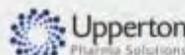
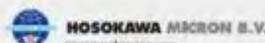
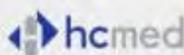


PULMONARY & NASAL DELIVERY



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THE UNTOLD STORY OF NEMERA'S INHALATION FRANCHISE

In this article, Raphaële Audibert, Global Category Manager, Inhalation & Dermal, and Niyati Sapatnekar, Global Communications Manager, both of Nemera, tell the story of the company's journey from contract manufacturer to end-to-end inhalation partner.

Based on an article that originally appeared on the Nemera website in October 2020.

Imagine the sheer joy and excitement of a child running towards an ice cream truck on a hot sunny day or an athlete as he crosses the finish line to win a sprint. Sounds terrific, right? But did you know that around 800 million people¹ around the world might not feel this joy because they suffer from respiratory disorders – notably, asthma and chronic obstructive pulmonary disease (COPD).

In simple terms, asthma is a medical condition that makes breathing difficult by causing the air passages to become narrow or blocked, especially during an asthma exacerbation. This, in turn, leads to wheezing, coughing, shortness of breath and chest tightness. Asthma is thought to be caused by a combination of genetic and environmental factors. For example, based on what we know about covid-19, people suffering from asthma might be more susceptible to severe illness. Under such circumstances, care and treatment options for these patient populations become all the more urgent. Unlike many other medical conditions, there is no cure for asthma. On the brighter side, medications help prevent exacerbation and attenuate the symptoms.

COPD is another debilitating disease characterised by long-term breathing problems and poor airflow. The most common cause of COPD is tobacco smoking. Diagnosing

COPD is a challenge as most people do not realise they have it and do not reveal their symptoms to their doctors. The breathing problems tend to worsen over time and can limit an individual's day-to-day activities.

UNMET MEDICAL NEEDS

Although asthma and COPD are long-term conditions with no permanent cure, the symptoms can be controlled with the right treatment. The oldest and simplest way to treat lung diseases is with inhalation therapy. This is proven by the fact that more than one billion inhalers² are sold globally every year. Moreover, these pulmonary conditions are expected to rise with the increasing elderly population, air pollution, climate change and evolving lifestyles.

There are still several unmet medical needs in this space and poor adherence remains a big challenge. Adherence in real-life studies varies from 8% to 73%.³ This challenge stems mainly from improper use of inhalation devices, as well as lack of learning and training for those who handle these devices. A potential way forward could be the involvement of digital in the treatment journey of these patients – a connected device that reminds them to take their medication, for example, or warns them of an increase in pollution levels to ensure they are well equipped with their treatment.

THE JOURNEY FROM CONTRACT MANUFACTURING TO AN END-TO-END PARTNER

Thanks to its robust manufacturing capabilities, coupled with outstanding



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"Nemera has been instrumental in the inhalation space for more than 20 years."

