

gnews update 35

customer newsletter, may 2022

Our new product selector g guide

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 **PHARMAPACK**
Drug Delivery & Packaging

May 18 – 19, 2022 | Paris, France

gerresheimer
innovating for a better life



Find the right packaging solution quickly and easily: the Gerresheimer g guide

Find the best packaging solution in no time at all: The g guide, our brand-new digital product selector, is now available on our website (www.gerresheimer.com/product-selector) The g guide leads users to the ideal solution simply by asking a handful of questions. The new tool is aimed at potential customers in the pharmaceutical, biopharma and veterinary medicine industries.

With its new g guide service, Gerresheimer has provided its customers and partners from the pharmaceutical, biopharma and veterinary medicine industries with a direct gateway to its broad range of products and solutions. "The benefits of the g guide will become clear immediately to our customers and partners," says Ueli Utzinger,

Group Senior Director Communication & Marketing. "The product selector brings our wide range of products to life in an intuitive way." "Start-ups and aspiring biotech companies will find the support and expertise they need here in their search for the best packaging and service solutions," adds Stefan Verheyden, Global Vice President Gx Biological Solutions.

The g guide product selector combines state-of-the-art online customer service with the highly acclaimed expertise of the Gerresheimer team. As a scientifically oriented, MDAX-listed company and global go-to partner for the pharmaceutical and biotech industries, the new g guide tool further expands our customer focus.

How it works

The g guide is available to anyone visiting the Gerresheimer website. The digital tool guides users intuitively through six targeted questions about the specific characteristics of the pharmaceutical product that needs to be packaged, before offering a selection of appropriate solutions from our broad portfolio. The g guide uses a special algorithm developed in-house to filter through more than 1,500 pharmaceutical products on the basis of the information provided by the user. Users go from answering questions to receiving their final recommendation in no time at all. Users are then given the opportunity to contact the Gerresheimer sales team directly, who will provide expert advice on the basis of the recommendations made by the g guide.

“The product selector brings our wide range of products to life in an intuitive way.”





Innovative Traceability Solutions

Container-level traceability throughout the value-chain

Our vision is to enable complete traceability and transparency from production to point-of-care. As the first party in the manufacturing chain, we apply unique codes to our primary packaging and medical devices. Thanks to our digital infrastructure for traceability, we and downstream parties will be able to link, analyze and share data with the individual product unit.

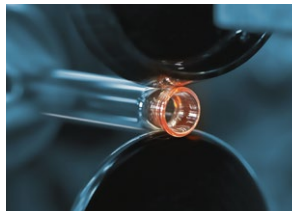
Benefits of traceability

Our vision promises transparency and traceability across the entire supply chain, from primary packaging to secondary packaging, and from drug filling and serialization up to the final application at the PoC. You will benefit in particular from the following advantages:

- Increase patient safety
- Eliminate sources of error
- Increase efficiency
- Limit damage in case of recalls
- Fight counterfeiting
- Enable patient and end-customer interaction
- Support circular economy
- Compliance

Traceability Solutions –
Gerresheimer AG

Example use cases for visible codes



1. Process optimization

- Facilitate root-cause analysis
- Prevent mix-ups prior to labeling
- Replace code rings
- Note special info and events



2. Quality assurance

- Link data of inspections to single product
- Link specification and quality documents to single product
- Proof compliance
- Connect with regulatory systems



