gnews update 42

customer newsletter, january 2025

PHARMAPACK By CPHI

January 22–23, 2025
Paris, France
Booth F55

two stories one future

Two strong companies are becoming one.
Two success stories will have one future!

gerresheimer
innovating for a better life

> We are convinced that our customers will benefit from the expansion of the product portfolio and new, integrated systems and solutions.”

Dietmar Siemssen
CEO of Gerresheimer AG

Acquisition of Blitz LuxCo Sarl, the holding company of the Bormioli Pharma Group, successfully completed

We have successfully completed the acquisition of Blitz LuxCo Sarl, the holding company of the Bormioli Pharma Group announced in May 2024. The closing was preceded by the fulfillment of customary closing conditions. Bormioli Pharma has a portfolio of pharmaceutical primary packaging made of glass and plastic as well as closure solutions, accessories and dosing systems that is complementary to our portfolio.

With this acquisition, we strengthen our European footprint with additional production sites and underpin our market position as a leading full-service provider and global partner for the pharma and biotech industries. We expect the acquisition to be accretive to our Group's Adj. EBITDA margin and Adj. EPS from the first year onwards through synergies. On February 26, 2025, we will publish a new guidance for the combined company together with the results for the financial year 2024.

Combined strength for your added value
How you benefit from the integration

1 Complementary, attractive product portfolio

Bormioli Pharma manufactures pharmaceutical primary packaging made of glass and plastic as well as closure solutions, accessories and dosing systems. In the plastics segment, Bormioli Pharma is one of the leading suppliers of pharmaceutical plastic systems and solutions. In the glass segment, Bormioli Pharma has an attractive portfolio for parenteral and other pharmaceutical primary packaging. The highly complementary portfolios of Bormioli and Gerresheimer will allow us to offer you an even broader portfolio of drug containment solutions.

2 Complete systems and solutions from one source

From primary packaging to advanced closure systems, you can expect more streamlined offerings — delivered from a single source. Compatibility between glass and plastic components is guaranteed, ensuring full functionality and patient safety. This means you can benefit from integrated, and customized solutions that meet your specific needs. We will be strengthening our market position as a full-service provider for the pharma and biotech industry.

3 Innovating for a better life – now a joint mission

Our combined, enhanced innovation capabilities will ensure that you continue to receive cutting-edge products that help you stay ahead in your market. Together we will be driving innovation and digitalization even stronger, clearly moving into a digital and connected world. We will use the shift toward a more patient-centric healthcare system to contribute to the well-being of the patients with more innovative and intelligent solutions for the application and use of our products.

4 Broad footprint in Europe

We are also strengthening our European presence. This will bring us even closer to you and allow us to serve you with greater agility. With nine plants in Europe, Bormioli Pharma contributes to the over 40 plants of the Gerresheimer Group in 16 countries across Europe, America, and Asia, producing locally for the regional markets. 4 of the 9 Bormioli plants produce glass packaging, the other 5 plants produce plastic and rubber packaging. With about 8 billion products sold in over 100 countries Bormioli is rooted in Europe and present in the world.

5 Even stronger focus on sustainability

Bormioli Pharma's products as well as the Gerresheimer products are designed and manufactured to drive innovation and deliver effective solutions to the growing challenges of sustainability. With its EcoPositive portfolio Bormioli adds a wide range of environmentally friendly pharmaceutical packaging made from sustainable materials such as recycled glass and plastics, bio-based polymers and closed-loop materials cycles to our existing sustainable portfolio. In 2024 both companies, Bormioli as well as Gerresheimer have once again been awarded Gold by the sustainability rating provider EcoVadis.

two stories one future

Our top level product: Gx® Elite Vials

Best-in-class quality and protection for highly sensitive drug

Our Gx® Elite vials are designed to maximize patient safety and production efficiency through a quality-by-design approach. The main advantages of the product are its superior quality, which is reflected, for example, in its high breakage resistance and production efficiency. The advanced primary packaging solution is particularly suitable for sophisticated drugs such as biopharmaceuticals and innovative vaccines. Gx® Elite vials can be delivered in bulk or pre-sterilized ready-to-fill (RTF) in our innovative EZ-fill Smart® packaging.