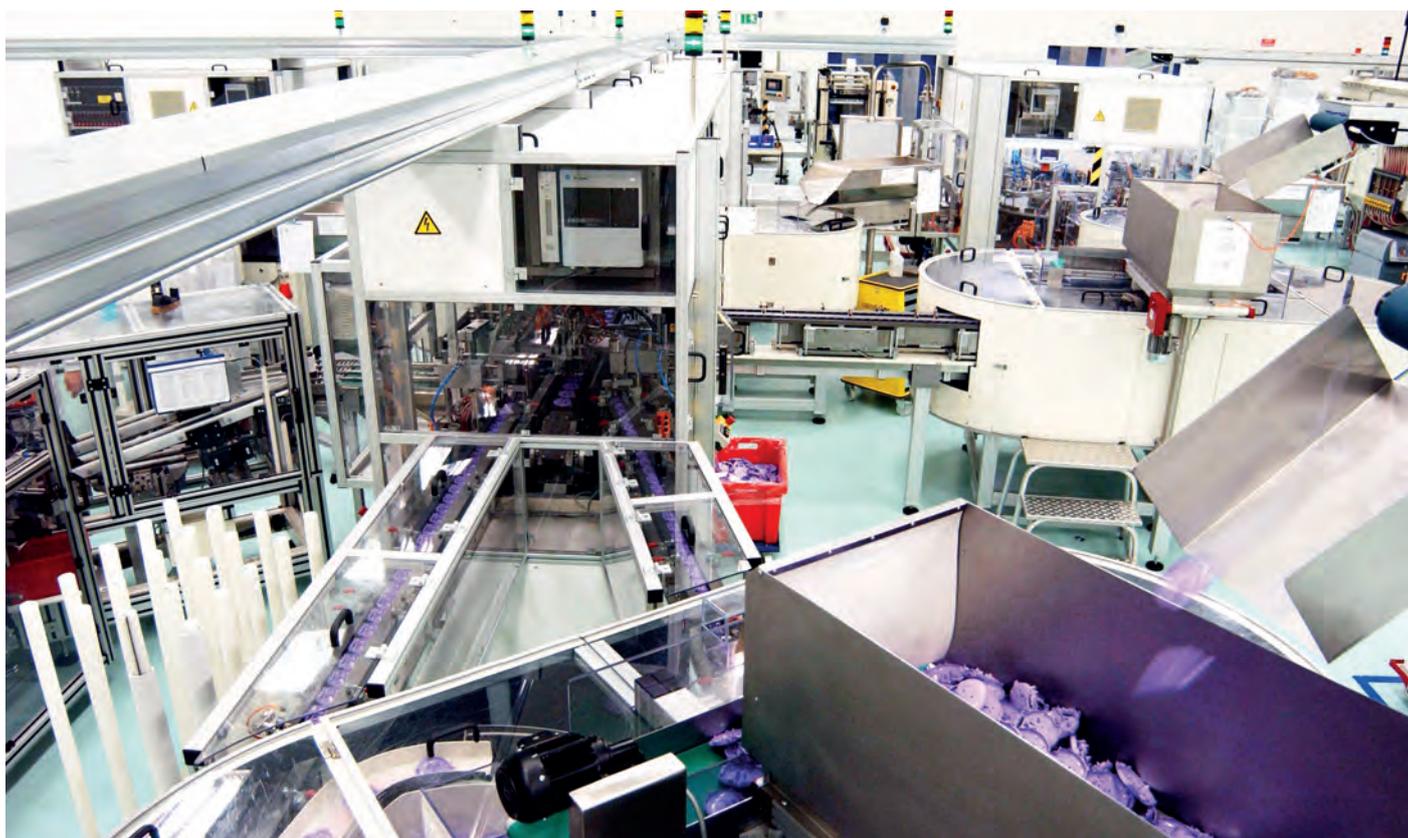


Figure 1: A Nemera production line.

“Nemera has significantly developed its injection, moulding and assembly capabilities over the last few years to improve speed and on-line control. It has added electronic devices to its portfolio and shares best practices within its different franchises.”

quality, Nemera has manufactured over a billion inhalers to date. Approximately 20 million patients rely on inhalers manufactured by the company every day. Historically known for contract manufacturing – which essentially means industrialisation of an already developed device – Nemera is now recognised as a holistic partner for inhalers. Nemera’s journey from a contract manufacturer to an end-to-end partner in inhalation is worth exploring.

Nemera set foot in the inhalation space with Diskus for GlaxoSmithKline in 1998. Today, the form and purple colour of Diskus, among others in the range, are a reference and a mark of trust across the world. This first success then snowballed into other collaborations with blockbusters in the pharma industry and generic players that specialise in inhalation (Figure 1).

More than 1,500 people are dedicated to industrialisation and manufacturing at Nemera to make sure the company responds to small- and large-scale manufacturing needs of customers with precision. Thanks to its robust manufacturing capabilities, coupled with outstanding quality, it has manufactured over a billion inhalers to date. Approximately 20 million patients rely on inhalers manufactured by Nemera every day.⁴ Numbers say a lot but they don’t tell the whole story.

Nemera’s people are driven by the aim of putting patients first. The end user of its products is a person who has trouble breathing or undertaking simple daily chores. The fact that its devices help these people motivates employees to learn and improve constantly. Nemera has significantly developed its injection, moulding and assembly capabilities over the last few years to improve speed and on-line control.

It has added electronic devices to its portfolio and shares best practices within its different franchises. For example, it is exploring how human factor studies and user-design experiences in its parenteral franchise can be applied within its inhalation franchise.

