

COMPANY PROFILE: NEMERA (INJECTABLES OFFERING)

Nemera



Figure 1: The Safe'n'Sound® platform for 1 mL and 2.25 mL syringes.

Parenteral administration of a drug exposes users (patients and healthcare professionals) to numerous hazards. In designing a medical device, it is critical to consider the device failure and use-related hazards to ensure the product is safe to use and fits patients' needs. Through good design, patients are empowered with intuitive, easy-to-use, ergonomic and reliable medical devices.

Nemera and its partners empower patients through good design with Nemera's extensive experience in developing and manufacturing parenteral drug delivery devices.

The company leverages decades of manufacturing and development experience in the parenteral device segment to offer patients premium products and customers a complete service. With the support of its global centre of expertise comprising more than 60 engineers and experts in creative design and human factors activities, Nemera is able to drive an idea from concept all the way to large-scale manufacturing.

Nemera's balanced business model includes: full proprietary product development, contract manufacturing and customised solutions. This model gives flexibility to customers, being able to enter the development and manufacturing process at any stage. Depending on their needs, pharmaceutical companies can leverage Nemera's knowhow and expertise to develop customised solutions based on either their own or Nemera's intellectual property.

NEMERA INNOVATIONS

Safe'n'Sound®

In the parenteral industry, needlestick injuries are a global concern. According to the WHO, more than two million exposures to blood occur every year, resulting in health, psychological and cost issues. Safe'n'Sound® (shown in Figure 1) is Nemera's fully passive solution to needlestick injuries for prefilled syringes that patients can count on.

US FDA 510k cleared, the system



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	Off-the-shelf range		Customised 1 mL & 2.25 mL	Concept
	1 mL Long	2.25 mL Long		
Component				
Sub-Assembly	Cut/Round Flange Small Round Flange* Luer Lock**	Extra Small Round Flange* Small Round Flange* Cut/Round Flange*	Customers' specific syringes	1 mL short staked 0.5 mL long staked
Plunger Rod	White/Transparent	White/Transparent	Colour specific	N/A
Option				
Add-on Extended Finger Flange	Portfolio of colours	Portfolio of colours	Colour specific	N/A

Table 1: Specifications and customisation options for the Safe'n'Sound® platform. (* In 2017. ** With BD Syringes)

protects healthcare professionals, patients who self-inject doctor-prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks. Not only does Safe'n'Sound® improve users' safety and injection conditions, but also the device complies with the recommendations of the WHO and the EU Council Directive 2010/32/EU.

Some of the specifications and customisation options for the Safe'n'Sound® platform are summarised in Table 1.

There are a numerous reasons to add Safe'n'Sound to a prefilled syringe, including:

- **Drop test.** Protects against drops thanks to its design holding the syringe in every orientation
- **Activation extra force.** Low extra force (<8N) required to activate
- **Override PUSH.** Requires high force (>100N) after the safety activation to break the safety feature by applying pressure on the plunger rod
- **Override PULL.** Requires high force (>100N) after the safety activation to disassemble the body and the sleeve
- **Device labelling surface.** Increased labelling surface thanks to safety device
- **Syringe loading.** Requires low force to snap the syringe into the safety device, lowering the risks of potential syringe breakage during insertion.
- **Syringe unloading.** Once the syringe is inserted into the device, the clips hold the syringe firmly



Figure 2: 1 mL and 2.25 mL versions of the Safelia® auto injector.

Expected benefits	Standard AI	Safelia	Safelia Features
Creating possibilities for viscous injections with the same AI platform as for standard glass syringes	x	✓	Injects fluid and viscous drugs up to several 100 cP
Risk of syringe breakage eliminated Possibility of using all (or no) syringe flanges	x	✓	No stress on syringe flanges
Enables increased spring force and use of small gauge needles (less patient pain) without risk of glass breakage	x	✓	No stress on syringe flanges
Reduction of injection force peaks	x	✓	Cam design to adjust injection speed
Drug is delivered at the right depth	x	✓	Needle insertion disconnected from injection

Table 2: Summary of Safelia® benefits and features compared with standard auto injector.

- **Residual volume.** Minimises residual volume variability due to its efficient design.
- **Patented product.** Freedom to operate performed
- **On the market.** Available for Luer and staked versions
- **Open platform.** Compatible with syringes of different filling volume and flange type from multiple suppliers.

Additionally, Safe'n'Sound® is a safe and easy to use, convenient and ergonomic system. It is a robust device, and provides audible feedback to indicate that the safety mechanism has completed final locking.

Safelia® Two-Step Auto Injector

Nemera's two-step auto injector platform, Safelia™ (Figure 2), eases the patient self-injection experience. It delivers a variety of drug products in glass syringes, ranging from more fluid formulations to the most challenging drugs such as viscous, sustained-released, concentrated



Figure 3: Nemerax's two solutions for RNS removal are A) an integrated device pre-assembled to Safe'n'Sound®; and B) a stand-alone, multiple use solution into which Safe'n'Sound® is inserted.



Figure 4: Solution for one-handed SC injection at 45° angle.



Figure 5: To prevent accidental removal of the stopper or plunger rod, Nemerax developed a back-stop feature.

formulations, products for subcutaneous and intramuscular injection, and including larger volumes.