EZ-fill Smart™ packaging

Gx® Elite vials are also available in the new, optimized EZ-fill Smart™ packaging. The innovative RTF packaging platform simplifies the filling process, lowers costs and reduces the particle load by more than 90% by replacing the Tyvek* lid with a polymer sealing film. This means that no Tyvek* fibers or adhesive particles are released when the film is peeled off just prior to the filling process. This greatly reduces the risk of particle contamination.

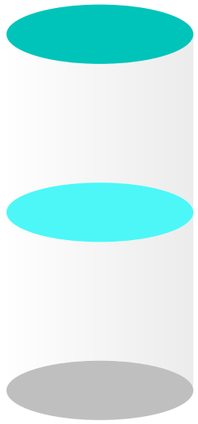
Sustainable Vapor Hydrogen Peroxide Sterilization

The cutting-edge Vapor Hydrogen Peroxide (VHP) sterilization offers an eco-friendly solution for maintaining the highest standards of product and workplace safety. This sustainable method efficiently eliminates contaminants without leaving harmful residues, reducing energy consumption and waste. Ideal for pharmaceutical and healthcare environments, we have implemented the VHP sterilization technology that fully complies with the latest FDA requirements and recommendations and supports the company's sustainability targets.

Presentation at Pharmapack 2025
Thursday, January 23
14:30h – 15:00h, Learning Lab K3

Holger Krenz, Global VP Business Development HVP Tubular Glass, will be speaking at Pharmapack in Paris about our vial platform solutions for primary packaging. His presentation will focus on the benefits of the EZ-fill Smart™ packaging as the new industry standard for RTF vials.

A clear structure: Gx® Performance Levels



Gx® Elite
Best-in-class quality and protection for highly sensitive drugs.

Gx® Advance
Improved quality for higher efficiency in fill & finish.

Gx® Value
Proven solutions in pharmaceutical quality.

*Tyvek is a registered trademark of the Dupont Group.

Strategic Industry “Alliance for RTU”

by Gerresheimer, Stevanato Group and SCHOTT Pharma

Together with Stevanato Group S.p.A. and SCHOTT Pharma AG & Co. KGaA we have entered into a strategic industry alliance ("Alliance for RTU") to support market adoption of Ready-to-Use (RTU) vials and cartridges.

The Alliance for RTU aims to share with pharmaceutical companies, CMOs and CDMOs expertise and technical knowledge in high-quality sterile primary packaging, specifically ready-to-fill vials and cartridges, highlighting RTU configurations' advantages over conventional bulk packaging.

Pharmaceutical companies, CMOs and CDMOs opting for ready-to-use containers also can benefit from higher-quality products, which helps minimize the release of glass particles and risks of breakage or rejection while preserving the drug inside throughout its entire life cycle.

Reduced risks and lower total cost of ownership

Traditional fill & finish processes present several operational risks and require increased efficiency. By adopting an industrial RTU setup, pharmaceutical companies and CMOs can benefit from reduced operational risks, enhanced flexibility and efficiency, and lower waste. RTU technology can help streamline processes, increase productivity, and thus lower total cost of ownership while reducing contamination risks and easing EU GMP Annex 1 compliance.

Open expert platform for RTU industry standard

The Alliance for RTU aims to create an expert platform open to other industry players to help industry manufacturers learn about the key benefits of RTU processes and products and to better evaluate investments for transitioning to efficient filling systems and meeting their unique needs from clinical applications to widespread commercial use.

“As an industry, we are fully prepared for the transition to RTU vials and cartridges. With recent advancements, RTU processing is now a mature technology which will improve our customers operations in terms of efficiency, cost and time to market.”

Lukas Burkhardt, Member of the Management Board of Gerresheimer AG.

