PHARMAPACK

By CPHI

Innovation Gallery eBook

2023

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PHARMAPACK
By CPHI

Welcome to the 2023 edition of the Pharmapack Europe Innovation Gallery eBook!

One of the most exciting elements of the Pharmapack Europe event is the opportunity to see the latest in products, solutions and technologies from our exhibitors and partners – many of which are launched on the show floor.

2023 is no exception, and we are delighted to offer a preview of market-leading innovations in this year's eBook.

I hope this provides an interesting prelude to the event, and that once you arrive in Paris, you'll add our Innovation Gallery to your schedule – where you can see more information on the products listed here.

Don't forget, each innovation is also entered into the prestigious Pharmapack Awards, and we'll be handing out trophies at our awards ceremony on the first day of the show – 1st February.

I hope you enjoy browsing through the latest innovations in the world of drug delivery and packaging, and very much hope to see you in Paris.

Tara Dougal, Content Director – Pharma, Informa Markets

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Intuity® Mix

2023

Company name: Eveon

Country: France

Product name: Intuity® Mix

Product type: Device for automatic preparation

Date of launch: 2024

Current development phase: Prototype

Target markets: Europe & USA

Target clients: Pharmaceutical companies

Business model: Licensing

FACT SHEET

PRODUCT DESCRIPTION

New formulations such as gels, highly-viscous products, suspensions, emulsions are challenging to prepare both for patients and healthcare professionals. According to your needs, EVEON offers a flexible solution: Intuity® Mix based system using PFS, syringe or cartridge as primary containers, Intuity® Mix is a fully automated device technology platform for the automatic preparation of drugs.

APPLICATION AREAS

Gels, highly-viscous products, suspensions and emulsions

KEY FEATURES

- Repeatability
- Non user dependent
- Reliability of the process
- Custom device
- Easy to use
- Time-saving
- Reallocate healthcare practitioner time

Website: www.eveon.eu

Printable Temperature Indicator

2023

Company name: Faller Packaging

Country: Germany

Product name: Printable Temperature Indicator

Product type: Label

Date of launch: 02.11.2022

Current development phase: Commercialisation

Target markets: Europe

Target clients: Pharmaceutical companies

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

The incorrect administration of medication can have unpleasant consequences for the patient. This is particularly the case with self-application medicines. Our printed sensor helps to improve the user-friendliness of your refrigerated medication. If the medication is still too cool, it is often painful to apply. In addition, the effectiveness of the medication could be delayed by the wrong viscosity. The label is equipped with sensor technology that turns blue when it is stored below eight degrees Celsius. As soon as the temperature warms above 18 degrees Celsius, the sensor changes colour and an 'OK' message is displayed on the label.

APPLICATION AREAS

- Assists the patient or user in the correct application of the medication
- Suitable for all medications that need to be warmed up from a refrigerated state to room temperature prior to use (e.g. Insulin, all plasma-based medications, Botox, etc.)
- Suitable for homecare medications, to assist in safe uses
- Also suitable for medications that are dosed for multiple uses
- Measurable temperature range: 2-8°C (but temperature range can be adjusted if required)

KEY FEATURES

- Sensor technology shows the current temperature and thus helps the patient or user to determine the correct temperature for the application
- The printable, temperature-sensitive sensor, replaces expensive data logger or bulky, rigid and protrude common solutions
- Thanks to the printable solution it is possible to print on all common label materials
- Increases safety and simplicity for the patient or user during application
- Can be used indefinitely: Temperature change can be repeated as often as required
- No restrictions in size, shape, temperature range, branding, text and colour

Website: https://www.faller-packaging.com/en/lp/temperature-indication-labels

Sustainable Covid Rapid Tester

2023

Company name: Körber Pharma Packaging Materials

Country: Switzerland

Product name: Sustainable Covid Rapid Tester

Product type: Covid Rapid Tester

Date of launch: TBC

Current development phase: Developed

Target clients: Pharma Industry

Business model: B2B

FACT SHEET

PRODUCT DESCRIPTION

Covid has changed the world. Not only in dealing with the pandemic and digitization, but also in relation to our own health security. Rapid Covid tests have become indispensable in day-to-day business. In order to be able to act quickly, millions of quick tests were manufactured and made of plastic. We thought one step ahead and developed a quick test completely without plastic- i.e. made of recyclable cardboard mono material.

APPLICATION AREAS

Rapid Test application for different kinds of usage

KEY FEATURES

100% Recyclable Monomaterial Cardboard = Plastic replacement

Website: https://www.koerber-pharma.com/en/about-us/press/from-development-to-market-readiness-koerber-offers-packaging-qualification-services-from-a-single-source

UniSafe® Reusable Auto-injector

2023

Company name: Owen Mumford Pharmaceutical Services

Country: United Kingdom

Product name: UniSafe® Reusable Auto-injector

Product type: Reusable auto-injector with optional connectivity

Date of launch: 01.12.2023

Current development phase: Pre-design verification

Target markets: Global

Target clients: Pharma and Biotech companies

Business model: B2B

FACT SHEET

PRODUCT DESCRIPTION

The UniSafe® reusable connected auto-injector is a companion device for UniSafe 1mL safety syringe designed for the delivery of subcutaneous medication.

The auto-injector's mechanical function ensures that the product is always ready for use as it does not rely on batteries or chargers to deliver the patient's medication. With both a continual dose progression indicator and true end of dose notification the auto-injector guides patients during their drug administration procedure helping to ensure complete dose delivery. UniSafe Auto-injector has the option of added connectivity features for data exchange between patients and healthcare providers helping to track therapy compliance. Data captured by the device is automatically transferred via Bluetooth® which is initiated when the injection commences therefore no docking stations are required.

UniSafe auto-injector has an internal memory and automatically stores 1098 records allowing medication history to be retained for the life of the device UniSafe Auto-injector's reusable design reduces waste and environmental impact compared to typical usage with disposable auto-injectors plus no charger or docking stations are required.

Once drug administration is completed the UniSafe syringe with shrouded needle is the only part, weighing just 5g, which requires disposal. The UniSafe Auto-injector electronics are housed in the lid and the device can be disassembled for separate disposal and recycling. As a reusable device the UniSafe Auto-injector has a shelf life of 2 years so contributes significantly to reducing waste compared with single use devices which may be used on a frequent basis dependent on the medication regimen.

Website: https://www.ompharmaservices.com/products/unisafe-platform/unisafe-auto-injector/

UniSafe® Reusable Auto-injector

2023

APPLICATION AREAS

UniSafe reusable auto-injector can be used for the subcutaneous delivery of medication for chronic diseases such as rheumatoid arthritis, multiple sclerosis, and Crohn's disease. The device has undergone thorough human factors testing program utilising a variety of intended patient groups and healthcare practitioners. Patients involved included those with dexterity and cognitive challenges and a range of ages. The device has been shown to be intuitive and simple to use.

The reusable auto-injector uses a UniSafe 1mL and as such is suitable for medication with volumes up to 1mL and viscosities up to 25cP using a 0.5" inch "27G thin wall needle. The device design allows the needle to be hidden and protected at all times. The initial opening and closing of the device allows it to be 'primed' and ready for use and the device will not operate if the UniSafe is not correctly positioned. Once the patient initiates the injection, they are guided through the drug delivery by a continuous dose progression LED indicator. The appearance of a yellow 'flag', and an audible indicator provides true end of dose confirmation. The indicators can be modified in line with different fill volumes & drug delivery times to help prevent patients fromremoving the device prematurely.

The auto-injector also has an inbuilt injection error indicator so patients are immediately notified of any drug delivery failure. The device has a lifetime battery, so no charging is required, and patients are able to use the device when-ever they need their medication

KEY FEATURES

UniSafe® 1mL Auto-injector's mechanical drug delivery is not dependent on battery function so the patient can always receive their medication. With a lifetime battery no charging is required. UniSafe® 1mL Auto-injector provides true end of dose confirmation via clear audible and visible feedback providing patients with reassurance that medication delivery is completed. There is no reliance on software for critical patient indicators. Patients can rely on the fail-safe design as medication can be administered independently of the auto-injector, using the UniSafe® 1mL safety syringe.

