YES, PEN INJECTORS CAN ACCOMMODATE MORE THAN JUST INSULIN

Nemera
we put patients first

Cécile Gross and **Mark Tunkel** of **Nemera** explore the benefits of pen injectors, highlighting their versatility and ease of use, and introduce the company's novel platforms and how they can be adapted for a wide range of indications, enhancing treatment options and the patient experience.

In anxiety-inducing social environments, the increasing burden of disease or widespread pathologies may be perceived as unhelpful. However, increasing awareness of pharmaceutical progress and technical solutions to assist patients daily can be beneficial (Figure 1).

According to WHO data from 2022, there are approximately 1.71 billion individuals in the world with musculoskeletal conditions, making these conditions the leading cause of disease or disability, closely followed by obesity (890 million) and diabetes (830 million). The number of individuals with diabetes is expected to increase fourfold over the next 30 years.

Harder to quantify, but not to be undervalued, is the number of children and young people suffering from growth deficiency, which affects between one in 3,000 and one in 10,000 people. Last but not least, infertility is estimated to affect 42–180 million people worldwide.

How are those conditions addressed? In the context of drug delivery devices, the insulin pen injector for diabetes comes to mind. Launched in the 1980s, it served

"INCREASING AWARENESS OF PHARMACEUTICAL PROGRESS AND TECHNICAL SOLUTIONS TO ASSIST PATIENTS DAILY CAN BE BENEFICIAL."

two purposes – to ensure accurate dosing and to provide a comfortable injection. In both cases, the objective was to improve on vials and syringes. Since then, its use has spread across other pathologies, such as obesity, growth disorders, bone disorders and fertility issues. This device is still relatively new in the grand scheme of things, but its use is expected to increase in the coming years.

ADVANTAGES OF USING A PEN INJECTOR

Access to diagnostics and treatment availability remain a challenge for health authorities, with several factors causing this globally prevalent issue. However, with treatments available in injectable form and drugs being increasingly adapted for self-administration via pen injectors, promoting their widespread adoption could help to alleviate the burden for patients.

When discussing injections, it is essential to consider needle phobia. Advances in insulin delivery have resulted in pen needles being very short and very thin, making injections less traumatic than those administered with a standard syringe. In the same way, needlestick injuries are very rare with this type of device. The risks associated with dealing with vials and syringes are also minimised by the ready-to-use cartridge already integrated in the pen injector. Patients do not need to manipulate the drug container, except in the case of reusable pen injectors; however, such containers are safe enough not to pose risks for patients.

Figure 1: Awareness of pharmaceutical progress and technical solutions to assist patients daily can be beneficial.

"NEMERA HAS DEVELOPED EACH DEVICE BASED ON ITS PLATFORMS, MEANING THAT A SINGLE DEVICE CAN BE USED FOR MULTIPLE PURPOSES, AND DIFFERENT PATIENT GROUPS AND POPULATIONS."

Lack of trained personnel, necessary equipment and infrastructure can sometimes lead to poor patient care. Pen injectors, which resemble writing pens, are very intuitive in their use and can be used independently by patients.

Nemera has developed various pen injectors to accommodate the drugs needed to treat patients suffering from one of the main pathologies mentioned above. All of its pen injectors can accommodate insulin, glucagon-like peptide 1 (GLP-1), follicle-stimulating hormone, parathyroid hormone and human growth hormone, as well as their analogues and new chemical entities. From the patient perspective, Nemera can address any need through various technical solutions, including reusable or disposable devices, manual or spring-assisted injections and variable or fixed doses (Figure 2).

Figure 2: Nemera's pen injector platforms to cover any indication.

PEN INJECTOR PLATFORMS TO MEET PHARMA REQUIREMENTS

Nemera has developed each device based on its platforms, meaning that a single device can be used for multiple

purposes, and different patient groups and populations. The main advantages of platforms are the optimised time to market, with a technical solution already validated and market proven; broad compatibility with available cartridges; cost effectiveness – especially for a drug pipeline; and derisking benefits when it comes to manufacturing. The platforms still offer opportunities for differentiation and customisation.