3. Consumer interaction

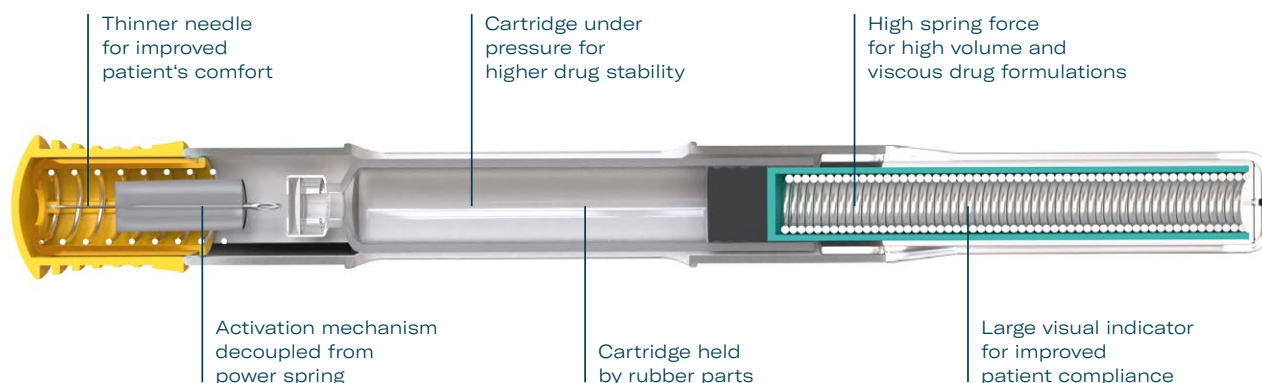
- Let the product talk
- Support circular economy
- Prevent mix-ups for personalized medicine

Example use cases for invisible codes



Anti-counterfeiting or design-sensitivity

- In the case of anti-counterfeiting a higher level of security is required to make copying more difficult
- We work on possibilities to identify or authenticate products using a common smartphone or a special detector



First own Gerresheimer autoinjector

Gerresheimer acquired the IP of a new generation cartridge-based autoinjector from Midas Pharma. This is the start of a strategic partnership. The joint project comprises the development and marketing of the new generation autoinjector. The go-to-market approach for the autoinjector combines the complementary strengths of both companies - Gerresheimer as a solution provider for medical devices and primary packaging solutions and Midas Pharma as experienced facilitator for global pharma projects and provider of products and services along the pharmaceutical value chain.

"The strategic partnership with Midas Pharma around this innovative autoinjector is an important milestone on our way to be a solution provider offering leading and innovative medical devices," said Dietmar Siemssen, CEO of Gerresheimer AG. "We see this as a starting point for a successful cooperation with Midas Pharma and their expertise as pharma service provider."

Karl-Heinz Schleicher, owner and CEO of Midas Pharma, added: "The alliance with Gerresheimer is based on trust, a similar mindset and mutual goals. We consider our cooperation as a highly important strategic alliance, which we are fully committed to."



"With an increasing focus on proprietary IP products, we are adding this cartridge-based autoinjector to our broad portfolio of devices and primary pharmaceutical packaging."

Dietmar Siemssen,
CEO of Gerresheimer AG



Gerresheimer presents the new autoinjector from May 18 to 19 at PHARMAPACK 2022 in Paris (France), Paris Expo, Porte de Versailles, Hall 7.2 at Booth B60/B64.

One-stop-shop for biotech

The two companies will offer biotech and pharma customers a one-stop-shop around the autoinjector solution: Starting with the selection and delivery for the best solution of a medical device and associated primary packaging plus sourcing of the active pharmaceutical ingredients, through the entire development (technical, pharmaceutical and clinical) and registration. It also includes commercial manufacturing and supply of the filled, sterilized and assembled drug-device-combination, supported by a full range of complementary services e.g. quality, technical and analytical, regulatory, IP or project management.

Variety of therapeutic areas

Our new autoinjector offers new opportunities in the treatment of various diseases. The new-generation autoinjector is suitable for subcutaneous injection with up to 3ml injection volume. The patient-friendly, robust cartridge-based autoinjector will serve as a flexible and adaptable platform for a range of different products in a variety of therapeutic areas. These include highly viscous formulations of biological APIs like new biological entities and biosimilars. With this autoinjector development - based on proprietary IP - we enhance our existing broad portfolio of medical devices such as various on-body injector solutions and wearable injector systems.



Innovative SensAIR® platform

for the administration of highly viscous biologics

With SensAIR®, Gerresheimer presents an innovative platform for on-body drug delivery which can deliver drugs of higher viscosity, such as monoclonal antibodies (mAb). The aim is to provide patients with the best possible support in the subcutaneous delivery of large-volume biologics.

