Snews update 34

CPhI worldwide®

November 9-11, 2021 | Milan, Italy

customer newsletter, november 2021

Agenda

Title story 2

Product solutions for parenteral applications 3

Customized solutions for drug delivery devices 6

Sustainability in focus 7

From our plants 10

Events 12

Innovative solution prevents needlestick injuries

Gx InnoSafe® syringe now available on the market



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 Ründe

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 assembled 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.

Gx InnoSafe® safety syringe



The Gx InnoSafe® safety syringe is the first syringe with a passive needle protection system to be launched on the market. In addition to the safety features, it can be processed on all existing filling lines without any additional preparation or assembly steps.



Injection vials of the best quality: Gx® Elite Vials

Now also available in RTF format



solution provider

The Gx® Elite vials are a solution that sets new standards for type I borosilicate glass packaging. They are the result of comprehensive improvement and optimization measures in the tube draw and vial forming processes. These high-end tubular glass vials are our response to increasingly stringent customer demands and expectations on the pharmaceutical market including greater demands for patient safety.

Gx® Elite vials are the result of a quality by design approach that spanned several years. The primary focus for Gx® Elite Glass products was to provide the safest product for our customers and patients. This effort and the results have impressed our customers. The highly shatter-resistant vials are extremely durable, free of cosmetic defects and can be customized for specialized requirements. Gx® Elite Glass vials are produced using a stateof-the-art manufacturing platform with proprietary technology that creates a product that will exceed your expectations. A specialized combination of design, manufacturing and handling



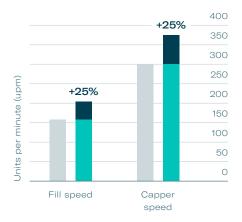
Gx® Elite vials are extremely durable and free of cosmetic defects

improvements along with customized final packaging ensures that Gx® Elite vials can be supplied for end-to-end improvements on all filling line applications. These types of advancements enable you to improve manufacturing efficiency and line throughput and thus reduce total cost of ownership. The application range includes custom solutions for high value products for combination healthcare devices, bioengineered drugs, and other specialized pharmaceutical applications.

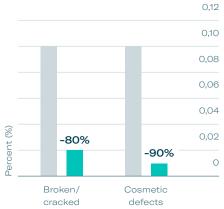
Now available in RTF format

The Gx® Elite vials are now also available in RTF format. 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.

Higher machine speed



Less breakage/cosmetic defects



Intelligent defect recognition

All our tubular glass plants that produce vials work with standardized monitoring, inspection, and packaging technologies, which consist of the Gx® G3 and Gx® RHOC systems. The inspection systems are developed by Gerresheimer Global Engineering and form a highly specialized vial testing platform that ensures the highest precision and quality assurance requirements for your glass packaging.

The Gx® Elite vials allow a significantly higher machine speed during filling and reduce breakage and cosmetic defects by 80% and 90% respectively.

Type II glass injection and infusion bottles for parenteral applications

Gerresheimer Essen: Center of Excellence for type II glass

As a leading provider of primary pharmaceutical packaging, Gerresheimer also specializes in manufacturing pharmaceutical containers made from type II glass. Internal treatment processes allow extremely small injection bottles as well as typical infusion bottles with larger volumes to be produced. Guaranteeing the quality and hydrolytic resistance of the type II glass is the top priority here. We are presenting type II glass packaging solutions at CPhI Worldwide in Milan in November.

"Our customers want safe, flawless products from us. So, we need to make sure that we have the best possible production process, even before treating the inside of the type II glass, by monitoring the situation constantly and intervening where required," says Silvio Carriço, Senior Product Manager Pharma, Food & Beverage.

Center of Excellence specializing in type II glass

For many years now, we have produced pharmaceutical bottles made from type II glass for drugs administered parenterally by injection or infusion. After overhauling and upgrading the clear-glass furnace in Essen, two new production lines were opened that will

mainly be used to make type II glass and link directly to the newly expanded cleanroom. As a Center of Excellence for type II glass for the whole of the Gerresheimer Group, the site will focus on further increasing its capacity and expertise, supplemented by sizable investment in state-of-the-art self-learning testing lines, among other things. We are thus reinforcing our position as an innovative provider of parenteral solutions.