For more information, visit www.alliance-for-rtu.com

Gx® Cap for Clinical Trials

Monitoring oral medication adherence

Medication adherence is essential for the success of clinical trials, yet non-adherence remains a critical challenge, impacting data integrity, trial efficiency, and participant safety. Our Gx® Cap for Clinical Trials, currently in development, aims to address these challenges by leveraging smart technology and a patient-centric design to redefine oral medication adherence monitoring during trials.

By automating adherence monitoring, providing real-time insights, and enhancing participant engagement through user-friendly features, the Gx® Cap for Clinical Trials is designed to streamline clinical trial operations and improve data quality.

Pharmapack Innovation Gallery
January 23
11:40h – 11:50h
booth F12
Sueyoung Yoon, Digital Solution Lead

Device features:

- Tracks each cap opening and closure.
- LTE connectivity for seamless real-time data transmission.
- Rechargeable battery designed for long-term, sustainable use.
- LED light pipe provides visual cues and guidance for participants.
- Classified as a Class I Device under FDA regulations (U.S. market) and compliant with EU MDR requirements (EU market).
- Designed for compatibiliy with Duma® containers.

Data capture and Integration:

- Internal memory on the device for secure adherence data storage.
- API integration capabilities for connecting with existing clinical trial systems.
- Compliant with strict data security and privacy standards.
- Customizable design to meet the specific needs of diverse trial protocols.

Adherence Tracking

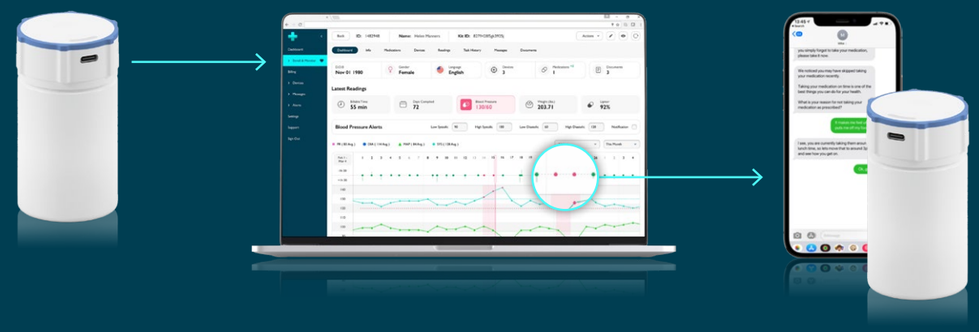
Smart cap tracks and sends patient’s adherence data

Real-time Monitoring

Patient adherence is monitored, and deviations flagged

Corrective Measures

Patients receive a reminder when they miss their medication via smartphone



Important Note: The Gx® Cap for Clinical Trials is a product concept under development and is not yet approved, registered, or available for sale. This information is for informational purposes only and does not constitute a clinical claim or an offer for sale.

FDA grants tentative approval of SQ Innovation's Lasix® ONYU*

The US Food and Drug Administration (FDA) granted SQ Innovation Tentative Approval for Lasix® ONYU for the home treatment of fluid overload in congestive heart failure. Lasix® ONYU is a combination product consisting of a novel high-concentration formulation of the diuretic furosemide and our on-body drug delivery device. Tentative Approval indicates here that Lasix® ONYU has met the regulatory standards for quality, safety and efficacy required for approval in the United States. Full approval was precluded because the FDA had granted market exclusivity in the USA for a competing product until October 2025.

"The regulatory authority's decision underlines the market readiness of our on-body drug delivery device,"

said Dietmar Siemssen,
CEO of Gerresheimer AG.

"It also clearly demonstrates our expertise as an innovative solution provider for our customers, from product design to regulatory submission and large-scale manufacturing. With our on-body devices for both small molecule drug formulations and large molecule biologics we can partner with our customers to address the global megatrend of home treatment, while also providing connectivity to remote therapeutic monitoring platforms."

Device based on our innovative micropump technology

The cartridge-based infusor was designed and developed by Gerresheimer based on our proprietary infusor platform for subcutaneous drug delivery. The core technology is an innovative micropump which enables controlled, precise administration of a drug product according to a defined therapy regimen.