The benefits and features of Safelia® compared with a standard auto injector are summarised in Table 2.

Safelia® administers a large range of formulations and injection volumes; the platform can adapt by design to handle both fluid and highly viscous formulations, taking care specifically of biologics, sustain-released formulations and shear-sensitive molecules, of up to 2.25 mL injection volumes. The device improves the patient experience, with the possibility to reduce needle gauge, reduce injection time, and slow down the needle penetration inside the body tissues, and gives the possibility of a delayed retraction, for viscous injections especially.

A detailed article focusing on the Safelia® platform, by Nemerax Business Development Director Isabelle Delcroix, appeared in ONdrugDelivery Magazine, Issue 67 (May 2016), pp 38-42.

Rigid Needle Shield Removal Concepts

Removing the rigid needle shield (RNS) of the syringe requires dexterity and minimum force. In order to facilitate device usage and overcome the issues of gripping or sticky RNS, Nemerax

has developed several solutions. Two options are available (see Figure 3):

- A) Integrated: single use solution to remove the RNS pre-assembled to Safe'n'Sound®
- B) Stand-alone: multiple use solution in which Safe'n'Sound® is inserted to remove the RNS.

One-Handed SC Injection with Half-Inch Needle

Performing a subcutaneous injection requires the user either to pinch the skin and inject at 90° or inject at 45°. As these steps are inconvenient, they can lead to injection in the wrong skin layer. With Nemerax's solution for subcutaneous injections (Figure 4), only part of the needle is exposed, allowing:

- One-handed subcutaneous injection (patient convenience)
- Drug delivery in the correct tissue layer (reduction of pain)
- Standard syringe usage while differentiating (cost & time to market/ no competition).

Backstop Concept

In order to prevent accidental removal of the stopper or plunger rod, Nemerax developed a back-stop feature comprising an add-on part (Figure 5) clipped at

customer's facility after syringe insertion.

Implanters

Sustained-release parenteral formulations are delivered subcutaneously through implants in order to provide slow release of the drug. Since implants are fragile, insertion into the body requires caution. Nemerax has developed several devices to deliver implants with integrated anti-needlestick safety including a safety depot syringe with telescopic plunger rod and a safety retro injector for soft implants. Key product features include:

- Suitable for different implant sizes
- Can accommodate multiple implants, soft implants
- Implants easily loaded
- Integrated safety feature
- Little effort and pressure applied on implant
- Retro-injection feature allows deposit of the implant at a defined depth with multiple implants separated one from the other.

NEMERAX CO-DEVELOPMENT

Nemerax has positioned and structured itself to become the partner of choice for successful parenteral programme management from concept through to industrialisation.

Nemera offers world-class excellence at each stage of the programme:

- **Concept Generation.** IP Management, patient insights & creative design; concept selection; and a compliant, structured stage gate progress
- **Design & Prototyping.** Human factors studies, DFSS and QbD; detailed design including design for manufacturing; strong programme management & governance; and quality, cost and lead-time
- **Scale Up & Pilot.** Design verification, process de-risking & validation; validated process & samples for clinical trials / stabilities; sourcing & supplier management; and key partnerships for equipment/moulds
- **Regulatory.** Facilitation of filing strategy; detailed design including Design for Manufacturing; long experience with EU & US authorities (FDA 510(k) / DMF / New Drug Applications); and regulatory experts in-house
- **Industrialisation.** Validation according to GMP and FDA requirements; validated commercial batches; and injection moulding and high-speed assembly expertise.

CONTRACT MANUFACTURING OF INJECTION DEVICES

Quality for Patients

More than five million diabetics rely every day on devices manufactured by Nemera. The company manufactures parenteral devices in best-in-class clean rooms. Manufacturing capabilities include injection moulding and complex assembly. Altogether our facilities have the following certifications:

- ISO 9001
- ISO 13485
- ISO 14001
- ISO 15378
- ISO 5001.

We are committed to providing excellence in the quality of our products and services:

- Full traceability, 100% in-line controls
- Production according to 21CFR820/ GMP
- Manufacturing in ISO CLASS 5 to 8 clean rooms
- Datapack available.

Insulin Pens & Auto Injectors

Nemera has proven expertise in managing large-scale industrial projects, manufacturing hundred millions of insulin pens and millions of auto injectors every year. With several decades of experience in manufacturing complex parenteral devices, Nemera offers its unique know-how in this field to its customers, along with premium service.

ABOUT THE COMPANY

Nemera is a world leader in the design, development and manufacturing of drug delivery solutions. It has more than 50 engineers working in development, over 30000 m² of clean-room manufacturing, sales in 47 countries, 750 million+ devices produced yearly and over 1300 employees. Nemera has four plants in Europe and the US at Neuenburg, Germany; La Verpillière, France (Figure 6); Le Tréport, France; and Buffalo Grove, IL, US.

Nemera's portfolio includes devices across the board of drug delivery routes including ear, nose and throat; pulmonary; dermal/transdermal; and ophthalmic. This is in addition to the parenteral offering described here.



Figure 6: Nemera's Innovation Centre at La Verpillière, near Lyon, France.