# **Snews** update 39

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Systems & Solutions for Pharma & Biotech

Containment Solutions Drug Delivery Systems Digital Therapy Support



gerresheimer

# New and innovative **Ready-To-Fill (RTF) vial** solutions

More flexibility, more productivity, more safety: With Gx<sup>®</sup> Ready-To-Fill (RTF) Vials you can only win. Our Gx® RTF glass vials made of borosilicate glass type I come washed and sterilized - so you can start filling immediately on your existing lines. Ready-To-Fill products allow the pharma industry to focus on their core competencies and save the costs and time required for washing and sterilizing primary packaging. As a consequence, drugs can be brought to market more quickly and with lower overall costs in the production process.

Contact our experts: rtfvials@gerresheimer.com

# **Gx<sup>®</sup> Elite Vials** in RTF quality

We are presenting Gx<sup>®</sup> Elite, a product line of glass injection vials designed to maximize patient safety and production efficiency. Superior quality and shatter resistance are the key priorities of the range. The advanced primary packaging solution is particularly suitable for

sophisticated drugs such as biopharmaceuticals and cytostatics. We offer the Gx<sup>®</sup> Elite platform in clear and amber glass in 2 ml / 2R to 30 ml / 30R sizes. Gx® Elite vials are part of our extensive Ready-To-Fill (RTF) portfolio.



Gx<sup>®</sup> Elite vials are also available in the new, optimized EZ-fill Smart<sup>™</sup> packaging. The innovative RTF packaging platform simplifies the filling process, cuts costs and reduces particle load by over 90 % by swapping Tyvek\* lids for a polymer sealing film. This means that no Tyvek fibers or adhesive particles are released when peeling off the film

As a result, the risk of such particle contamination is considerably reduced. At the same time, EZ-fill Smart<sup>™</sup> packaging lowers the customer's carbon footprint by using biopolymers, reusable materials and a resource-saving sterilization process (VHP), for example.

Sustainable

**Containment Solutions** 

# EZ-fill Smart<sup>™</sup> packaging



immediately before the filling process.



### **De-risking** of fill & finish



### Lower particles improved quality



# Supply chain security



# Reduced CO<sub>2</sub> footprint



Alternative sterilization



**Reduced TCO** 

# **Gx<sup>®</sup> COP Vials:**

Ice cold solution for biopharmaceuticals

Gerresheimer launches a particularly good solution for the filling and storage of sensitive biopharmaceutics with its vials made of COP (Cyclic Olefin Polymer). This enables, for example, mRNA active ingredients to be stored at cryogenic temperatures from -80°C. We thus extend our High-Value-Solutions in the field of injection vials by a product made of high-quality plastic which combines the best material properties of glass and plastic. The vials are crystal clear, particularly break-resistant and have good oxygen and moisture barriers. They can be filled and packaged in various filling systems, for example in multi-filling systems or isolators. With the COP vials, we are adding a product made of plastic to our well-known Gx<sup>®</sup> RTF portfolio. The COP vials are offered in 2, 5, 10, 20 and 50 mL sizes with matching dimensions such as height, diameter or neck diameter according to ISO 8362. A new additional size of 100 mL is under development.

### Contact our expert:

wolfgang.dirk@gerresheimer.com

# New Clinical Trial Kit

to accelerate drug development We are is presenting our new Clinical Trial Kit. This kit consists of sterile Gx® RTF vials in nest & tub or tray with matching closures and is tailored to requirements to support the development of new drugs, vaccines and biologics in early phases. The Clinical

Contact our expert: jean-edouard.rabier@gerresheimer.com





Vials	<b>6 Tubs</b> No. of Vials	<b>4 Trays</b> No. of Vials	Rubber Stopper	Aluminium Seal
Gx <sup>®</sup> 2R RTF	720		1000	1000
		912	1000	1000
Gx <sup>®</sup> 6R RTF	288		500	500
		384	500	500
Gx <sup>®</sup> 10R RTF	288		500	500
		384	500	500



Trial Kit is suitable for small batch manufacturing from first line trials to validation and clinical batches. It can be ordered in six different configurations of Gx<sup>®</sup> RTF Glass Vials. Kits including Gx<sup>®</sup> Elite and Gx<sup>®</sup> RTF COP vials will follow soon.



**Drug Delivery Systems** 

# Sustainable Design of a Drug Delivery Device for Biopharmaceuticals

Medical devices are indispensable tools that deliver life-saving drugs to patients, but their environmental impact cannot be ignored. This is why Gerresheimer has placed sustainability at the core of its strategic agenda, aligning with its mission to "innovate and deliver for a better life every day." This commitment is divided into three pillars: GxPure for climate and water, GxCare for employee well-being and community engagement, and GxCircular for sustainable product design and responsible supply chain management.