For patients, having a month's treatment available in a single device instead of four separate devices makes it less cumbersome, eases portability when travelling or going to work, and fosters familiarity with the device through longer use of the same device. Some of Nemera's devices even have a dose counter to facilitate treatment monitoring, and the company can add connectivity to ease tracking. Pen injectors are also beneficial in terms of sustainability, as they are multi-use, so they can be reused until the cartridge is empty. Reusable pen injectors can be reused for several years.

PenDIA: Variable Dose Spring-Assisted Platform for GLP-1

Focusing on high-volume doses requiring frequent but not daily injection, Nemera developed a spring-assisted feature for a smooth injection experience (Figure 3). Volumes to be injected are larger than the "standard" insulin doses, therefore, using a spring to assist the patient helps to guarantee low force and a constant speed. This is especially helpful for patients who may not be as familiar with multiple daily injections as people with diabetes. The risk of misdosing is reduced, as there is no possibility of overdosing during the 4-week period – the dose to be administered is in the same device, rather than a separate one with a higher dosage.

"Autoinjector-Like" PenSET for Novel Drugs

Similarly, for this platform, Nemera kept the spring-assisted feature for a smooth injection while combining the advantages of the multidose capability of pens with the fixed-dose feature of autoinjectors (Figure 4). Patients do not need to be concerned about accurate dosing or associated risks, as everything is controlled by the device itself. The dose is pre-set, which means that the dose is accurate by default – it is not possible to alter it and therefore there is no risk of under- or overdosing. Additionally, several doses remain in the device, making it more sustainable.

Figure 3: PenDIA – a spring-assisted pen injector for seamless GLP-1 administration.

Usage steps are labelled very clearly so that patients know which step they are at, such as before an injection, priming or administering a dose. One interesting feature is priming – it is a one-time process that occurs until the device is completely used. If the patient forgets whether the priming has been performed, it is not an issue because the device will not allow administration of a dose until priming is complete.

The capabilities of Insight by Nemera – the company's independent development and consulting team within its services business unit – were called upon to create this modern design, selecting a cylindrical form with rounded ends and integrating the anti-roll feature subtly by flattening the surface. Special attention was given to the dose window, which only displays symbols – no numbers – to signal the device's status. It is a circular design, with a gloss finish to create a visual highlight. The push button features a concave finger placement to makes the spring-assisted injection more comfortable.

INTEGRATED SERVICES AND MANUFACTURING CAPABILITIES TO SUPPORT THE DRUG-DEVICE COMBINATION

For specific customer applications, Insight by Nemera can support any pen-platform-based combination product from registration through to commercialisation. Nemera's suite of consulting services provides this support, and is able to address every aspect of combination product development. With a proven track record in helping customers to achieve regulatory approvals in over 50 countries,

Figure 4: PenSET – a fixed-dose spring-assisted pen injector for an injection experience similar to an autoinjector.

Nemera created customised strategies to meet the unique needs of each programme with the following services:

- **Functional/Analytical Lab Testing and Design Verification:** Nemera's state-of-the-art facilities and customised methodologies ensure that products meet safety, quality and compliance standards. Nemera supports performance and functionality testing, analytical testing (including stability and biocompatibility) and design verification for final combination products. Nemera's processes align with ISO and US FDA requirements, supporting a wide range of administration routes beyond parenteral.
- **Human Factors Management and Design Validation:** Nemera ensures devices and combination products are safe and effective for target users while enhancing patient experiences and adherence. The company can support human factors strategy development, risk analyses, usability testing (formative and summative) and preparation of regulatory documentation.
- **Instructional Materials and Secondary Packaging Development:** Nemera creates tailored instructions for use, value-added packaging and integrated digital assets that improve the user experience, increase adherence, boost engagement and support platform value.
- **Regulatory Strategy and Registration Support:** Nemera's team navigates the complexities of global regulatory processes and standards from strategy and pre-market activities to registration and post-market support. The company develops strategies, engages with regulatory bodies and prepares submission-ready materials to ensure compliance with global requirements.