The auto-injector indicator shows continual dose progression and can be adjusted to required drug delivery time to provide dose delivery confirmation for the patient whatever the drug. UniSafe® 1mL Auto-injector's dampening glide technology creates a smooth and controlled drug delivery providing comfort and reassurance for the patient while also helping to prevent syringe damage. UniSafe® 1mL Auto-injector helps to protect against needlestick injuries as the needle is concealed before, during and after use.

UniSafe® 1mL Auto-injector has the option for inbuilt connectivity for data exchange between patients and healthcare providers helping to track therapy compliance and also provide interventions. The device automatically turns on the Bluetooth® communications when the shroud is pressed onto the injection site and no docking is required as automatic data transfer takes place once Bluetooth® connection is made.
The internal memory automatically stores data for 100 doses. The reusable design reduces waste and environmental impact compared to typical usage with disposable auto-injectors. UniSafe® 1mL safety syringe is the only disposable part.

Sonceboz OBI Platform

2023

FACT SHEET

Company name: Sonceboz SA

Country: Switzerland

Product name: Sonceboz OBI Platform

Product type: On-Body Injectors

Date of launch: TBD

Current development phase: Preclinical

Target markets: Biopharma, US, EU

Target clients: Pharmaceutical Companies

Business model: Partnering, Licensing

PRODUCT DESCRIPTION

High-Dose/High-Volume subcutaneous (SC) drug delivery requires dedicated delivery technology to enable patient-centric and effective drug administration. The trend towards such high-volume delivery via the SC route is increasing and the Sonceboz OBI-Platform is the answer to many unresolved challenges in drug delivery such as proper feedback, tolerability, system flexibility. The Sonceboz OBI Platform is designed with three main requirements in mind:

1. Ease of use for patients and caregivers to prevent user errors through a combination of intuitive design and clear visual and audible messages. Furthermore, the devices are designed in such that users intuitively understand the mode of operation and preparation of the devices, proven by a number of human factors studies

2. Adaptation to Pharma's preferred primary packaging such as vials, cartridges. Sonceboz does not impose proprietary containers or fill and finish processes. This reduces risk, cost and time to market. In addition, the LVI-V device can accommodate any volume from 1-20mL which provides a great deal of flexibility to Pharma when, for example considering use in clinical trial scenarios

3. Ease of integration into Pharma processes with the ability to stay outside the primary supply chain. By providing the possibility to store drug and device separately one greatly simplifies storage and supply related processes. Additionally, due to the frequent cold-storage requirements of Biologics, a separate drug and device logistics may reduce complexity and costly cold-chain storage space.

Website: medical.sonceboz.com

Sonceboz OBI Platform

2023

APPLICATION AREAS

High-Dose and High-Volume injection of parenteral drug formulations with a focus on:

- Immuno-Oncology
- Neuroscience
- Autoimmune disease
- Cardiovascular and metabolic disease
- Clinical Trials
- Lifecycle Management/transition from intravenous (IV) to subcutaneous
- Improvement of efficiency in hospital-borne treatments by simplifying subcutaneous delivery

KEY FEATURES

- Biologics compatible fluid-path
- Compatible with standard vials with 13 or 20mm neck sizes (glass and polymer)
- High-convenience compact footprint
- Full programmability of delivery (Speed, Timing, Pauses, Messages, Connectivity)
- Orientation independent dosing to ensure required dose is delivered
- Clear audible, haptic and visual feedback to prevent user errors and provide peace of mind
- Leverage on proven technologies derived from high volume manufacturing automotive applications

AdhereIT® 360 Product Platform

2023

Company name: Aptar Pharma

Country: France

Product name: AdhereIT® 360 Product Platform

Product type: Packaging Innovation

Date of launch: 31.08.2023

Current development phase: Commercialization

Target markets: North America, Europe

Target clients: Pharmaceutical Companies

Business model: Out-Licence

FACT SHEET

PRODUCT DESCRIPTION

Aptar Pharma's AdhereIT® product platform addresses patient adherence to self-injected medication by supporting patients with initial onboarding and ongoing adherence to their therapeutic treatments. Available in two design options, the AdhereIT® 360 Base and AdhereIT® 360 Clip integrate with self-injection devices and provide visual, audio and haptic feedback during the injection process to guide dosing success. Encrypted data is then transferred to the secure AdhereIT® smartphone app via Bluetooth® technology, which incorporates complementary resources for patients such as training videos, injection reminders and drug re-order notifications. Data can be shared with HCPs for simple tracking of patient performance through a dashboard, providing accurate real-world data to support ongoing therapeutic programs. Aggregated, anonymized data can also be made available to pharmaceutical companies, closing the patient feedback loop, providing valuable insight to address poor adherence.

APPLICATION AREAS

Aptar Pharma's AdhereIT® is focused on improving adherence for patients who self-administer injectable drugs on a regular basis. AdhereIT® can be used jointly with drugs already marketed or during clinical trials for more efficiency.

KEY FEATURES

A complete connected ecosystem for auto-injection, Aptar Pharma's AdhereIT® is a cutting-edge example of how innovative technology can support better patient experiences and outcomes. - Supports the patient onboarding process, accelerating the patient's learning curve.

Website: https://www.aptar.com/products/pharmaceutical/adhereit/

APF futurity

2023

Company name: Aptar Pharma

Country: France

Product name: APF futurity

Product type: Nasal Spray Device

Date of launch: 01.02.2023

Current development phase: Prototype

Target markets: Worldwide

Target clients: CMO / CDMO

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

APF futurity, Aptar Pharma's first highly recyclable nasal spray pump - this device is a metal-free nasal spray pump, made from only polyolefin without any disrupting materials. APF futurity achieved a "highly recyclable rate" by the cyclos-HTP institute (November 2022) when associated to a HDPE container. Based on Aptar Pharma's Tip Seal technology for preservative-free formulations and applicable for nasal saline or comparable OTC compounds, this nasal spray enables direct and easy recycling for the consumer, when empty after use. It minimizes separation efforts in recycling streams, supports higher quality of recyclates and reduces the CO2 footprint of nasal spray products without causing trade-off on performance and safety. The APF futurity has been assessed with Aptar's Eco-design tool to ensure the recyclable nasal spray pump fulfils state of the art sustainability requirements.

APPLICATION AREAS

Nasal application using isotonic or hypertonic saline solution including seawater product types. The aim is to lessen nasal congestion, sinus pressure and breathing issues. Non-prescription remedies (non-API).

KEY FEATURES

- Will be the first 100% metal-free nasal spray pump on the market highly recyclable *
- No trade-off on performance or safety. Pure Polyolefin materials without recycling disruptors
- Preservative-free pump based on Aptar Pharma's Tip-Seal technology** appropriate for Preservative-free nasal saline and comparable formulations
- Option for circular material (e.g. renewable feedstock / Mass Balance)

* validated by the cyclos-HTP institute as of November 2022, when associated to a 10 or 30ml HDPE container

** https://www.aptar.com/resources/overview-of-microbial-integrity-tests-for-preservative-free-nasal-spray-pumps-and-multidose-eye-droppers/

Website: https://www.aptar.com/pharmaceutical/

Polyfoil® Mono-Material Barrier Tube Designed for Recyclability

2023

Company name: Hoffmann Neopac AG

Country: Switzerland

Product name: Polyfoil® Mono-Material Barrier Tube Designed for Recyclability

Product type: Tube Packaging

Date of launch: February 2023

Current development phase: Marketed

Target markets: Pharma, OTC, Cosmetics, Dental

Target clients: MCG

Business model: B2B

FACT SHEET

PRODUCT DESCRIPTION

Polyfoil® Mono-Material Barrier tube (MMB) is a high-performance tube, offering superior protection to pharma formulas and is recyclable! Due to the application of innovative oriented and combined barrier technologies as well as pharma grade contact layers, the tubes provide excellent product compatibility and maintain premium product protection while keeping the known aesthetic characteristics of Neopac's conventional Polyfoil® tubes. Combined with HDPE screw and hinge closures, the tube is ready for recycling in the PE rigid streams.