The easy-to-use SensAIR® on-body drug delivery device enables patients to start medication in a self-determined manner in familiar surroundings, for example at home. The device can be adapted to medications of different viscosities and with different requirements. This applies to the size of the medical device as well as to the needle used, variable cartridge sizes and possible connectivity, for example to the patient's smartphone. Together with Gerresheimer's one-stop-shop quality promise, which includes a solution from the cartridge to the drug delivery device from a single source, SensAIR® enables optimized delivery of biologics. "Everyone benefits from SensAIR®: patients, their relatives and doctors. It is an innovative medical device which, when worn on the body, delivers up to 20 ml of biologics subcutaneously

to the patient," says Oliver Haferbeck, Head of the Advanced Technology & Innovation Unit at Gerresheimer and CEO of Sensile Medical AG. He explains that patients gain significantly in quality of life because they can administer their medication themselves at home. The easy-to-use concept ensures that the patient does not have to carry out any lengthy and complicated preparation steps but can operate the device easily.

More quality of life for the patient

To date, many patients with a wide variety of indications must endure long and stressful infusions in a hospital setting to treat their condition. How much easier would it be if patients could carry out the treatment at home? SensAIR® makes life easier for these patients, as they can care for themselves over a longer period and - depending on the indication - only need to visit the doctor or hospital for check-ups.

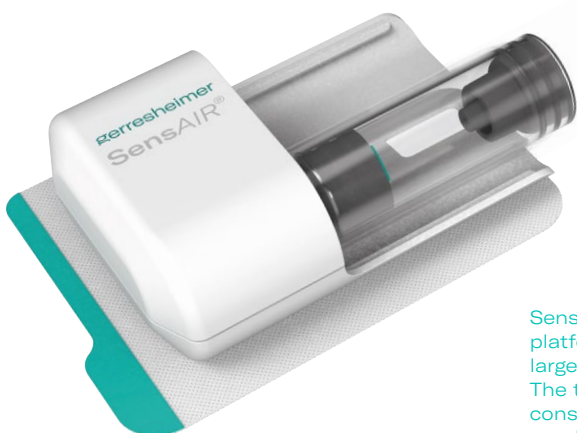


SensAIR® is an innovative product platform for the administration of large-volume and highly viscous biologics. The technology, function, design and construction of the platform were developed by Gerresheimer experts and the product is supplied from a single source.



A simple concept

The SensAIR® drug delivery device is characterized by a simple concept which can be cost-effectively adapted to different needs. Gerresheimer thus offers a platform solution which provides a wide range of options regarding the biologic to be applied, starting with the drug flow rate (0.15–1.00 ml/min), through type (for example glass cartridge) and volume (up to 20ml) of the primary packaging, to connectivity. The electronic module can easily be removed from the device after use. This is an important contribution to sustainability. Gerresheimer is therefore both a partner for the SensAIR® device and a manufacturer of the cartridge containing the active ingredient. This represents significant added value as a long-term partner and system supplier. SensAIR® is attractive to the market even with varying quantities of devices per year, as existing developments and processes can be adapted in the shortest possible time. This is a significant advantage in terms of time-to-market, among other things by quickly enabling clinical trials.



More about SensAIR®
On-Body Devices ([gerresheimer.com](https://www.gerresheimer.com))

Gx® RTF Vials at PHARMAPACK 2022

Sterile ready-to-fill vials for injectables



Gx® RTF Vials are high-quality injection vials for vaccines and numerous other liquid medications as well as biologics.

Gerresheimer, a leading global manufacturer of primary packaging for the pharmaceutical industry, is presenting its high-quality Gx® RTF vials product offering. Gerresheimer offers its own packaging configurations, but also the well-known EZ-fill packaging format.

Gx® RTF vials – ready for filling

The Gx® RTF injection vials are made from type I borosilicate glass and meet all current requirements of the applicable ISO standards and pharmacopeias (USP and Ph. Eur.). They are manufactured in accordance with cGMP, washed in a clean room, packed in trays or in nests and tub and finally sterilized. Gerresheimer offers its own packaging as well as the well-known EZ-fill packaging design. This means the vials are ready for the next steps in the filling process without any further and/or additional handling. The benefits are obvious: sterile delivery, a simplified fill and finish process, the highest quality standards, flexibility thanks to various possible packaging options and a wide range of filling and sealing technologies. These all lead

to a significant reduction on overall manufacturing costs across the product's entire lifecycle and improve patient safety.

