

Nemera

COMPLEX DEVICES, SIMPLE PATIENT CARE

Adrien Tisserand, Global Category Manager – Parenteral, Nemera, explains how the recent granting of German Pharmaceutical Drug Manufacturing Authorisation for Nemera's facility in Neuenburg enhances the company's offering to industry, before going on to discuss the Safelia® auto-injector and Safe'n'Sound® safety device platforms.

GROWING INDUSTRIALISATION CAPABILITIES

Nemera is known for collaborating with its customers in the development and manufacture of multiple market reference devices for parenteral usage. The company engages at all stages of the design process, from concept generation to large-scale manufacturing. Its service offering includes:

- First class, clean-room manufacturing
- Cutting-edge development processes
- Industry-leading injection and assembly capabilities
- Expertise in programme management for project success
- A scalable approach for reduced lead-time and costs.

DRUG HANDLING VIA AN INNOVATIVE SUPPLY CHAIN

To provide flexibility and convenience to its customers, Nemera has integrated pharmaceutical drug handling capabilities,

“The certification under the German Medicinal Products Act approves the manufacturing plant for handling, assembling, sterilising and storing pharmaceutical drugs and medicinal products for auto-injectors.”

providing the company with the ability to assemble a prefilled primary container together with a combination device.

Specifically, in September 2017, Nemera's manufacturing facility in Neuenburg, Germany (Figure 1) received Pharmaceutical Drug Manufacturing Authorisation. This certification under the German Medicinal Products Act (Arzneimittelgesetz, AMG) approves the manufacturing plant for handling, assembling, sterilising and storing pharmaceutical drugs and medicinal products for auto-injectors.

The authorisation is an important achievement for Nemera, reflecting the company's commitment to quality in developing and manufacturing drug delivery devices. It confirms that Nemera meets the highest standards, ensuring quality manufacturing and testing of therapeutics. It is a crucial regulatory step and allows Nemera to provide its customers with a complete set of services, including additional support for the development and manufacturing of pharmaceutical combination products and drug delivery devices.

“Achieving this pharmaceutical drug manufacturing approval highlights our commitment to ensuring the safety of our drug delivery devices for the benefit of patients. It also represents confirmation that our quality systems and processes consistently meet regulatory requirements and patient expectations,” commented Christian Meusinger, Nemera's Vice-President of Quality.

The Neuenburg plant has been manufacturing high quality products since 1953. Covering more than 20,000 m²,



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Figure 1: In September Nemera's Neuenburg facility received German Pharmaceutical Drug Manufacturing Authorisation.

the plant features Class 8 clean-rooms and employs more than 400 members of staff to guarantee production 24 hours a day, seven days a week. The plant produces billions of injection moulded parts and assembled devices every year. Recent key quality management achievements include:

- Short reaction times
- Detailed and comprehensive root cause analysis
- Reduction of scrap rates
- Elimination of inefficiencies.

LEADING EXPERTISE IN DEVELOPING & MANUFACTURING PARENTERAL DEVICES

Being granted the German Pharmaceutical Drug Manufacturing Authorisation has strengthened Nemera's offering to its customers considerably. The platforms Nemera will now be able to handle, assemble, sterilise and store pharmaceutical drugs for include Safe'n'Sound®, a customisable passive safety device for prefilled syringes, and Safelia®, an innovative two-step auto-injector platform.

Safe'n'Sound®

Safe'n'Sound® is a single-use safety device to protect patients and healthcare professionals from accidental needlestick injuries. It is activated passively with one hand, suitable for low fill-volumes and higher viscosity formulations, robust against shocks and vibrations and compatible with all scales of assembly line, from manual to fully automated.

It is also compatible with both prefilled

ISO standard glass syringes and PLA/JEX plastic syringes, fitting 1 mL "long" and 2.25 mL long staked syringes with a maximum needle length of half an inch (12.7 mm).

Ergonomically designed, Safe'n'Sound® is intended for naive users, experienced users and healthcare professionals alike. It features a large thumb pad for ease of use, clear visibility of the tip for easy inspection of the drug and a rounded shape for increased labelling surface.

Safe'n'Sound® is a highly customisable platform (Figure 2), able to respond to pharma and user needs. There are, for example, the options of an extended finger flange, coloured plunger rod, a "soft touch" thumb pad and a one-handed, subcutaneous rigid needle shield (RNS) removal feature.



Figure 2: The highly customisable Safe'n'Sound® single-use safety device.

Safelia®

Nemera's new generation two-step auto-injector, Safelia® (Figure 3), has been designed to improve the patient self-injection experience and to deliver a variety of drug products in glass syringes. These range from more fluid formulations to the most challenging drugs, such as viscous, sustained-release, concentrated formulations and products for subcutaneous and intramuscular injection (including larger volumes). To be competitive, new generation auto-injectors have to be able to deliver highly viscous formulations, in larger volumes.

The Safelia® auto-injector:

- Administers a large range of formulations and injection volumes; by design the platform can adapt to handle both fluid and highly viscous formulations, taking care specifically of biologics, sustained-release formulations and shear-sensitive molecules, of up to 2.25 mL injection volumes
- Improves the patient experience, with the possibility to reduce needle gauge, reduce injection time and slow down the needle penetration inside body tissues (giving the possibility of a delayed retraction for viscous injections especially).

The injection speed profile of Safelia® can be tailored to minimise injection forces. This injection force control should prevent the initial injection peak force, and allow a better drug absorption, and could also lead to a lower pain perception.



Figure 3: 1 mL and 2.25 mL versions of the Safelia® auto-injector.

CONCLUSIONS

Parenteral drug administration exposes patients and healthcare professionals to

many hazards. To ensure adherence and users' safety, reliable and easy-to-use devices are needed.

With decades of experience in developing and manufacturing some of the most complex and innovative parenteral drug delivery solutions, Nemera is the ideal partner for a successful product launch.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacture of drug delivery devices for the pharmaceutical, biotechnology & generics industries.

Nemera's services and products cover several key delivery routes:

- Parenteral (auto-injectors, pens, safety devices & implanters)
- Ophthalmic (multi-dose, preservative-free eyedroppers)
- Nasal, buccal, auricular (pumps, valves and actuators for sprays)
- Inhalation (pMDIs, DPIs)
- Dermal and transdermal (airless & atmospheric dispensers).

Within the injectables field specifically, Nemera's experience in drug delivery devices include:

- Insulin Pens (more than one billion insulin delivered to the market)
- Auto-injectors for pharma and military usage
- Customised plastic syringes for human and animal usage
- Safety devices for prefilled syringes
- Implanters (devices for delivering sustained-release formulations).

Nemera always puts patients first, providing the most comprehensive range of devices in the industry, including innovative off-the-shelf systems, customised design development, and contract manufacturing.

ABOUT THE AUTHORS

Adrien Tisserand is Category Manager at Nemera in charge of the parenteral range of proprietary products including Safe'n'Sound®, the passive safety device platform for prefilled syringes. Adrien joined the company in 2013. He previously worked for Janssen: Pharmaceutical Companies of Johnson & Johnson in the strategic marketing division. He holds three diplomas: a Bachelors in International Business from HUBS (Hull UK), a Masters in Marketing from Universidad Rey Juan Carlos (Madrid, Spain) and a Masters from Kedge Business School, France.



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parenteral



pulmonary



ophthalmic



dermal/
transdermal



nasal/
buccal/
auricular

INNOVATIONS FOR INJECTION DEVICES



Nemera provides solutions for the pharmaceutical industry, including standard innovative products, development of custom devices and contract manufacturing.