injecting new ideas

Nemera
INJECTING NEW IDEAS

Empower patients through good design...

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.

...with Nemera’s extensive experience in developing and manufacturing parenteral drug delivery devices

Nemera 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 Nemera’s global centre of expertise which is composed of more than 50 engineers and experts in creative design and human factor activities, Nemera is able to drive an idea from concept all the way to high scale manufacturing.

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

Parenteral device portfolio
- Safe’n’Sound® passive safety device for prefilled syringes
- Safelia™ autoinjectors for 1ml & 2.25ml fluid or viscous formulations

Customized solutions based on parenteral technologies
- Autoinjectors
- Implanters
- Other injection devices

Large-scale industrial capabilities
- Insulin pens
- Autoinjectors
- Ready-to-fill plastic syringes
Quality for patients

Nemera manufactures parenteral devices in best-in-class clean rooms. Manufacturing of devices at Nemera includes injection molding and complex assembly. All together 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

THE RIGHT PARTNER FOR SUCCESSFUL PARENTERAL PROGRAM MANAGEMENT

CONCEPT GENERATION

IP Management, patients insights & creative design

Concept selection

DESIGN & PROTOTYPING

Human Factor Studies, DFSS and QBD

Detailed Design including Design For Manufacturing

SCALE UP & PILOT

Final Design verification
Process derisking & validation

Validated process & samples for clinical trials / stabilities

INDUSTRIALIZATION

Validation according to GMP and FDA requirements

Validated commercial batches

REGULATORY

Facilitation of filling strategy

Long experience with EU & US authorities (FDA 510(k) / DMF / New Drug Applications)

Compliant structured stage gate progress

Strong program management & governance

Quality, Cost and Lead-time

Sourcing & Supplier management
Key partnerships equipment/molds

Injection molding & high-speed assembly expertise

Regulatory experts in-house
THE FULLY PASSIVE SAFETY DEVICE FOR PREFILLED SYRINGES THAT PATIENTS CAN COUNT ON

**NEMERA’S SOLUTION TO NEEDLESTICK INJURIES**

In the parenteral industry, needlestick injuries are a global concern. According to World Health Organization, over 3 million exposures to blood occur every year, resulting in health, psychological and cost issues.

Nemera has developed Safe’n'Sound®, a **fully passive safety device for prefilled syringes** to aid in the protection of 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 World Health Organization and the EU Council Directive 2010/32/EU.

**SAFE’N’SOUND® PLATFORM RANGE**

<table>
<thead>
<tr>
<th>Safe’n’Sound®</th>
<th>Off-the-shelf range</th>
<th>Customized</th>
<th>Development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 ml</td>
<td>2.25 ml</td>
<td>1 ml &amp; 2.25 ml</td>
</tr>
<tr>
<td>Sub-Assembly</td>
<td>Cut/Round flange, Small Round Flange, Luer Lock</td>
<td>Small Round Flange, Extra Small Round Flange, Cut/Round Flange</td>
<td>Customers’ specific syringes</td>
</tr>
<tr>
<td>Plunger Rod</td>
<td>White / Transparent</td>
<td>White / Transparent</td>
<td>Colored specific</td>
</tr>
</tbody>
</table>

**Option**

| Add-on Extended Finger Flange | Portfolio of colors | Portfolio of colors | Colored specific | White |
**KEY REASONS TO ADD SAFE’N’ SOUND® (SnS) TO YOUR PREFILLED SYRINGE**

- **Activation extra force**
  Low extra force (<8N) required to activate the safety device of SnS.

- **Override PUSH**
  SnS requires high force (>100N) after the safety activation to break the safety feature by applying pressure on the plunger rod.

- **Override PULL**
  SnS requires high force (>100N) after the safety activation to disassemble the body and the sleeve.

- **Drop test**
  SnS protects against drops thanks to its design holding the syringe in every orientation.

- **Residual volume**
  SnS minimizes residual volume due to its efficient design.

- **Syringe unloading**
  Once the syringe is inserted into SnS safety device, the clips hold the syringe firmly.

- **Syringe loading**
  SnS requires low force to snap the syringe into the safety device, lowering the risks of potential syringe breakage during insertion.