Flexibility through various packaging configurations

The range for Gx® RTF vials includes various end-of-line packaging solutions. These new packaging formats allow customers to use Gx® RTF vials to support their operations in all phases of drug and new drug product development, as well as in small or large commercial production. EZ-fill Nest & Tub packaging products offering 2R, 6R and 10R vial formats are special tray packaging formats that support all tubular glass products from 2ml to 30ml (clear and amber). Additional packaging solutions are currently being developed to support molded glass products ranging in size from 5ml to 50ml (clear and amber).

Highest quality requirements

Gx® RTF injection vials meet all specified requirements of applicable ISO standards and pharmacopeias (USP and Ph. Eur.). They are offered

in Gx® Elite, Gx® Armor and Gx® Pharma Plus quality formats to meet or exceed customer or industry quality requirements. Gx® RTF packaging solutions offered with EZ-fill packaging platforms further improve end-product quality by avoiding glass-to-glass contact, which can lead to glass breakage and the development of cosmetic defects.

 Gerresheimer presents its Gx® RTF vials from May 18 to 19 at PHARMAPACK 2022 in Paris (France), Paris Expo, Porte de Versailles, Hall 7.2 at Booth B60/B64.

[RTF vials – Gerresheimer AG](#)



Win across the board now with our Gx® RTF Vials.

Reduce the required production steps and thus effort and costs with our ready-to-fill format. Respond flexibly to capacity fluctuations and minimize risks in the filling process. And do it in just a few days, because thanks to expanded production capacity and a large sample stock, we can supply you with Gx® RTF vials very quickly, even in large quantities.

For further information and technical specifications, please refer to our experts at rtfvials@gerresheimer.de.

EZ-fill® is a registered trademark of the Stevanato Group.

Gx InnoSafe® – the first easy-fill syringe with passive needle protection system

No additional investment required



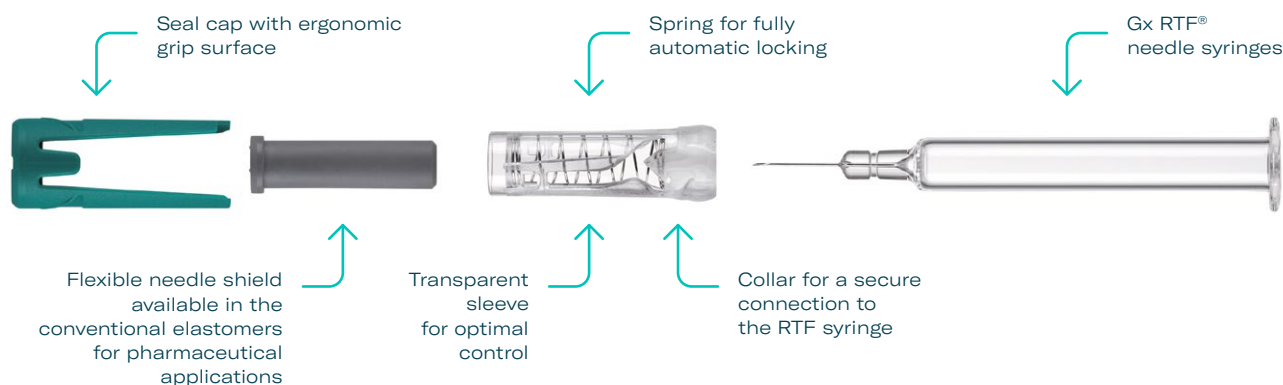
Nurses are among the occupational groups with the most frequent cuts and puncture wounds. This can lead to infection with dangerous pathogens such as hepatitis B and C viruses or HIV. The Gx InnoSafe® safety syringe is the first syringe on the market with an integrated passive safety system. Its function prevents someone from accidentally injuring themselves on an already used syringe by an unintentional needle stick, as the needle is fixed in a sleeve after use. In addition to these unique safety features, a special feature of the Gx InnoSafe® is that it can be processed on all existing filling lines without any additional preparation or assembly steps. Furthermore, it complies with all regulations without any additional investment.