APPLICATION AREAS

Polyfoil® MMB tubes are particularly relevant to the oral care and pharmaceutical sectors, as they sustainably yet responsibly house both consumer items like toothpastes and cosmetics and pharma products in the dermatological or pain-relief sectors.

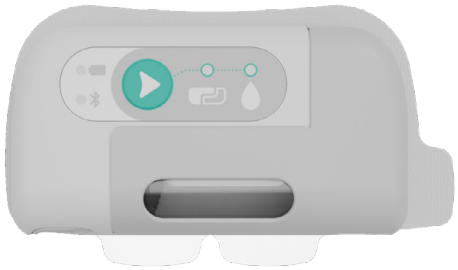
KEY FEATURES

- Premium product protection
- Ready for recycling in the PE rigid streams
- Pharma grade
- Premium look and decoration options - silver body, white or coloured body, offset, silkscreen or digital print available
- Reduced product carbon footprint
- Recyclass Approval, Meets APR critical guidance protocol

Website: https://www.neopac.com/en/tubes/recyclable-polyfoil-mono-material-barrier-tube

Symbioze®

2023



FACT SHEET

Company name: Nemera

Country: France

Product name: Symbioze®

Product type: Wearable / On-body injector

Date of launch: 2021

Current development phase: Representative prototype

Target markets: USA, Japan, Europe

Target clients: Patients with chronic conditions requiring lifelong treatments

Business model: TBD

PRODUCT DESCRIPTION

Symbioze® is specifically tailored to administer complex drugs, such as biologic therapies, thanks to a highly engineered, reliable drug delivery system. It is suitable for various drug platforms and compatible with market-proven cartridges, as well as standard manufacturing processes. The cartridge is prefilled and preloaded in the disposable part for patient safety and ease of use feature. It accommodates large volumes such as 20ml and beyond, while preserving the formulation integrity – which is critical especially with monoclonal antibodies. It is designed to reconcile complex drug injection with stakeholders' (patients, HCP or payers) most demanding needs, with enough flexibility for adjustment to any pathology, targeted patient population and drug posology with different volumes, flowrates, and viscosities. Its reusable core technology can be re-used across multiple injections, leveraging its sustainable benefit for pharmaceutical players. It also includes connectivity features, to improve patients' adherence and compliance.

To improve the patient injection experience, our on-body injector offers a safe and reliable injection thanks to the state-of-the-art engineering, including automatic soft canula insertion and needle retraction.

APPLICATION AREAS

A rising number of pipelines in biologics and biosimilars require adequate drug delivery device solutions to accommodate sensitive drugs for safe self-administration. Moreover, the switch from intravenous to subcutaneous drug administration in a home-care therapy setting is emerging, and requires a robust, reliable drug delivery device to administer high volume and viscosity. To cater to these needs, our smart on-body injector, Symbioze®, answers the needs for digital health to foster patient adherence and injection experience. Our wearable platform is designed for flexibility to be adjusted to any pathology, targeted patient population and drug posology.

Website: https://www.nemera.net/products/parenteral/wearables-symbioze/

KEY FEATURES

- Patch-worn on-body injector
- Reusable: Consists of drug-containing disposable element and is reusable due to rechargable onboard electronic modules Locking system for safe assembly and disassembly of reusable and disposable parts
- Ready to use: Prefilled and preloaded drug cartridge for patient's safety Automatic soft canula insertion via needle safety system with hidden needle throughout the injection Innovative fluid path to maintain sterility from manufacturing to device use
- Platform approach: Provides customization flexibility for adjustments to any pathology, targeted patient population and drug posology. Can accommodate various drug volumes especially large-volume administration (20ml)
- Connected: Drug recognition and verification via NFC communication Bluetooth built-in communication offers connectivity option
- Sustainable and cost-effective, as well as multiple-use of reusable electromechanical part with disposable drug-containing module
- Intuitive and easy to use for optimum treatment adherence
    - Simultaneous removal of ergonomic needle safety cap and adhesive liner, minimizing steps-of-use
    - Provides live injection monitoring, audio-visual feedback, and failure mode control
    - Enhanced treatment management with a broad range of connectivity features: treatment information, historical trending, infusion status, compliance…
    - Easy pairing between device manager application with the core system
- Ideal for complex, novel drugs administration whilst staying in line with pharma standards.
    - Enables large volume injection, with adjustable parameters (i.e: flowrate, viscosities, dose volume…)
    - It is specifically tailored for biologics to preserve formulation integrity
    - It is compatible with standard cartridges, filling and manufacturing processes

Aria Smart Autoinjector

2023

Company name: Phillips-Medisize

Country: Global

Product name: Aria Smart Autoinjector

Product type: Autoinjector

Date of launch: 31.12.2023

Current development phase: Prototype

Target markets: Global Self Injection

Target clients: Bio Pharmaceutical

Business model: Platform Products

FACT SHEET

PRODUCT DESCRIPTION

Aria is a novel reusable electronic autoinjector, designed to meet current and emerging needs of the self-injection market for biopharmaceuticals. It consists of a reusable electronic power unit, coupled with a disposable cassette, which contains either a 1ml or 2.25mL pre-filled syringe and provides needle safety, using a moveable shield, similar to most disposable devices.

The reusable format significantly improves sustainability over conventional disposable autoinjectors, offers built in Bluetooth connectivity and clear audible and visual feedback to guide users through the injection process. It therefore aims to offer an improved performance vs alternatives in the market, enhanced usability, and a more sustainable product, all whilst offering a competitive cost per injection and fast to market solution. It is being developed as a device platform for multiple therapies and pharmaceutical customers.

APPLICATION AREAS

The Aria Smart Autoinjector is aimed at the subcutaneous self injection market. Due to its reusable nature, with the reusable device part having a 3-year life, it is aimed at the large and growing market of injectable biologic drugs and other self injectables used for chronic, long term, treatment rather than acute, short term, treatments. Due to the flexibility of this platform and the offering of a standard version with a simple user interface and a more advanced version with a screen-based user interface, it can cover a range of dosing and injection regimens from simple once a week low viscosity through to more complex dosing and higher viscosities and volumes up to 2.25ml.

Website: https://www.phillipsmedisize.com/products/smart-autoinjector/

Aria Smart Autoinjector

2023

KEY FEATURES

Operates in a very similar and familiar way to a two-step single use mechanical autoinjector once the cassette has been loaded. It is also a familiar and similar size Aria has sound and visual light indication for injection progress and clear green light and check mark for dose completion with an associated audible sound – dwell time is included in the signalling so no manual counting is required for dwell time once the plunger has stopped Aria includes audible and visual signals for early lifting of device, inserting the wrong/used cassette, battery depleted Aria has a safety feature which locks the cap onto the cassette to prevent removal of the cap until the cassette is inserted in the device The needle sleeve extends when removing the device, locking in the extended position to prevent needlestick injury and contamination.

Maggie® 5.0 Autoinjector

2023

Company name: SHL Medical

Country: Switzerland

Product name: Maggie® 5.0 Autoinjector

Product type: Drug Delivery Device

Date of launch: 18.05.2022

Current development phase: Prototype

Target markets: Global

Target clients: Bio/Pharma Companies

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

Maggie® 5.0 is an innovative, large-volume, cartridge-based autoinjector built with SHL's market-proven Needle Isolation Technology (NIT®). A two-step autoinjector, it was developed with a focus on opening a new pathway for handheld devices to accommodate a wider variety of formulation characteristics, such as larger volumes, higher viscosities, suspension drugs, as well as formulations sensitive to contact with steel and air.

The NIT sub-assembly is based on a pre-attached and sterile needle housed within the device cap. This eliminates the need for patients to manually attach the needle during injection – simplifying the whole injection process while underscoring the interconnected importance of patient safety and convenience. As a cartridge-based technology that features a customizable cannula, Maggie 5.0 paves the way for the possibility of large-volume/high-dose autoinjector combination product development – a significant design attribute trade-off for PFS-based devices.