- **Device labelling surface**
  Increased labelling surface thanks to SnS safety device and customizable plunger rod or extended finger flange.

- **Easy to use, convenient and ergonomic system**

- **Reliable device ensuring safer injection**

- **Robust & cost effective solution**

- **Audible feedback to indicate safety feature final locking**

- **Patented product / Freedom to Operate performed**

- **510(k) cleared product / On the market for Luer and Staked versions**

- **Open platform of add-on safety devices compatible with syringes of different filling volume and flange type from multiple suppliers**

*Safe’n’SOUND® safety feature activated*
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, Nemera has developed several solutions.

**Two options are available:**
- **Integrated**: single use solution to remove the RNS pre-assembled to Safe’n’Sound® (1)
- **Stand-alone**: multiple use solution in which Safe’n’Sound® is inserted to remove the RNS (2)

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ONE-HANDED SUBCUTANEOUS INJECTIONS WITH ½ 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 Nemera’s solution for subcutaneous injections, only part of the needle is exposed, allowing:

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

BACK-STOP CONCEPT

In order to prevent accidental removal of the stopper or plunger rod, Nemera developed a back-stop feature: an add-on part (4) clipped at customer’s facility after syringe insertion.

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BREAKTHROUGH TECHNOLOGY OF AUTOINJECTOR

**SAFELIA® - 2-STEP AUTOINJECTOR (AI) FOR 1ML AND 2.25 ML FLUID AND VISCOS FORMULATIONS**

<table>
<thead>
<tr>
<th>Expected benefits</th>
<th>Standard AI</th>
<th>Safelia® AI</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating possibilities for viscous injections with the same AI platform as for standard glass syringes</td>
<td>✗</td>
<td>✓</td>
<td>Injects fluid and viscous drugs up to 1000 cP</td>
</tr>
<tr>
<td>Risk of syringe breakage eliminated Possibility of using all (or no) syringe flanges</td>
<td>✗</td>
<td>✓</td>
<td>No stress on syringe flanges</td>
</tr>
<tr>
<td>Enables increased spring force and use of small gauge needles (less patient pain) without risk of glass breakage</td>
<td>✗</td>
<td>✓</td>
<td>No stress on syringe flanges</td>
</tr>
<tr>
<td>Reduction of pain at needle insertion</td>
<td>✗</td>
<td>✓</td>
<td>Adjust needle insertion speed</td>
</tr>
<tr>
<td>Reduction of pain during injection</td>
<td>✗</td>
<td>✓</td>
<td>No initial injection peak</td>
</tr>
<tr>
<td>Drug is delivered at the right depth</td>
<td>✗</td>
<td>✓</td>
<td>Needle insertion disconnected from injection</td>
</tr>
</tbody>
</table>
INSULIN PENS & AUTOINJECTORS
Nemera has proven expertise in managing large-scale industrial projects, manufacturing hundreds of millions of insulin pens and millions of autoinjectors every year.

INJECTION DEVICES
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.

IMPLANTERS
Sustained release parenteral drug 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.

Nemera has developed several devices to deliver implants with integrated anti-needlestick safety feature:
- A safety depot syringe with telescopic plunger rod (6)
- A safety retro injector for soft implants (7)

Key product features
- 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 implant at defined depth with multiple implants separated one from the other
Nemera is a world leader in the design, development and manufacturing of drug delivery solutions.

50+ OVER 50 ENGINEERS IN DEVELOPMENT

30000+ OVER 30,000 SQM OF CLEAN ROOM MANUFACTURING

47 SALES IN 47 COUNTRIES

750 OVER 750 MILLION DEVICES PRODUCED YEARLY

1300+ OVER 1,300 EMPLOYEES

50+

30000+

47

750

1300+

OVER 50 ENGINEERS IN DEVELOPMENT

OVER 30,000 SQM OF CLEAN ROOM MANUFACTURING

SALES IN 47 COUNTRIES

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OVER 1,300 EMPLOYEES

4 PLANTS IN EUROPE & THE USA

• Neuenburg, Germany
• La Verpillière, France
• Le Tréport, France
• Buffalo Grove, IL, USA

OUR PORTFOLIO

- ear, nose, throat
- pulmonary
- dermal/ transdermal
- parenteral
- ophthalmic

we put patients first

Nemera

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