Designed with patient comfort and the environment in mind

The lightweight, compact device is patched onto the patient's body, making it comfortable for the patient to wear while the drug is gently infused. The user-friendly design features a simple one-button operation with automatic needle insertion and retraction. The Lasix® ONYU infusor has two components, a reusable electromechanical component, and a single-use sterile disposable component that is in contact with the drug solution and the body. The reusable component, which is rated for delivery of 48 treatments with diuretic furosemide, is recyclable. Because only the disposable unit requires sterilization, radiation can be used instead of chemical sterilization, and no electronic components end up in medical waste. This two-component concept was developed in line with our EcoDesign principles, which aim to increase product lifespan and reduce waste.

Reducing total cost of care and improving patients' quality of life

The combination product Lasix® ONYU also opens up possibilities to reduce the total cost of care. The two-component design results in a lower cost per treatment, because only the disposable part of the device needs to be replaced. Most importantly, the infusor allows for home treatment, reducing the length of hospital stay or avoiding the need for hospitalization for intravenous diuretic administration altogether.

First products expected to be available end of 2025

In addition to our role in design and development we also manage production of the device as a full-service solution provider. The disposable unit for the infusor is, for example, produced at our facility in Wackersdorf, Germany, on a high-capacity semi-automated line.

SQ Innovation will seek full approval in the U.S. after the competitive product's regulatory exclusivity period expires in October 2025. First products of Lasix® ONYU are now expected to be available on the market by the end of 2025.

About SQ Innovation

SQ Innovation, Inc. is a privately held Swiss biopharmaceutical company with offices in Zug, Switzerland, and Burlington, MA, USA. Founded to develop and commercialize innovative, cost-effective therapies for subcutaneous delivery, the company aims to enable at-home treatment for conditions traditionally managed in hospitals. SQ Innovation has developed a novel drug-device combination for treating fluid overload in adult patients with chronic heart failure — a condition typically requiring intravenous administration of medications in a hospital setting. This product, Lasix® ONYU, was developed with consideration for patients, payors, healthcare providers, and environmental impact.

www.sqinnovation.com

New production capacities for glass syringes

Gerresheimer Skopje (North Macedonia)

We are expanding our production capacity in Skopje, North Macedonia, with a new production hall for glass syringes. Since 2019, we have been producing drug delivery systems, diagnostic and medical products made of plastic on around 14,600 m² at this site.

With an investment of over EUR 100 million we add around 7,600 m² of production space for glass syringes. The expansion will double the number of employees in Skopje from around 250 to 500 over the next three to five years. The new production hall in Skopje is currently one of the key projects in the global capacity expansion for drug delivery systems and syringes for long-term customer contracts.

Glass and plastics production

Since 2019, we have been producing drug delivery systems as well as diagnostic and medical products and components made of plastic on around 14,600 m² in Skopje, including ISO class 7, 8 and 9 clean rooms. This also includes syringe accessories such as our Gx TELC® syringe closure system and the Gx InnoSafe® safety system, which protects against accidental needlestick injuries.

One advantage of our plant in Skopje, with its 7,600 m² extension, is the combination of production capacities for pharmaceutical plastic and glass products at one location. This enables efficient production of integrated solutions with optimized logistics. For example, customers can obtain fully assembled Gx RTF® syringe systems in a wide variety of configurations from Skopje. The site in Skopje also offers growth potential. 100,000 m² of additional space is available on the site for future expansion.

State-of-the-art technology

We use state-of-the-art inspection systems for quality assurance as part of our certified quality management system, including, for example, the Gx® G3 inspection system with high-speed camera technology and AI-based image processing developed in-house for the syringe production. In addition, the plant in Skopje has two in-house laboratories with high precision measurement technology and laboratory equipment for optical, mechanical, chemical and microbiological testing.

Excellent infrastructure

Our Skopje site is located in a well-connected industrial area close to the international airport of the North Macedonian capital. Larger Mediterranean ports in Greece and Albania are each around 250 km away. The country has a well-trained workforce. In addition, we cooperate with the University of Skopje in order to recruit qualified young talents.