These services can be augmented by preclinical, clinical and small series device supply, accelerating development timelines while deferring capital expenses. This ensures a cost-effective and streamlined process. A holistic approach to these activities is crucial for success.

With the aim of providing a fully automated industrial line to its partners, Nemera has invested in a new plant, offering its capability to produce prototypes, small series for clinical batches, as well as large-scale automated volumes. Gathering state-of-the-art equipment from moulding to assembly and quality control testing, this brand-new facility includes an ISO 8 clean room and complies with Building Research Establishment Environmental Assessment Methodology (BREEAM) recommendations. For example, heat is recovered from the process line, and the facility also segregates and sorts all waste, aiming for 100% recycling of waste (Figure 5).

Figure 5: State-of-the-art manufacturing facility, hosting cleanrooms compliant with BREEAM recommendations.

By combining its comprehensive service offerings with its global manufacturing facilities and a commitment to sustainability, Nemera delivers unmatched value to its customers. Its holistic approach ensures that every aspect of combination product development is seamlessly integrated.

> "BY COMBINING ITS COMPREHENSIVE SERVICE OFFERINGS WITH ITS GLOBAL MANUFACTURING FACILITIES AND A COMMITMENT TO SUSTAINABILITY, NEMERA DELIVERS UNMATCHED VALUE TO ITS CUSTOMERS."

BENEFITS OF PARTNERING WITH AN INTEGRATED PRODUCT AND SERVICE PROVIDER

Partnering with Nemera means working with a proactive, integrated partner capable of delivering comprehensive solutions from proven pen platforms, development, manufacturing and consulting to support its partners' combination products from concept to market. Insight by Nemera's experience with pen platforms streamlines project onboarding and execution, ensuring efficient progress and on-track programmes. At every stage, Nemera's development and consulting excellence is dedicated to driving improved outcomes for patients and delivering confidence to its customers.

Nemera eliminates the need to co-ordinate multiple specialised partners. By simplifying the process, reducing complexity and risk, and accelerating regulatory approval and market access, Nemera's agile and integrated approach allows customers to focus on their core business while managing combination product development to ensure a safe, effective and differentiated result.

To conclude, the aforementioned pathologies are by no means exhaustive. Ongoing clinical trials aimed at expanding indications for existing drugs are expected to lead to treatment advances and an increase in the number of patients receiving care. Nemera strongly believes that the pen injector journey is warranted even more now than ever before!

Cécile Gross

Cécile Gross is Marketing Global Category Manager – Parenteral/ICO at Nemera, focusing on parenteral devices. She oversees the product portfolio strategy, development and lifecycle for safety system, pen injector and on-body injector platforms. Ms Gross has more than two decades of experience in the medical device industry, marketing business-to-business technological products and implementing product lifecycle management for various kinds of devices. A graduate in International Business, she completed her initial training with a master's degree in Marketing and Management in the Healthcare Industry at the IMIS Institute (Lyon, France).

E: cecile.gross@nemera.net

Mark Tunkel

Mark Tunkel is Services Strategy & Marketing Director at Nemera. He was previously a partner at Insight Product Development, which was acquired by Nemera in 2019 and became the Insight Innovation Center. With more than 20 years of global business development experience and a deep understanding of the marketplace challenges and trends impacting the pharma industry, Mr Tunkel has advised many of the world's leading companies on their product development and innovation strategies, with an emphasis on driving realisation and highly favourable business outcomes.

E: mark.tunkel@nemera.net

Nemera

63-65 Avenue Tony Garnier, 69007 Lyon, France

www.nemera.net

ONE PEN AT A TIME

Nemera
we put patients first