Website: https://www.shl-medical.com/products-and-services/maggie-5-0-auto-injector/

Maggie® 5.0 Autoinjector

2023

APPLICATION AREAS

In parenteral drug delivery, translational advancements in formulation science open new pathways for large-volume drugs to be deliverable subcutaneously. The outcomes of the most recent pandemic have since highlighted the imminent need for combination products and drug delivery systems that provide a greater level of independence to patients. The development of the Maggie® 5.0 autoinjector technology is thus a result of the convergence of various factors, which include:

1. The global transformation of therapies being delivered from in-clinic to at-home treatment
2. Evidence of intravenous treatments moving to subcutaneous
3. Physicochemical properties of new molecules
4. Drugs that require higher doses and larger presentation volumes
5. The propensity for patients to choose less frequent injections
6. The development of absorption enhancers allows for “fast” delivery of large-volume injections.

Ultimately, the Maggie 5.0 autoinjector is designed to support the safe and effective self-administration of combination products – seamlessly navigating the complexities of drug-device development between pharma and medtech while underscoring the need for a safe and effective device solution in the higher volume therapy (≤ 5.0 mL) range. For specialty treatments that require longer injection times, the Maggie 5.0 autoinjector has been co-developed with an optional injection support pad – an accessory device targeting improved injection adherence and comfort.

KEY FEATURES

The cartridge-based Maggie® 5.0 autoinjector is developed for the delivery of large-volume drugs targeting ≤ 5.0 mL delivered volumes. The device technology combines the usability and convenience of an autoinjector with the delivered volume of an on-body device. The Maggie 5.0 autoinjector also features a form factor that is familiar to end users and is compact enough even for a large-volume/high-dose device. The device is an expansion of SHL’s Maggie family of autoinjectors, which feature the proprietary and market-proven Needle Isolation Technology (NIT®). The NIT is isolated from the cartridge until the point of use and eliminates the need for patients to manually attach the needle during injection – simplifying the whole injection process while underscoring the interconnected importance of patient safety and convenience. On the market since 2017, the NIT has since delivered millions of doses to patients – supporting the injection experience of patients worldwide. The NIT-enabled Maggie 5.0 autoinjector is thus the industry platform of choice in large-volume/high-dosing therapy development that addresses customer requirements for specialty formulations, priming and drug delivery volumes, as well as injection time, cannula size, and injection depth.

- Features: Simple: Easy-to-use device for large-volume/high-dose autoinjections featuring a compact design
- Ergonomic: One-handed operation with continuous audible and visual feedback during injection
- Safe: Device is triggered by push-on-skin needle cover activation that passively locks after the injection; needle is permanently hidden throughout the injection process
- Modular: The market-proven and pre-attached NIT has a modular cannula that supports a variety of needle lengths and gauges to fulfill specific formulation requirements
- Flexible: The platform-based technology can be customized according to client specifications, supported by a commercially available cartridge system.

Immucise Intradermal Injection System

2023

FACT SHEET

Company name: Terumo Corporation

Country: Japan

Product name: Immucise Intradermal Injection System

Product type: Drug Delivery Device

Date of launch: 01.02.2023

Current development phase: Commercialization

Target markets: Pharmaceutical Industry

Target clients: Pharmaceutical Companies

Business model: Direct Sales

PRODUCT DESCRIPTION

Expanding the potential of intradermal injection. Immucise was born from Terumo's passionate spirit to achieve its mission.
The developed needle structure in combination with a vertical injection aims for a simple and precise intradermal injection, to deliver drug to the dermis layer.

APPLICATION AREAS

The dermis is extremely rich in various resident and recruited types of dendritic cells, potentially resulting in quantitatively or qualitatively superior immune responses compared to intramuscular or subcutaneous injection. Vaccine is thus one of our main applications we target. We have already reported clinical efficacy and safety of seasonal influenza vaccine using Immucise Intradermal Injection System. Moreover, in the past decades, numerous studies by intradermal administration showed dose-sparing effects in several vaccines, such as seasonal influenza and rabies. WHO has also authorized effective antigen uptake and dose-sparing strategy by intradermal administration. As a next step, we are currently investigating the device's potential in wider applications such as allergy vaccines, cancer treatments, and emergency areas aiming for rapid pharmacokinetics. We see huge potential in intradermal injection and aim to seek for new potential of the administration route, and ultimately to contribute to global health by utilizing Immucise.

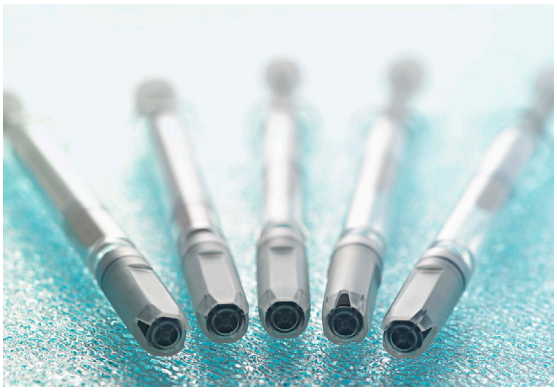
KEY FEATURES

The three keys are the needle, the limiter ring, and the flange. The needle is 33G in diameter, and its length is 1.15 mm. With this needle length, we aim for intradermal injections to 2 months old infants to elderly patients (>65). The limiter ring's structure is intended to stretch the skin and help needle insertion in a vertical direction. The flange is a guide for proper pressure; to help preventing the needle to be inserted in the subcutaneous layer, and this short needle is meant to be inserted into the dermis without leakage.

Website: www.terumopharmaceuticalsolutions.com

Daikyo® Crystal Zenith® 2.25mL Insert Needle Syringe System

2023



Company name: West Pharmaceutical Services, Inc.

Country: United States

Product name: Daikyo® Crystal Zenith® 2.25mL Insert Needle Syringe System

Product type: Insert Needle Syringe System

Date of launch: February 2023

Current development phase: Commercialization

Target markets: Predominantly North America and Europe for biologic molecule drug development

Target clients: Biopharmaceutical Companies

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

The Daikyo® Crystal Zenith® (CZ) 2.25mL insert needle is a break-resistant, polymer syringe of choice to protect larger volume sensitive molecules during self-administration. For drug developers wishing to avoid glass, this syringe system protects delicate molecules as there is no silicone oil added for functionality, no lubricants, tungsten, or glue, making it a low-risk solution to the challenges of particles, interactions, and protein aggregation. Their break-resistance also reduces concern of injection malfunctions during high force, large volume injections.

APPLICATION AREAS

The hospital to home trend of moving drug administration out of the hands of clinical settings and into the hands of patients themselves has been exacerbated by the COVID-19 pandemic. A new 2.25mL auto-injector market has been created after human factor studies showed patients can tolerate >10 seconds self-injection. Administering a dose of up to 2.25mL via an auto-injector in a non-clinical setting is a fantastic option to widen patient choice as this self-administration is typically used to treat a range of chronic illnesses such as atopic dermatitis, asthma, migraine & plaque psoriasis. These are conditions previously would have required more frequent injections to achieve the therapeutic dose, and would have been administered via a healthcare professional, commonly in a clinical setting. One approved drug in this injection volume is for the treatment of plaque psoriasis which required 2 doses at week 0, 1 & 2 and every two weeks thereafter. With the availability of a 2.25mL primary container and auto-injector, this packaging option will cut the number of injections to achieve a therapeutic dose in half.

Website: www.westpharma.com/cz-syringe

Daikyo® Crystal Zenith® 2.25mL Insert Needle Syringe System

2023

KEY FEATURES

One key feature is the glue used for needle fixation to the syringe and the tungsten pin used for glass-forming are sources of contamination within the primary container. In addition, glass cartridges can break during transportation and during injection due to high force generated in delivery larger volume injections, which can render the auto-injector as redundant. There are key positive differentiators with the COP CZ 2.25mL IN syringe system because it:

1. Protects modern biologics
2. Mitigates risk of breakage Protects Modern Biologics:
    - There is no added silicone oil for functionality, no lubricants, no glue, and no tungsten used in the manufacture of this syringe system
    - It has a low potential for extractables
    - It is manufactured in an endotoxin-controlled environment Mitigates Risk of Breakage: Drug developers can limit their concerns association with syringe breakage during high-force, larger volume injections. Also, the primary polymer container will allow more faith in the delivery system process as there is a less likeliness of breakage.