Type II glass - perfect for parenteral applications

Primary packaging made from moulded glass has always been the go-to container for liquid and solid drugs. Type II glass is soda-lime glass that has been



You can now walk straight from the type II glass production line into the cleanroom.



subject to a special internal surface treatment process, which significantly increases its hydrolytic resistance. It is the best option for many parenteral

Additional safety and improved restitution

By an internal coating an improved restitution rate of the filled product can be further achieved. Gerresheimer developed a process to coat the inner wall of the glass bottles with a fine silicone layer after washing. The silicone is fixed to the glass by heat, passing an annealing lehr. The silicone supports a reduced variability of the hydrolytic resistance, as well as it provides an additional protection layer for the productto-glass-contact. Hereby the filled medicine can be further safeguarded throughout its lifecycle.

Prevention is better than cure

At Gerresheimer, the emphasis is on preventing errors - rather than picking up on them later. The specific requirements are taken into account at an early stage, right when the glass is melted. Special materials are used for this process, such as fused-cast alumina blocks. Among other things, these ensure that the stringent quality requirements made of the glass can be met reliably. The automated monitoring of drop (gob) formation, insertion into controlled tools and inspection of our glass quality already at

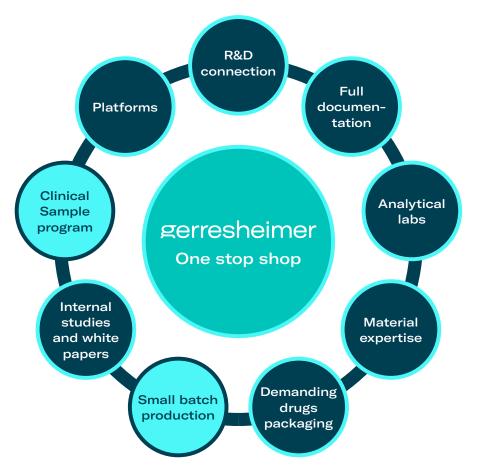
the Hot End support the end-to-end control of the glassmaking pro-



solution provider

Primary packaging solutions for biologics

Specialized services and expertise



Gerresheimer's clinical supply program and the small batch production are only two elements of a wide range of services.

Gerresheimer's Clinical supply program is part of a wide range of services

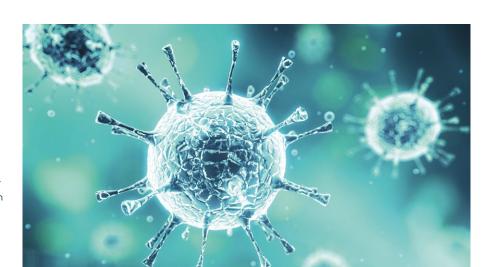
In addition to our broad product range, we offer a wide variety of services, particularly for small and medium-sized biotech companies, including advice on the right primary packaging material and container for the relevant clinical phase, support with approval and regulatory processes, laboratory services and much more. A new service offer is the establishment of a sample supply, especially for Gx® RTF vials in North America. This means that the most commonly used container formats for biopharmaceutical development are kept in stock, enabling customers to respond quickly to urgent market requirements.

Small Batch Production in Germany

When filling biological products, smaller batch sizes are often requested, hence we have invested in a small batch production facility in Wackersdorf (Germany). When the filled biological agent is sensitive to its storage environment, the container must be individually adapted to its properties.

The most important trend forecast by pharmaceutical experts is the continuing, worldwide increasing demand for biological drugs and biosimilars. With the Gx® Biological Solutions organization. Gerresheimer installed a dedicated solution-orientated team to serve the highly specific demands in the biologicals playfield.