We aim to reduce Scope 1 and Scope 2 CO<sub>2</sub>e emissions by 50% by 2030, largely by transitioning to 100% renewable electricity. We have already garnered recognition for our sustainability efforts, including a gold medal from EcoVadis, an A-rating from the Carbon Disclosure Project (CDP), and an MSCI ESG Ratings Assessment of AA. Moreover, we are developing science-based targets in line with the United Nations' Sustainable Development Goals (SDGs).

Designing for sustainability is a key element of our GxCircular strategy with EcoDesign principles integrated into all new product development projects. The activities are linked to the commonly used principles of reduce, reuse, recycle and rethink. One of the first products to follow these principles is the Gx SensAir<sup>®</sup> on-body injector for subcutaneous delivery of biopharmaceuticals. From product concept stage the team prioritized patient experience and reduction of environmental impact.

Gx SensAir® allows patients to administer therapies at home, reducing the need for hospital visits and, consequently, cutting carbon emissions. This translates to a significant reduction in CO<sub>2</sub> emissions if adopted on a large scale.

Gx SensAir® has two parts: a reusable module containing the electronics and air pump, and a disposable module with fluid path and the drug-delivery needle. This design minimizes materials, reduces waste and eliminates the need for sterilizing the reusable module, thus also reducing energy and water consumption.

The reusable module offers additional patient usability and adherence benefits such as indicators for injection progress, on-body and occlusion detection, audible signals, and automatic needle insertion. It also features Bluetooth® connectivity to our digital ecosystem. Patient feedback during a formative usability study highlighted the device's simplicity and ease of use for self-administration.

The Gx SensAir® also addresses the environmental impact of cold-storage through the value chain. Unlike integrated devices, only the pre-filled cartridge needs refrigeration, reducing energy consumption and emissions.

Sterile disposable module

Our sustainability strategy extends beyond product development. To be able to fully implement sustainability goals, collaboration is key. Support from internal stakeholders, external investors, customers and suppliers is needed. For example by 2024, 100% of strategic

suppliers will need to acknowledge the supplier code of conduct to ensure compliance with environmental standards. We also work closely with customers to not only comply with legal requirements and patient usability, but to proactively and systematically integrate EcoDesign principles into product design and through the value chain.

Our commitment to sustainability demonstrates how the medical device industry can align with environmentally responsible solutions while enhancing

# Designing for sustainability is a key element of Gerresheimer's GxCircular strategy.



patient therapy experiences. By focusing on sustainability and patient-centric design, we not only mitigate resource depletion and waste generation but also maximize energy efficiency and minimize CO<sub>2</sub> emissions. This paves the way for a healthier planet and underpins our mission to "innovate and deliver for a better life every day".

Learn more from our publication in the latest OndrugDelivery: https://lnkd.in/evwgXHGH

# The Gx Inbeneo® **Autoinjector:**

# Meeting the Challenges of Biologic **Drug Delivery** GxInbeneo



In recent years, the pharmaceutical landscape has seen a significant growth in the development of biologic drugs, due to their effectiveness in treating chronic conditions. There is also a growing preference for subcutaneous self-administration in the home setting as it empowers patients and reduces healthcare costs. However, delivering biologics presents challenges, including increased viscosity, larger volumes, and the delicate nature of biomolecules.

We have created the Gx Inbeneo® autoinjector to facilitate effective delivery of biologic drugs as well as aiding autonomous patient usage. The unique, patented design employs a cartridgebased, pre-pressurized system with a double ended needle separated from the primary container. A robust prefilled glass cartridge retains the spring force. thus making the primary container the force barrier. Unlike with staked-in needle prefilled syringes there is no spring locking mechanism, which eliminates the associated risk of failure. The design enables delivery of drug products with viscosities up to 100 cP in volumes up to 3 ml.

Sensitive biotherapeutics, such as monoclonal antibodies are vulnerable to aggregation, which can result in a loss of biologic functionality. As the drug product is kept separate from the needle during storage, risk of protein aggregation in the needle and thus clogging is eliminated. Additionally using cartridges with baked-on siliconization reduces the risk of protein aggregation caused by silicone oil droplets. Finally aggregation resulting from the gas-liquid interface in the primary container is minimized due to the pre-pressurized system which reduces or dissolves gas bubbles.

The design of the Gx Inbeneo® enables straightforward activation. When the patient presses the device against their skin, the needle safety shield retracts, and one end of the double-ended needle pierces the skin while the other pierces the cartridge septum. This establishes the fluid pathway for safe and effective drug injection with only one user step.

The double-ended needle also helps balance injection time and patient experience, as it has a thicker end to pierce the septum and a thinner end to pierce the patient's skin. This innovation allows for the delivery of higher viscosities in less time, while minimizing patient discomfort.