The syringe system has no added silicone oil for functionality enabling optimum compatibility with the precious drug product. Unlike glass syringes, there is no tungsten or glue used to manufacture the barrel assembly, meaning there is a clear positive differentiator between the CZ syringe system and the incumbent. This CZ syringe is manufactured with tight dimensional control and with a clean and simple needle attachment method. Improved flange strength has been designed into this engineered polymer to reduce the risk of breakage inside auto-injectors when high forces are exerted by firing springs or with viscous drugs.

West Ready Pack™ with NovaPure® Stoppers, Flip-Off® CCS Seals and Corning Valor® RTU Vials with SG EZ-fill® Technology

2023

FACT SHEET

Company name: West Pharmaceutical Services, Inc.

Country: United States

Product name: West Ready Pack™ with NovaPure® Stoppers, Flip-Off® CCS Seals and Corning Valor® RTU Vials with SG EZ-fill® Technology

Product type: Stoppers, Seals and Vials

Date of launch: February 2023

Current development phase: Commercialization

Target markets: North America, Europe and Asia Pacific

Target clients: Biopharmaceutical Companies

Business model: Direct Sales

PRODUCT DESCRIPTION

Through a strategic partnership with Corning, one of the world's leaders in glass science, West is redefining the future of containment solutions by creating a truly integrated system that will help de-risk customers' drug development and manufacturing processes by providing comprehensive product information in one DMF and end-to-end support. West is pleased to present our first offering from the partnership with the introduction of Ready Pack with Corning's Valor® RTU Vials with SG EZ-fill Technology, a revolutionary new pharmaceutical glass packaging technology. Valor RTU Vials with SG EZ-fill Technology pharmaceutical packaging helps to enhance the storage and delivery of drugs, provide more reliable access to medicines essential to public health, and optimize production efficiency. This purpose-built pharmaceutical glass is specifically designed to address the challenges of today's manufacturing operations. Ready Pack, NovaPure, and Flip-Off are trademarks or registered trademarks of West Pharmaceutical Services, Inc. in the United States and other jurisdictions. Valor® Glass is a trademark of Corning Incorporated.

APPLICATION AREAS

The combination of Ready Pack NovaPure® Stoppers, Flip-Off CCS Seals & Valor RTU Vials with SG EZ-fill Technology provides the following benefits to drug developers:

- Proven Container Closure Integrity (CCI) including the ability to maintain cold storage CCI when cooled to and stored at -80°C
- Sterile ready-to-use format that can be directly introduced into filling operations, eliminating the need for component preparation
- Premium components with the tightest particulate specifications in West's offering
- Availability in quantities suitable for small-scale filling operations with continuity to quantity options for large scale commercial operations.

Website: www.westpharma.com/products/vial-containment-solutions/west-ready-pack-system

West Ready Pack™ with NovaPure® Stoppers, Flip-Off® CCS Seals and Corning Valor® RTU Vials with SG EZ-fill® Technology

2023

KEY FEATURES

West Ready Pack® high quality vial containment system consists of sterile ready-to-use NovaPure® stoppers, Flip-Off® CCS (clean, certified, sterilized) seals and Valor® Glass vials in a proven system to give you peace of mind that the components work together as a complete vial containment system.

- Ready Pack now includes Valor® Glass vial technology for highly sensitive drugs with proven CCI including temperatures as low as -80C and eliminates delamination, provides a lower extractables profile, reduces glass particle generation, prevents crack and reduces damage and breakage while enabling higher throughput through smoother filling line operations to decrease the total cost of ownership.
- Ready Pack components are available for order in small minimum order quantities from stock.
- Ready Pack components are particularly well-suited for R&D purposes or small filling operations and are designed to support a smooth transition from early-stage pilot manufacturing to larger commercial-scale operations.

IDC® New Desiccant Closure

2023

Company name: Airnov Healthcare Packaging

Country: France

Product name: IDC® New Desiccant Closure

Product type: Desiccant Closure

Date of launch: 01.02.2023

Current development phase: Pilot

Target markets: Global pharmaceutical, nutraceutical & diagnostic market

Target clients: Pharmaceutical, Nutraceutical & diagnostic customers

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

IDC® (Integrated Desiccant Closure), is the latest innovation that has been developed and launched by Airnov, adding to its already extensive range of desiccant closure solutions serving the health and medical packaging industry.

The unique design closure is expected to be adaptable on SP 400 bottles which also include a child-resistant system and a tamper-evident disk on the top. The company's inspiration for designing the product was to reduce the number of components needed to have a complete desiccant system for pharmaceutical bottles. Typically, systems which ensure the protection of medicines inside a bottle are comprised of numerous components, including a two-piece child resistant closure (CRC), an added desiccant and an induction seal, as well as the bottle itself.

Compared to these traditional multi-component systems, Airnov offers a solution that is made up of just two parts. Because the desiccant has been integrated into the closure, Airnov eliminates the need for a separate desiccant. Airnov's new IDC is also designed to support companies operating in the pharmaceutical, nutraceutical and diagnostic sectors by removing several operational steps on their filling lines. Indeed, with IDC, no desiccant needs to be dropped and no induction seal operation is required online.

These efficiency gains also translate into significant environmental footprint benefits versus the incumbents currently on the market, this development being in line with Airnov's commitment to include sustainability as a key consideration in the development of new products.

Website: https://www.airnov-healthcare.com/

IDC® New Desiccant Closure

2023

APPLICATION AREAS

Airnov's newly launched IDC® (Integrated Desiccant Closure) has a wide variety of applications and use cases. The product, which is patent protected, can be used for the protection of all sensitive products in need of safeguarding against humidity. This includes a number of pharmaceutical products and medicines that risk being spoiled by the invasion of moisture into their packaging. Specifically, the IDC was developed for use in the pharmaceutical, nutraceutical and diagnostic sectors in a bid to unify packaging standards globally. In the US and European markets, there are different sizes and approaches to standard bottles and the ways in which desiccants are integrated into them.

With newly launched IDC®, Airnov is offering a solution that covers both market standards, reducing the need for complex bottle packaging in each region Having listened to customers' opinions, Airnov identified several needs and applications that the IDC had to help fulfil. These included:

- Using the same standard bottle around the world
- Having standardised/uniform packaging in both the US and Europe
- Integrating desiccant into the closure system
- Adapted the tamper-evident system for standard neck finish
- Leveraging a CRC push and turn system

It is important to note that the price of this product will depend on the configurations that will be adjusted to best suit the customer's needs.

KEY FEATURES

The IDC® (Integrated Desiccant Closure) has many unique feature designs, some of which being protected by patents, that provide numerous benefits to those operating within the pharmaceutical, nutraceutical and diagnostic sectors. Some of the most important features and benefits are listed below.

- IDC is developed to be compatible with a large range of SP 33/400 bottles, providing flexibility when selecting a compatible bottle supplier
- Inside the integrated desiccant chamber, the fill can be made of different sorbents, including silica gel, molecular sieve or EQius ®
- The new tamper-evident system is located on top of the closure. Through the colour contrast between the upper and the inner cap, the first opening is made obvious to the end-user
- The child resistant system is integrated with a push and turn. This makes it easy to open and reclose for a wide section of the public, including for the elderly
- Once reclosed, the IDC is airtight, ensuring the in-use shelf-life for sensitive products. These features are combined to provide a high-performance solution to Airnov's customers

BD Effivax™ Glass Prefillable Syringe

2023

Company name: BD Medical - Pharmaceutical Systems

Country: France

Product name: BD Effivax™ Glass Prefillable Syringe

Product type: Glass Prefillable Syringe

Date of launch: 13.09.2022

Current development phase: Commercial

Target markets: Global

Target clients: Pharmaceutical companies

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

BD Effivax™ Glass Prefillable Syringe, the next generation vaccine syringe, will further help customers meet the stringent demands of today's vaccine manufacturing through design enhancements focused on fill/finish and container reliability. Through improved quality specifications, BD Effivax™ is designed to reduce the risk of line stoppage and improve the total cost of ownership, manufacturing capacity and supply availability.

