessarily have the resources and expertise they need available in-house. Our aim is to offer a complete value proposition and make our customers' drug development journeys with us as smooth, reliable and easy as possible.

Q Could you outline how the expansion of Aptar Pharma's injectables division fits within AptarGroup's broader position with respect to environmental sustainability?

A All of our Aptar Pharma sites are certified landfill-free, with our French and US sites using electricity produced from 100% renewable sources. Our new site in Granville includes improved water and waste management, as well as

"Our aim is to offer a complete value proposition and make our customers' drug development journeys with us as smooth, reliable and easy as possible."

solar energy-generation for optimised energy efficiency. The new factory has obtained the Silver LEED Certification for sustainable manufacturing, and Aptar Group as a whole has received several accolades for its sustainability achievements. Our goal, all the way up to the corporate level, is to operate with care for the environment.

Q To wrap up, do you have any final thoughts on the topics we've discussed?

A To conclude, our objective is to transform the expectations of what an injectable partner can be, working very closely with our customers with agility and responsiveness. The core message I want to get across is that we try harder, and we will continue to try harder to make our customers' projects successful.

ABOUT THE COMPANY

For pharma customers worldwide, Aptar Pharma is the go-to drug delivery expert, from formulation to patient, providing innovative drug delivery systems, components and active material solutions across the widest range of delivery

routes, including nasal, pulmonary, ophthalmic, dermal and injectables. Aptar Pharma Services provides early-stage to commercialisation support to accelerate and de-risk the development journey. With a strong focus on innovation, Aptar Digital Health is leading the way in developing digital health solutions to help improve the patient treatment experience. With a global manufacturing footprint of 14 manufacturing sites, Aptar Pharma provides security of supply and local support to customers. Aptar Pharma is part of AptarGroup, Inc.

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We're increasing our capacity and capabilities in a big way



...to help you deliver billions of essential doses.

Big health challenges require transformative thinking. At Aptar Pharma, we're transforming expectations of what an injectables partner can be.

Our expansion program of close to \$180 million USD is already derisking drug development pipelines, and enhancing quality and service. We're deploying advanced robotics and digital systems, adding more clean rooms, and expanding our global manufacturing footprint to deliver billions of additional injectable components each year.

With our increased capacity and agility, together we can meet the world's biggest health challenges, today and tomorrow. Join us.



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