Nemera’s early contract manufacturing included primarily dry powder inhalers (DPIs). DPIs can be preloaded with the medication(s) or a patient can load them with capsules as the dose-holding system, prior to use. A single dose of the medication is loaded and ready to be inhaled, for example, by sliding a lever, twisting a part of the device or, in the case of capsule devices, pressing buttons to pierce the capsule. Patients simply take a deep breath while their lips are sealed around the mouthpiece of the inhaler, and the dose is delivered.

Then came actuator and dose counters for pressurised metered dose inhalers (pMDIs). These devices consist of an aluminium canister of medication covered by a valve fitted into a plastic body with a mouthpiece (the actuator). Each dose is delivered by pressing the canister into the actuator while inhaling through the mouthpiece. Sometimes, a dose counter can be added or integrated into the system.

Inhalation devices are often complex because the inspiratory flow is linked to device resistance. In DPIs, for example,



Figure 2: Cloud solutions can help with data analysis to improve patient outcomes.

“Nemera is part of the Cupido project, which aims to tackle cardiovascular disease by developing inhalable nanoparticles that can deliver a therapy directly to the diseased heart.”

a patient’s breathing capacity is critical in generating the desired therapeutic outcome as the dispersed powder needs to be broken into particles of the right size and be deposited appropriately into the lungs.

The best way of addressing these complexities is through early-stage research. Nemera’s innovation team works extensively on understanding the needs of patients and doctors – and fulfilling pharmaceutical requirements – so that the design it develops aims to resolve their issues. This also includes anticipating the needs of the future. Thus, from early-stage concept development to manufacturing, Nemera is a holistic partner in inhalation.

INHALERS OF TOMORROW

Nemera’s inhalation franchise stands on a solid foundation. It learns from the past, acts in the present and builds for the future. The company’s ambition is to participate more and more in discussions around the inhalers of tomorrow: striving to ensure that its research takes into account sustainability and environment-related factors, evolving patient needs, increasing preference for digital and more. Nemera embeds digital organically. It has developed electronic devices that are tailored to enhance the patient experience to facilitate treatment

adherence. These smart devices are capable of monitoring drug dosages for patient safety. In addition, Nemera proposes cloud solutions to illustrate how the data generated can be analysed for the best outcomes. This will help extend its digital offering in inhalation (Figure 2).

Nemera is part of the Cupido project, which aims to tackle cardiovascular disease by developing inhalable nanoparticles that can deliver a therapy directly to the diseased heart. The EU-based consortium – composed of six academic research groups, five SMEs, two industries and one pharmaceutical company – gathers a vast array of expertise and joins cutting-edge research with preclinical experience and industrial manufacturing. Nemera’s role in the consortium is to develop the inhaler that administers the nanoparticles to the diseased heart.

What we do today has a long-lasting impact on our future. And the future is full of unexplored opportunities and hope.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacturing of drug delivery devices for the pharmaceutical, biotechnology and generics industries. It offers a comprehensive portfolio of products

and services across ophthalmology, nasal, inhalation, dermal, transdermal and parenteral delivery. Nemera’s vision is to be the most patient-centric drug delivery device company. The company always puts patients first, providing high-quality solutions that have a demonstrable impact on patients’ health. Nemera’s Insight Innovation Center, with offices in North America and Europe, provides consultative services to support clients’ overall device strategies. Providing user research, human factors, user experience design, and design for manufacturing, the Insight Innovation Center helps customers navigate their device strategy for both novel and platform solutions. Users are at the centre of everything Nemera does in its efforts to always put patients first.

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ABOUT THE AUTHORS

Raphaële Audibert holds a biomedical engineering degree from ISIFC (Besançon, France). She has worked in the medical device industry as a project manager for five years, where she led the development of a surgical instrument set for neurosurgery. Ms Audibert joined Nemera in 2016 as Category Manager for Inhalation & Dermal. Since then, she has helped identify the needs of tomorrow and in building the franchise strategies.

Niyati Sapatnekar holds two Masters degrees, including communications, from Sciences Po (Rennes, France). She believes that focusing on healthcare communications is the best way to nurture her passion for language, science and people. At Nemera, her goal is to support the vision, mission and ambition of the company through engaging and impactful communications.