"Any bottler (pharmaceutical company) can easily fill the Gx InnoSafe® safety syringe on existing syringe filling lines without any investment. It is precisely this feature of the Gx InnoSafe® syringe which distinguishes it from conventional safety syringes and makes it a world first," says Wenzel Novak, Global Senior Director Business Development at Gerresheimer in Bünde.

Simply filled without additional investment

Gx InnoSafe® is a passive integrated safety system that prevents unintentional needlestick injuries and eliminates reuse. The tested and simple design eliminates incorrect operation or unwanted triggering of the safety syringe. The safety system is assem-

bled fully automatically in Gerresheimer's RTF (ready-to-fill) process. The syringes are packaged, sealed and sterilized. Gx InnoSafe® is supplied in the established, ISO-compliant packaging consisting of a nest and tub. Filling equipment adaptation is not required in pharmaceutical filling compared to normal cannula syringes.



Gerresheimer establishes small series production in the USA



The equipment in small series production currently includes an injection molding machine with a clamping force of 120 tons that connects with handling systems and parts conveyors.

DIN EN ISO 14644-1. Small series production then took up operation in 2021. "The equipment in small series production adapts to the project. We are currently producing an innovative product for ophthalmology, an innovative point-of-care test system and a combination product in accordance with the FDA definition," explains Manfred Baumann (Global Executive VP Sales & Marketing, Administration & TCC, Gerresheimer Regensburg GmbH). Based on these projects, the equipment in small series production currently includes an injection molding machine with a clamping force of 120 tons that connects with handling systems and parts conveyors. Project-specific assembly and packaging units such as granulation, fill & seal plants as well as manual assembly stations, including ultrasonic welding systems, are also available. For quality assurance, small series production has its own fully equipped measurement laboratory with product-specific testing equipment with optical and tactile measuring machines and other testing equipment.

Pilot production in series quality at the Peachtree City production plant: Development samples, clinical samples all the way to small series production in every project phase for our American customers.

Pharma and medical technology specialist Gerresheimer has established small series production at its Technical Competence Center at its Peachtree City, GA (USA) location. Small quantities of products can now be manufactured under series conditions and in ISO class 8 cleanroom. During the development and approval of pharmaceutical products and medical devices, this kind of small series is regularly needed for clinical samples or stability batches.

Prior to series production, pharmaceutical products and medical devices run through an exhaustive approval process for which small numbers of units need to be produced repeatedly, for example, as clinical samples, development samples or stability batches. In 2013, Gerresheimer opened its own small series production at its Technical Competence Center in Wackersdorf, Germany, to accomplish this task. The company is now continuing this success story, starting small series production at its Peachtree City production location to be able to offer American customers small series production locally.

Besides providing small volumes of product, small series production also enables Gerresheimer to optimize the production process in the pilot phase. All the expertise required for series production can be established, while processes can be developed and streamlined. The experience gained during mold making and automation can be harnessed to design series molds and series equipment.

Setup of small series production began at the Technical Competence Center at the Peachtree City location in 2020 with the conversion of an existing building as well as setup of an ISO class 8 cleanroom in accordance with



The equipment in small series production adapts to the project.

Production in Wertheim (Germany) expanded

Increasing capacity by 150 million vials per year

Gerresheimer is expanding its capacities for glass vials at the Wertheim site in Germany and at two further sites in China and the USA. The company is investing in production in Wertheim to increase vials capacity by 150 million vials per year and plans to create 70 new jobs for this purpose. The Federal Ministry of Economy and Climate Action supports the investment within the framework of federal funding of production equipment of borosilicate tubular glass and glass vials for use in vaccine production.



cosmetic and dimensional properties, vials made of this glass lead to significantly better results in the filling of vaccines by Gerresheimer's customers. They also feature increased strength compared to standard vials. Gerresheimer has significantly increased its production capacities for vials. Compared to the level before the pandemic, they are now almost 50 percent higher. As a supplier of critical healthcare infrastructure, the company is a reliable partner for the pharma and biotech industry as well as for national and international governments. In the long term, Gerresheimer's management expects an increasing demand for drugs which have to be injected - and therefore a higher demand for vials. The global pandemic has highlighted the importance of a reliable and high-quality supply of injection solutions.