APPLICATION AREAS

BD Effivax™ is a single use SCF™ (Sterile, Clean, ready to Fill) syringe, designed for intramuscular or subcutaneous injection of medical products for the Vaccines market segment.

KEY FEATURES

BD Effivax™ Glass Prefillable Syringe features enhanced technology that builds on company's decades of expertise in the prefillable syringe market and supports customers' manufacturing needs. This is a next-generation glass prefillable syringe (PFS) that sets a new standard in performance for vaccine PFS with new and tightened specifications for processability, cosmetics, contamination and integrity. BD Effivax™ is a step forward in product performance and carrier for future innovation thanks to its new and tightened specifications for processability, cosmetics, contamination and integrity, and enhanced and harmonized control plan across manufacturing sites. BD Effivax™ comes with regulatory documentation and support as well as technical deployment support.

Website: https://go.bd.com/effivax

Congruence Autoinjector with Injection Pause™ Technology

2023

Company name: Congruence Medical Solutions

Country: United States

Product name: Congruence Autoinjector with Injection use Technology

Product type: Autoinjector

Date of launch: Marketing Launch in 2022

Current development phase: Evaluation Devices Available

Target markets: Global

Target clients: Pharmaceutical & Biotech

Business model: B2B, Licensing

FACT SHEET

PRODUCT DESCRIPTION

The Congruence Autoinjector is a next generation disposable autoinjector platform, designed for self-injection applications. It utilizes a proprietary compressed-gas power source making it compact yet powerful for viscous formulations. It also incorporates novel usability features, such as Injection Pause™ to mitigate risk of premature removal from the skin prior to end of dose. The Congruence Autoinjector provides capabilities beyond legacy autoinjectors to meet current and future needs of patients and the biopharma market. It offers:

1. ENHANCED USABILITY, and in particular addresses the perennial issue of premature removal from skin
2. HIGH FORCE CAPABILITY to rapidly deliver larger volume (2mL and greater) and/or higher viscosity (30 to 100+cP) drugs and/or through fine injection needle
3. GREATER VERSATILITY - suitable not just for higher viscosities and larger volumes, but also “standard” viscosities and volumes
4. EASIER CUSTOMIZATION for faster, lower risk device development
5. INCORPORATES STANDARD PRIMARY CONTAINERS, such as standard glass or polymer pre-fillable syringes
6. SUSTAINABILITY ALIGNED, through compact size reducing materials, supply chain costs, and minimizing drug waste with Injection Pause feature

Website: https://congruencemedical.com/autoinjector/

Congruence Autoinjector with Injection Pause™ Technology

2023

APPLICATION AREAS

The Congruence Autoinjector platform is designed to have broad suitability across a wide range of self-injection drugs (volume, viscosity) and broad patient populations (autoimmune, oncology, neuro, dermatology, etc.). The platform's ability to deliver viscous drugs and/or larger volume doses means it can be used for delivering high-strength biologic formulations. As the platform can be easily customized, it is suitable for use across the drug lifecycle (including during drug development) and/or across multiple formulations or drugs in a portfolio.

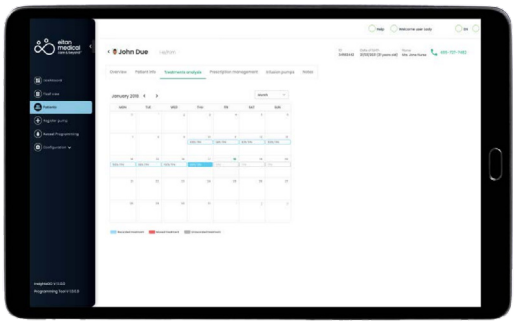
KEY FEATURES

The Congruence Autoinjector has several key features that combine to provide a unique combination of benefits in one platform:

- ENHANCED USABILITY
- INJECTION PAUSE feature stops an injection if the device is removed from skin before end of dose, ensuring no drug is lost, and the VISUAL DOSE PROGRESS INDICATOR indicates the dose remaining. The patient can then have an informed conversation with their HCP and/or continue to dose completion, as the Pause feature allows needle reinsertion and for the injection to resume.
- HIGH FORCE DELIVERY. Can rapidly deliver larger volume (2mL and greater) and/or higher viscosity (30 to 100+cP) drugs and/or through fine injection needle. Shown to deliver 2mL 100cP solution in 15 seconds from a 2.25mL glass PFS with a 27G staked needle.
- 2-STEP USE (Push-on-skin actuation), with PASSIVE NEEDLE SAFETY
- IMPERCEPTIBLE ACTUATION AND RECOIL FORCES. A Congruence user study showed these forces were imperceptible and well accepted.
- COMPACT SIZE. The 2.25mL Congruence Autoinjector (14.1 cm height, 2.4cm wide) is the same height or smaller than current 1mL Autoinjectors. ENABLING RAPID DEPLOYMENT
- INCORPORATES STANDARD PRIMARY CONTAINERS - glass or polymer prefillable syringes or cartridges
- VERSATILE PLATFORM. The proprietary power source can be readily adjusted to deliver a range of different drug viscosities and volumes. Furthermore, the same form factor could be used for both 1mL and 2.25ml PFS.
- RAPID CUSTOMIZATION lowers risk device development, minimizes the time and cost of customizing injection time, syringe (or cartridge) size and drug fill volume. ALIGNED WITH SUSTAINABILITY OBJECTIVES
- COMPACT SIZE enables reduced transportation costs and a smaller footprint in the drug cold chain
- INJECTION PAUSE feature ensures that drug is not wasted upon inadvertent, premature autoinjector removal from the injection site.

Eitan Insights™

2023



Company name: Eitan Medical

Country: Israel

Product name: Eitan Insights

Product type: Connected Devices & Wearables

Date of launch: November 2023

Current development phase: Commercialization

Target markets: Global

Target clients: Pharmaceutical Companies, Biopharmaceutical Companies & CMO/CDMO Distributor

Business model: Direct Sales

FACT SHEET

PRODUCT DESCRIPTION

Eitan Insights™ is a cloud-based platform, providing clinicians and homecare providers remote visibility of treatment date from Eitan Medical's suite of advanced infusion and drug delivery devices, which include the Sapphire™ infusion pump platform, Avoset™*, a connected infusion system for the homecare market, and Sorrel™ a wearable drug delivery platform designed for on-body subcutaneous injections.

Eitan Insights™ empowers healthcare providers to confidently provide infusion and drug delivery therapies from the comfort of the patient's home.

*Avoset is not for sale, pending regulatory approval/clearance. Specifications are subject to change.

Website: www.eitanmedical.com

Eitan Insights™

2023

APPLICATION AREAS

The Eitan Insights platform is intended for the three Eitan Medical drug delivery product lines: Sapphire™, Avoset™, and Sorrel™, specifically in the homecare market. Eitan's infusion and drug delivery solutions service patients across the continuum of care, in prehospital medicine, acute-care settings, emergency medical services, infusion centres, hospitals, and in patients' homes. Through data collection and cloud-based processing, Eitan Insights™ provides clinicians with infusion data and actionable insights in near real-time. Analyzed aggregated patient data allows caregivers to identify treatment patterns and enable them to make data-driven decisions to improve care outcomes. The recorded patient data offer a deeper view of the patient treatment status and allows for continuity of care throughout the course of treatment and despite any changes in staffing/attending healthcare professionals. Additionally, the connected platform aims to improve the patient experience by providing patients with reassurance in their at-home infusion therapy. Auto-documented data, the reduced need for ad-hoc home visits from clinicians, and the knowledge of remote access to treatment data increase patients' confidence in their treatment.

Monitoring may also increase patient compliance to support better health outcomes. The Sapphire infusion pump family is commercially available globally, while both the Avoset and Sorrel platforms are currently under regulatory review and various stages of development. Eitan Insights is not currently commercially available with launch anticipated in 2023.

KEY FEATURES

From mobile medical apps that support the clinical decisions doctors make every day to artificial intelligence and machine learning, digital technology is driving a revolution in health care. Digital health tools have the vast potential to improve the ability to accurately diagnose and treat disease and enhance the delivery of healthcare.