As well as simple push-on-skin activation, there is no need for the patient to attach the needle themselves, as is the case with some other cartridgebased autoinjectors. This reduces user steps and complexity, thus decreasing the potential for use errors. The Gx Inbeneo® also has transparent top casing in addition to a window in the middle which enables patients to track injection progress even when the middle window is covered by the hand. An audible click further signals the end of the dose. In a usability study these features were well received by participants.

Moreover, the Gx Inbeneo® platform is modular, making it easily customizable to a wide range of drug formulations. This versatility, combined with our extensive experience in primary packaging, device development, manufacturing, and regulatory compliance, reduces the timeframe for clinical trial readiness and market launch

### Learn more from our publication in the latest OndrugDelivery:

https://www.ondrugdelivery.com/ gx-inbeneo-developing-an-autoinjector-that-responds-to-the-challengesof-biologics/

### State 1



### State 2

### State 3





Gerresheimer joins the **Science Based Targets initiative** 

We have joined the Science Based Targets initiative (SBTi). The organization supports companies in using sound science to set and work toward targets for reducing greenhouse gas emissions. The SBTi will verify whether our own CO<sub>2</sub> reduction targets are in line with the Paris Agreement before transparently documenting the company's progress on its platform. By 2030, we aim to reduce our Scope 1 and Scope 2 emissions by 50% compared to the base year 2019. In addition, we have committed ourselves to setting a specific reduction target for Scope 3 emissions within the next 24 months. Joining the SBTi underpins our goal of providing transparent, sound, and comparable information on our sustainability activities, targets, measures, and outcomes in accordance with best practice standards.

# SBTi - framework for sciencebased climate change mitigation

The Science Based Targets initiative was founded in 2015 by CDP (formerly the Carbon Disclosure Project), the United Nations Global Compact (UNGC), the World Resources Institute (WRI), and the World Wide Fund for Nature (WWF). It provides companies with a clearly defined framework for reducing emissions in accordance with the latest scientific findings and in line with the goals of the Paris Agreement, allowing them to help limit global warming. More than 5,700 companies around the world have already joined the initiative.

# Transparent sustainability reporting

In addition to publishing a sustainability report every year, we also disclose relevant data as part of the ratings issued by CDP, EcoVadis, and other organizations. MSCI, Sustainalytics, and ISS also evaluate Gerresheimer's sustainability performance. An overview of our external sustainability ratings can be found here.

In 2023 we have once again been awarded Gold status by EcoVadis. Gerresheimer earned a spot in the top 5% of all companies assessed by EcoVadis and the top 1% of the the industry, and improved its score to 72 out of 100 points, despite the increasingly strict requirements from year to year.



Gerresheimer awarded EcoVadis Gold status again **Technical Competence Center** 

# Continuing the success story

Gerresheimer expands its Technical Competence Center in Wackersdorf with the addition of new Small Batch Production Sampling Area



Gerresheimer is dedicating even more space to Small Batch Production. We have expanded the capacity of our Small Batch Production (SBP) area in Wackersdorf by removing a section of the high-bay warehouse and converting it to a manufacturing space. The new Small Batch Production Sampling Area Wackersdorf measures 700 square meters and will be used to manufacture pre-series parts for assembly systems. The expansion is a further display of our far-reaching industrialization expertise in the manufacture of containment solutions, drug delivery systems, and medical devices.

We have taken the next strategic step in our future by expanding our Technical Competence Center and SBP facilities at the Wackersdorf location for the third time in just five years. The new 700 square meters Small Batch Production Sampling Area is where pre-series parts - samples used to

set up manufacturing systems - can be produced at series quality. An area that previously housed a high-bay warehouse has been converted and equipped to meet the latest production standards.

# **Pre-series parts in documented** series quality

"This is our response to the changing project environment, which involves a growing number of large-scale industrialization projects with many different tools and large machinery," says Holger Heining, Head of Small Batch Production Gerresheimer Regensburg GmbH, Wackersdorf." For their high-volume assembly systems, industrialization projects require a large quantity of preseries parts in documented series quality at an early stage of the project cycle. With our new Small Batch Production Sampling Area, we can now meet these demands and handle the rising number of large-scale industrialization projects in the best possible manner."



"As a global partner to the pharma and biotech industry, we want to help improve the quality of life of millions of patients worldwide through our products and solutions."

Dietmar Siemssen **CEO of Gerresheimer AG** 

### Automatic tool handling

Unlike development projects, industrialization projects require automatic tool handling for high-volume manufacturing. The new area reflects these new parameters, featuring 10 injection molding machines with a clamping force of 175 to 420 metric tons.

Wackersdorf now has 2,170 square meters of class 7 and 8 clean room production space, a 220 square-meter controlled area, and a 360 squaremeter clean room for pharmaceutical glass products that meets GMP class C and D requirements.

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# COP parenteral vials for biological solutions

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# Solving the challenges for CGT

- Suitable for deep cold storage
- High break resistance
- Treated to prevent delamination
- Available gamma irradiated
- Meets ISO standards



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