Gerresheimer is already one of the world's largest manufacturers of the products required for vaccination campaigns, among other things. Until now, the company has primarily served the European demand for vials from its plants in Boleslawiec (Poland) and Chalon (France). The investment will make the Wertheim plant one of the leading vial production sites in Europe. Dietmar Siemssen, CEO of Gerresheimer AG, emphasizes the importance of the production expansion: "We already produce almost a third of the world's glass vials worldwide. With the expansion of our global capacities we are consistently implementing our

growth strategy. By the end of 2022, we will be the world's leading producer of glass vials and manufacture the highest-quality and most innovative products."

The German Federal Ministry for Economic Affairs and Climate Action is supporting the investment in Wertheim. By expanding its production capacity in Wertheim, Gerresheimer is making an important contribution to improving the supply of glass vials to European vaccine manufacturers, among other things. The technology used in Wertheim enables vials to be produced in Gx Elite quality. With their outstanding

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Gerresheimer opens a new plant in Berlin, OH (USA)

Clean room production for pharmaceutical plastic container solutions

Gerresheimer ceremoniously took over a new building in Berlin, OH (USA). In the future, the square plastic containers of the Duma Twist-Off Q brand with a 40ml filling volume, child-resistant closure, and desiccant for filling with medications for the North American market will be produced here in a clean room. The new building is Gerresheimer's eighth location in total on American soil and is being built directly next to our prescription packaging production facility. A major customer has now audited the new site for its orders.

"Many companies around the world produce bottles and closures from plastic. However, very few of them are produced in controlled areas and even fewer in classified cleanrooms like those at Gerresheimer. This is because it is the only way Gerresheimer can guarantee and ensure the quality and purity of the container solution used to package medicines. This is what Gerresheimer offers at each of its primary production sites for plastic packaging around the world. This project is a great example of successful knowledge sharing between the teams in the US and Denmark," said Niels Düring, Global Executive Vice President Plastic Packaging, who cut the blue ribbon at the dedication ceremony.

Produced in a clean room: Duma Twist-Off Q

In the future, primary plastic packaging of the Duma Twist Off square brand with a 40 ml filling volume with a child-resistant closure and desiccant for filling solid medications will be produced at this new production facility in a clean room classified to ISO 8



"This project is a great example of successful knowledge sharing between the teams in the US and Denmark,"

Niels Düring,
Global Executive Vice
President Plastic Packaging

Duma Twist-Off Q, 40 ml

standards. Using injection blow molding, the container is made of HDPE (high density polyethylene) and has a closure made of PP (polypropylene). The Duma Twist-Off square product family consists of seven products with volumes ranging from 30-200 ml. All bottles have injection-molded screw systems and are safety-packed. They are offered with senior-friendly closures, which can also be supplied with child safety locks as an option. They are available with inserted or integrated desiccant and can be additionally sealed with the Duma OneLiner closure. The containers have all the necessary approvals, in particular FDA, US and Canada Drug Master File.

Broad range of plastic packaging solutions

As a specialist in plastic packaging solutions for the pharmaceutical industry, Gerresheimer offers a wide range of packaging solutions for solid, liquid and ophthalmic products. The leading brands Duma, Dudek, and Triveni for solid dosage forms, PET bottles of the edp brand for liquid dosage forms,

and products for ophthalmic applications are part of the comprehensive and innovative product range. The broadly diversified standard range includes a wide variety of containers and closures, PET bottles, eye drop-pers, nasal sprays, nebulizers, applicators, accessories, and countless customer-specific developments.