Eitan Medical recognized the need to implement innovative digital health solutions within the infusion and drug delivery space and saw the potential for the improved healthcare outcomes it could provide. This, along with the shift of hospital to homecare—which created a strong need for connectivity—inspired the creation of the Eitan Insights™ connected drug delivery platform. The platform tracks treatment data, as well as the infusion device's location, allowing care teams to assess events and conduct remote follow-ups on treatment progress. Eitan Insights™ also allow clinicians to virtually view their patients' pump alarms and event logs, enabling efficient alarm troubleshooting remotely and viewing problems in real-time. Additionally, the system offers homecare providers geo-tracking of the devices to manage their pump fleet, paving the path for improved operational efficiency in remote care settings.

SCHOTT TOPPAC® 1ml lg

2023

FACT SHEET

Company name: SCHOTT Pharma & Co. KGaA

Country: Germany

Product name: SCHOTT TOPPAC® 1ml lg

Product type: ml lg PFS out of COC material

Date of launch: 2022

Current development phase: N/A

Target markets: low temperature stored drugs (e.g. mRNA vaccine)

Target clients: Biotech

Business model: N/A

PRODUCT DESCRIPTION

The COVID pandemic is transitioning to an endemic. Similar to the flu, a periodic booster shot could greatly improve the protection for risk for high-risk patients against future COVID strains.

In order to make it faster and easier for Health Care Workers, reduce drug waste and reduce potential medical errors, a single dose drug package is required in this phase. Prefilled syringes (PFS) are a preferred choice. However, the extremely low cold chain temperature provides some challenges to the existing PFS.

SCHOTT TOPPAC® 1ml lg syringe could be a preferred PFS solution for this extremely low temperature range. An extensive data package is available that shows superior performance for the entire syringe system at these extremely low temperatures (up to -80°C): container closure integrity, break-loose and gliding forces, plunger movement, sub-visible particles, and even LNP (lipid nanoparticles) stability.

APPLICATION AREAS

Various kinds of drugs that need to be stored at extremely low temperatures (up to -80°C)

- COVID vaccines
- mRNA vaccines
- other mRNA therapeutic applications
- cell & gene therapy

Website: https://www.schott-pharma.com/mrna

SCHOTT TOPPAC® 1ml lg

2023

KEY FEATURES

It is a PFS made of Cyclic Olefin Copolymer (COC) which has a similar thermal expansion coefficient as the rubber components which ensures the container closure integrity up to -80°C. The COC material is exceptionally inert, no ion release, no heavy metals and low adsorption. This is also confirmed in our LNP stability study where we compared the stability of LNP's in glass vials and COC syringes. SCHOTT Pharma´s proprietary cross-linked siliconization process supports great injection forces, even after multiple cycles of freeze-thawing while still being the benchmark for extractable silicone quantity and sub-visible particle load. The full system offering incl. plunger that minimize the plunger movement during challenging freezing and transport conditions and therefore keeps the sterility barrier intact.

EZ-fill Smart – Nest & Tub

2023

FACT SHEET

Company name: Stevanato Group

Country: Italy

Product name: EZ-fill Smart - Nest & Tub

Product type: Nest & Tub platform for pre-sterilized vials

Date of launch: 01.11.2022

Current development phase: Design Verification Testing

Target markets: Biologics & Biosimilars (Incl. GT and ADCs), mRNA Tech, Vaccines, Cytotoxic, Hazardous Drugs & High Value Small Molecules

Target clients: Pharmaceutical Companies, CM & CDMO, CRO

Business model: Supply of pre-sterilized vials in Nest & Tub configuration

PRODUCT DESCRIPTION

Leveraging our market-leading EZ-fill® technology, Stevanato Group developed EZ-fill Smart™: an enhanced version of our pre-sterilized platform aiming to make RTU vials a standard, ultimately increasing patient safety. The secondary packaging is redesigned to yield a significant reduction of contamination risks during customers operations. This optimized platform features no glass-to-glass and no glass-to-metal contact process which improves quality and integrity of the vials throughout the product life cycle. By using biopolymers and reusable material for the packaging, EZ-fill Smart Nest & Tub is a more sustainable solution for the industry.

APPLICATION AREAS

EZ-fill Smart Nest & Tub is designed to face the needs of Pharmaceuticals companies working with Biologics & Biosimilars (Including Gene Therapy and Antibody Drug Conjugates), mRNA technologies , Vaccines, Cytotoxic, Hazardous Drugs & High Value Small Molecules, and in general those focused on quality of the process and patient safety. The new EZ-fill Smart packaging can be processed both on combi lines and on dedicated lines for nested vials, bringing value in the drug development and manufacturing.

Website: https://www.stevanatogroup.com/en/offering/drug-containment-solutions/ez-fill-smart/

EZ-fill Smart - Nest & Tub

2023

KEY FEATURES

- Transparent polymer film reducing >90%* particles generated compared to Tyvek Lid
- Tub re-design studied to guarantee machinability on already installed equipment
- Use of biopolymers and weight reduction in Nest & Tuband of reusable materials for External boxes leading to improved sustainability
- Compatible with VHP and EtO sterilization methods

On-Body Delivery System for the treatment of Acute Post-Operative Pain

2023

FACT SHEET

Company name: Stevanato Group, in Partnership with Bexso

Country: Italy (SG), United States (BB)

Product name: On-Body Delivery System for the treatment of Acute Post-Operative Pain

Product type: On-Body Delivery System

Date of launch: Under Development

Current development phase: Under Development

Target markets: United States, Europe, Canada

Target clients: Pharmaceutical & Biotech Companies

Business model: Partnership-based

PRODUCT DESCRIPTION

Stevanato Group's On-Body Delivery System is being developed in collaboration with Bexson Biomedical Inc. – an early-stage US-based biopharmaceutical company – for the subcutaneous treatment of moderate-to-severe acute post-operative pain.

The therapy is based on a new formulation of a controlled substance (ketamine), providing an alternative to highly addictive and easily misused opioids. By combining this new therapy with a state-of-the-art On-Body Delivery System, patients will be able to self-administer controlled doses of pain medication at home.
The device is composed of a disposable pod with a pre-filled and pre-loaded 3mL cartridge and a controller which is reusable up to 10 times. The controller has the ability to interrogate each pod and only function when an appropriate unused Pod is attached through a patented magnetic-coupling drive system. At completion of the therapy using the prescribed number of pods, the controller locks-out and is no longer usable. This provides for extended controlled therapy while reducing the single costs of each dose and the associated environmental impact of the controller's electronic components.

The device is fully programmable and capable of delivering micro-precision basal doses and on-demand bolus injections, making it particularly suited for complex injectable therapies like pain management. It has a simple user interface including buttons, visual indications and icons, providing audible, visual and tactile feedback. It also comes with a tamper resistant feature to mitigate potential abuse or misuse of the controlled substance. The device is highly modular and can accommodate small-molecule formulations for many other indications, such as mental health disorders like Treatment-Resistant Depression and Post-Traumatic Stress Disorder.

Website: https://www.stevanatogroup.com/en/offering/drug-delivery-systems/proprietary-and-licensed-devices/on-body-delivery-system/

On-Body Delivery System for the treatment of Acute Post-Operative Pain

2023

APPLICATION AREAS

Stevanato Group's On-Body Delivery System is being developed for the delivery of BB106, Bexson Biomedical's innovative ketamine formulation for the subcutaneous treatment of acute post-operative pain. Every year tens of millions of invasive surgeries are performed in the United States, with over 70% of patients reporting moderate-to-severe pain[1].

Bexson Biomedical's BB106 provides a safe and effective alternative to opioids, commonly prescribed for post-operative pain management, but considered a gateway to opioid addiction. With over 10 million people misusing prescription opioids every year in the United States alone[2], the result is a high number of hospitalizations and deaths from overdose. Therefore, the healthcare industry needs a non-opioid pain management solution that is designed to reduce dependency on opioids and, at the same time, is convenient and effective for administration in the home setting. Compared to current ketamine intravenous infusions that have a high procedural burden and high cost, Stevanato Group's On-Body Delivery System is designed to enable dynamic and convenient subcutaneous delivery for patients. The device is highly modular and can accommodate small-molecule formulations for many other indications, such as mental health disorders like Treatment-Resistant Depression and Post-Traumatic Stress Disorder.