Ramp-up of syringe production

The first syringe production lines in Skopje are running, with more to be added in the course of 2025. This means that we are currently concentrating syringe production at our sites in Bünde (Germany), Querétaro (Mexico) and Skopje (Republic of North Macedonia).

Events & Fairs

Gx Inbeneo® wins Red Dot Award

Design concept award for our autoinjector for highly viscous liquid biologic drugs

We received the prestigious Red Dot Design Concept award for our Gx Inbeneo® autoinjector platform. The jury recognized Gx Inbeneo® due to its “high design quality”. Established more than 60 years ago, the Red Dot label has become a global hallmark of good design and innovation. Red Dot annually awards outstanding design in the three categories Product Design, Brands & Communication Design and Design Concept. The 2024 Red Dot Design Concept award for the Gx Inbeneo® recognizes the unique pre-pressurized concept and user-centric design of the autoinjector that enable patients to simply and safely self-administer highly viscous liquid biologic drugs.

A unique concept

The Gx Inbeneo® has a unique “pre-pressurized” design – it incorporates a pre-filled glass cartridge to retain the spring force. This innovation enables the use of springs strong enough to inject very high viscosities and up to 3 mL volume. Another feature of the design is the separation of the needle from the primary packaging until use, thus eliminating the potential risk of viscous biologics clogging the needle during storage.

Design supports home-use

The Gx Inbeneo® also incorporates a number of enhanced patient usability and safety features. To help avoid needle stick injuries and alleviate patient anxiety, the needle of the autoinjector is concealed with a safety shield before and after use. Patients simply need to press the Gx Inbeneo® against the skin and the drug is smoothly injected. The transparent top casing of the autoinjector, in addition to the central window, makes it easy for patients to track injection progress even if they have dexterity issues.

On behalf of Gerresheimer Jürgen Pfrang (left), Global Head of Technology and Packaging Development, and the industrial designer of the Gx Inbeneo®, Simon Bürdel (right), proudly received the Red Dot award at the 2024 award ceremony in Singapore. The Gx Inbeneo® is now part of the winners’ exhibition at the Red Dot Design Museum in Singapore.

Gerresheimer Presentations at Pharmapack 2025

Wednesday, January 22
12:55 – 13:25h, Learning Lab K85

Adrian Johnson, Sustainability Manager Primary Packaging Plastics

Reducing the carbon footprint of our products – renewable energy and material innovation as viable solutions

Thursday, January 23,
10:10 – 10:40h, Learning Lab K3

Bernd Zeiss, Head of Scientific Affairs and Application Technologies, Sébastien Cordier (Aptar) and Lucy Lee (SHL)

A Partnership worth more than the sum of its parts – Device component manufacturers fulfil syringe and system performance requirements

Thursday, January 23
14:30 – 15:00h, Learning Lab K3

Holger Krenz, Global VP Business Development HVP Tubular Glass

The innovation journey: developing EZ-fill Smart™ as the new industry standard for ready-to-use vials

Upcoming Events

PCD Paris Packaging Week 2025
January 28 – 29, 2025
Paris Expo, Booth L160

PDA Webinar
Advancing quality and efficiency with RTU vials and cartridges
January 28, 2025 | 15:00h – 16:00h
contact@gerresheimer.com

MD&M West
February 04 – 06, 2025
Anaheim Convention Center, CA (USA)
Booth #3447

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Optimized fill-finish and full lifecycle drug protection

Pharmapack Paris | January 22–23, 2025 | Paris, France | Booth F55

Gx® Elite Vials

Optimum drug product protection
- Industry-leading strength
- Drug protection in cold storage (-80°C)

De-risking fill-finish operations
- Smoother handling, fewer line stoppages and interventions
- Quality by Design vial to ensure CCI & excellent capping performance

Optimized total cost of ownership (TCO)
- Reduced cost of non-conformity
- Increase line speed

Available in non-sterile bulk & pre-sterilized RTF packaging formats

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