Pharmaceutical primary packaging solutions from Gerresheimer

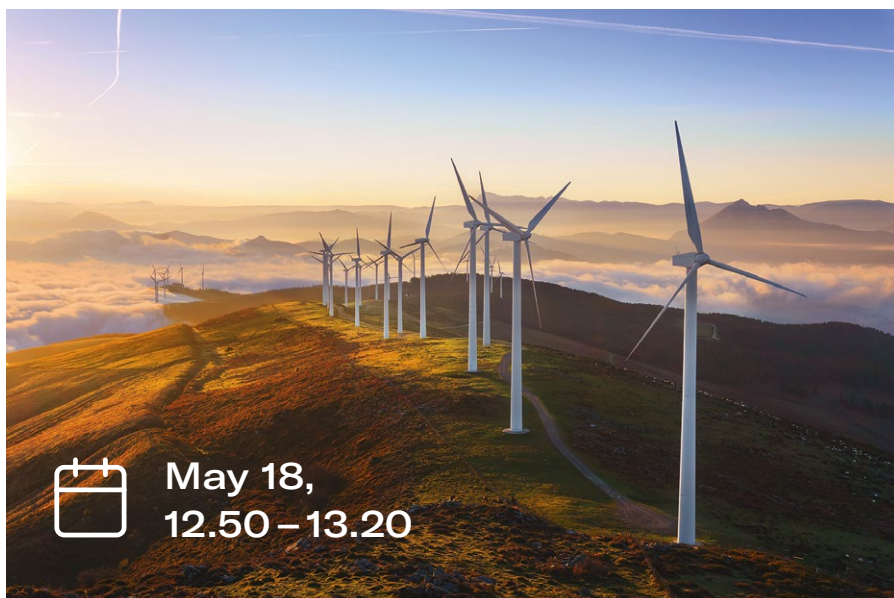


The inauguration team cutting the ribbon: Mitchell Stein, Senior Plant Director, Katrine Petersen, Quality Manager; Sherry Newsome, Production Manager; Niels Düring, Global Executive Vice President; Tony Haba, President

Presentation at Pharmapack 2022: Gerresheimer on the Road to Decarbonization



Patrick Kraft, our Global Sustainability Manager Moulded Glass, will present our road to decarbonization, one of the key topics of our new innovation center. His presentation will cover Gerresheimer-specific approaches like the furnace technology and the sourcing of renewable electricity. Furthermore value-chain-comprising approaches in pharma business (e.g. eco-design-development including lightweight) will be explained. The presentation closes by showing an already realized value-chain-comprising decarbonization roadmap, thus underlining that in glass sustainability is not one measure, instead it is a set of measures on which collaboration over the value chain can take the highest effect.



Parenteral Packaging Conference (EU) June 02–03, 2022

Basel, Switzerland
Congress Center #26

Drug Delivery Formulation (DDF) Summit June 27–29, 2022

Berlin, Germany

AACC Annual Scientific Meeting + Clinical Lab Expo July 24–28, 2022

Chicago, Illinois
McCormick Place Convention Center
Booth 4837

CMEF China International Equipment Fair August 21–24, 2022

Shanghai, China
National Exhibition and
Convention Center,
Booth 8.1M10

Medtec China August 31 – September 02, 2022

Shanghai, China
Shanghai World Expo Exhibition &
Convention Center
Booth 2D402

Connect in Pharma September 14–15, 2022

Geneva, Switzerland
Palexpo
Booth A20

PDA – The Universe of Prefilled Syringes and Injection Devices (U.S.) October 18–19, 2022

Palm Springs, CA, USA

PODD Partnership Opportunities in Drug Delivery October 24–25, 2022

Boston, MA, USA
The Westin Boston Seaport

CPhI Worldwide November 01–03, 2022

Frankfurt, Germany
Trade Fair Frankfurt
Hall 3.0, booth 30B21



Protection against needlestick injuries

Visit us at Pharmapack | May 18 – 19, 2022 | Paris, France | Hall 7.2, booth B60/B64



Gx InnoSafe®

- Protection mechanism is activated automatically
- No accidental reuse possible
- Delivered pre-assembled in nest and tub

gerresheimer.com

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