[1] Gan et al., 2017; 2013

[2] 2019 National Survey on Drug use and Health, 2020

KEY FEATURES

The main benefits of subcutaneous delivery of ketamine using a semi-reusable On-Body Delivery System with disposable pod and reusable controller are:

- Continuous multi-day controlled therapy
- High dosing accuracy
- Tamper resistant to mitigate misuse and abuse
- Uses standard 3ml cartridge
- Delivered "ready-to-use"
- Automated and convenient for patients
- Simple user interface
- Suitable for clinic or home setting
- Lower therapy cost per dose
- Reduced environmental impact of electronic components
- Ability to integrate digital health applications

YpsoMate 5.5

2023

Company name: Ypsomed

Country: Switzerland

Product name: YpsoMate 5.5

Product type: Large Volume Injector

Date of launch: 31.12.2023

Current development phase: Prototype

Target markets: Global

Target clients: Pharmaceutical Companies

Business model: Commercialized in collaboration with partnering pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

YpsoMate 5.5 autoinjector is an automated injection device for 5.5 mL pre-filled glass syringes suitable for all patient groups. The device is triggered by push-on-skin activation which is convenient, ergonomic and preferred by patients.

- Taking handheld self-injection beyond volumes of 2.0 mL
- New ready-to-use 5.5 mL staked-needle pre-filled syringe format
- Market-proven two-step YpsoMate technology
- Bespoke user interface increases confidence during injection
- Easy customisation for a broad range of fill volumes, viscosities and injection times

APPLICATION AREAS

With YpsoMate 5.5, Ypsomed extends the limits of current handheld autoinjectors and opens up the new segment of large volume, high-rate injections in combination with SCHOTT Pharma's syriQ BioPure® 5.5 mL RTU PFS. As such, YpsoMate 5.5 offers new administration options for biologics in therapy areas such as autoimmune diseases, rare diseases and immuno-oncology. After successful completion of extensive concept and human factors testing, Ypsomed has initiated a development and industrialisation programme, together with its lead customers, to bring YpsoMate 5.5 into clinical studies. Non-GMP devices and syringes are available for feasibility testing with further drug candidates.

Website: https://yds.ypsomed.com/en/products/autoinjectors/ypsomate-5-5.html

YpsoMate 5.5

2023

KEY FEATURES

YpsoMate 5.5 represents the newest member of the YpsoMate autoinjector family, extending the design space of today's handheld autoinjectors and enabling the administration of injection volumes in the 2.0–5.5 mL range. YpsoMate 5.5 is based on the proven YpsoMate 2.25 Pro technology and leverages a similar type of constant force drive mechanism. This ensures that large drug volumes are injected reproducibly, even with higher-viscosity formulations, which would not be possible using a conventional compression spring. Different spring configurations with different force profiles allow the system to be adapted to accommodate a broad range of drug viscosities, up to 30–50 cP. Furthermore, it allows the adjustment of the flow rate to the desired target value. Configurable injection times are in the range of approximately 10–60 s for an injection volume of 5 mL.

The YpsoMate 5.5 autoinjector features the market-proven and broadly accepted two-step handling principle: the user removes the cap and injects the drug by pushing the device against the skin. As with the other YpsoMate family members, the design is suitable for fully automated manufacturing. YpsoMate 5.5 can be leveraged for a broad range of applications, and offers quick time-to-market and attractive pricing models. As such, YpsoMate 5.5 is the world's first staked-needle-syringe-based autoinjector for volumes above 2mL.

Digi-Cap Smart Child-Resistant Closure

2023

Company name: Berry Global

Country: France

Product name: Digi-Cap

Product type: Smart Child Resistant Closure

Date of launch: February 2023

Current development phase: Commercial

Target markets: CRO, Biotech, Biopharma, pharmaceutical

Target clients: Clinical Trials, Research Studies, Drug Development Trials, Academic Purposes

Business model: Direct - Distribution

FACT SHEET

PRODUCT DESCRIPTION

Berry Digi-Cap digital child-resistant closure is ideal for clinical trials, drug development, research and academic studies. Patient behaviour data is analysed to enhance medicine adherence and gain insights into its effectiveness relative to the prescribed regime.

A microprocessor incorporated into the closure records patient openings and stores usage history in its memory. In addition, the closure continuously monitors and logs temperature storage levels, which can provide valuable data for research and development. The 38mm child-resistant closure features a fine-ribbed sidewall for enhanced grip, providing ease of use for patients. The push-down and turn child-resistant mechanism ensures product security, and clear pictorial opening instructions further simplify the patient experience. An audible click feature gives a sound indication of opening for added reassurance.

APPLICATION AREAS

Clinical trials, research studies, drug development trials, academic purposes. Patient profile:

- Clinical trials patients who are actively engaged in the treatment

Website: https://www.berryglobal.com/en/product/caps-closures/38400-digicap-closure-13748473

Digi-Cap Smart Child-Resistant Closure

2023

KEY FEATURES

Packaging Specifications:
- 2 piece push and turn closure.
- 38 mm neck size.
- SPI-400.
- Unique audible ¨clic¨ feature.
- Pictorial opening instructions on the top surface.
- Floating liner.
- Compatible with Berry Stock items.
- CE and FCC compliant.

Technology Features & Specifications:
- Electronic PCB: Mounted between inner & outer components without changes to filling lines.
- Long battery life and ability to communicate with a smartphone for remote monitoring.
- Integrated Clock/Calendar: Allows for easy scheduling of medication dosage times.
- Temperature Monitoring: Ensures medication is stored at safe temperatures to maintain effectiveness.
- Data transfer: Information stored on PCB is transferred to phone or other NFC device when placed nearby.

Optional Features:
- LED lights can be incorporated on the PCB to show whether or not an opening is on time, too early, etc.

RS01X Connected and Intelligent Single-Dose Dry Powder Inhaler

2023

FACT SHEET

Company name: Berry Global

Country: France

Product name: RS01X

Product type: Dry Powder Inhaler

Date of launch: June 2021

Current development phase: Commercial

Target markets: Asthma, COPD, Respiratory Diseases

Target clients: Asthma and COPD Companies

Business model: Direct

PRODUCT DESCRIPTION

RS01X is a digital Capsule based Dry Powder Inhaler with built-in sensors and digital services. Used mainly for the control and treatment of any lung disease or any systemic disease for which inhalation is the chosen route of delivery.

- Improved compliance to the patient: Improves inhalation techniques.
- Improved medication adherence: reduces drug wastage and wrong administration techniques.
- The new RS01X™ tracks inhaler use and connects to a companion app which provides personalized guidance to improve adherence and inhaler technique.

Berry has put in place a global agreement with Amiko Digital Health and the RS01X is integrated with Amiko's Respiro™, a digital medicine platform for use with connected inhalers that combines data, artificial intelligence (AI), and elegant digital experiences to upgrade respiratory care.

RS01X meets the demand for high accuracy, integrated digital health solutions; this has resulted from the growing trend towards precision medicine, where targeted, individualised care is provided for each patient, tailored to their specific profile and medical history.

APPLICATION AREAS

COPD, Asthma, respiratory lung disease

Website: https://www.berryglobal.com/en/product/medical-devices/412mm-64mm-capsule-based-rs01x-13207315

RS01X Connected and Intelligent Single-Dose Dry Powder Inhaler

2023

KEY FEATURES

The RS01X automatically captures, stores and encrypts objective inhaler data, including user generated inhalations through the inhaler, and connects wirelessly to the Respiro app. The Respiro app serves as a companion to the inhaler, reminding patients when it is time to inhale a dose and providing personalised insights and tips powered by data and artificial intelligence to help patients self-manage more effectively. Patients can instantly and securely choose to share their data with healthcare providers both in person and digitally to improve collaborative.

RS01X™ Maintains Equivalent RS01™ Usability and Performance decision-making and enable data-driven treatment adjustments.