At CPhI in Milano, we will present our products for the safe, innovative, and sustainable packaging of biologicals. "We want to provide our customers in the pharmaceutical industry with customized packaging solutions and services for their biologics so that they can be assured that all of their requirements are met 100 percent" said Stefan Verheyden, Global Vice President of the Gx® Biological Solutions team. As a leading manufacturer of syringes, injection vials as well as cartridges and drug delivery systems, Gerresheimer covers a very broad spectrum for the parenteral administration of biologicals within its portfolio.





Innovative SensAIR™ platform

For delivering drugs of higher viscosity

With SensAIR™, Gerresheimer presents a platform for on-body drug delivery which can deliver drugs of different 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 easyto-use SensAIR™ On-Body Drug **Delivery Device enables patients** to start medication in a selfdetermined manner in familiar surroundings, for example at home. The SensAIR™ On-Body Drug Delivery 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 our 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 Sens AIR^{TM} : patients, their relatives and also doctors. This device 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 easyto-use concept ensures that the patient does not have to carry out any lengthy and complicated preparation steps but can operate the device easily.

Sens AIR^{TM} is an innovative product platform for the administration of largevolume 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.

More about SensAIR

On-Body Devices (gerresheimer.com)



Scalability

innovation

The design allows for a wide range of flow rates for biologics of different viscosities. The drug can be delivered from a 10 ml or a 20 ml cartridge.

Cost efficiency

The number of components and moving parts is kept to a minimum to help ensure cost efficiency.

Easy to use

The primary packaging is crucial for this easy to use prefilled and preloaded on-body delivery device. Gerresheimer provides both, the glass cartridge and the complete device.

Reliability

The SensAIR™ on-body delivery device is equipped with audible and visual signals. The injection can only start when the device is patched onto the skin and the needle is retracted automatically after use.

Accuracy

The innovative device architecture allows a controlled drug delivery of the cartridge content.

Connectivity

The optional Bluetooth wireless connection to smartphones and computers enables easy connection of the device with mobile apps and other digital services.



EcoVadis audit: Strong success in our sustainability strategy



Gerresheimer belongs to the Top 3 percent in its comparative sector

We have set ambitious targets in terms of sustainability and consistently implement corresponding measures. This is also reflected in the result of the current EcoVadis rating, because with 64 out of a maximum of 100 possible points, Gerresheimer is currently among the top three percent of companies assessed by EcoVadis in a CSR audit in the comparative sector of pharmaceutical suppliers and medical technology.

Numerous international pharma and cosmetics customers regularly evaluate measures and results about responsible business practices of their suppliers. They either assess these individually in terms of sustainability through questionnaires and audits or handle this through recognized external sustainability rating agencies such as Eco-Vadis. EcoVadis scorecards make it easier for customers, but also investors and other stakeholders, to assess the performance and continuous improvements of their suppliers across different dimensions of responsible business practices.

Silver status with 64 Points -Progress towards gold

In 2018 we succeeded in making the leap from bronze to silver rating with 46 out of 100 possible points and have further improved the EcoVadis score to 58 points in 2019. As part of imple-

menting the our sustainability strategy, which was published end of 2020, we now received once again a better evaluation. With 64-point we belong to the top 3% of companies assessed by EcoVadis in the comparative sector of pharmaceutical suppliers and medical technology. At the same time, we are only 2 points below the next level, the gold score, which is awarded from 66 points onward as per the current scoring methodology.

Sustainability is a strategic Gerresheimer goal

At Gerresheimer sustainability is one of the five strategic pillars. As a global production company, we bear a great responsibility for our products and customers as well as patients, employees, partners, suppliers, neighborhoods and the environment. We set the goal to be a strong partner and solution provider integrating sustainability into core pro-

The EcoVadis rating process

EcoVadis is a sustainability assessment platform. The methodology is based on international CSR standards such as the Global Reporting Initiative, the United Nations Global Compact and ISO 26000 and considers 198 purchasing categories and 155 countries. The EcoVadis scoring model contains 21 criteria from the four subject areas of environment, social affairs, ethics and sustainable procurement. Suppliers demonstrate the extent to which they meet these criteria in whole or in part and are eval-updated on this basis. Once a year EcoVadis then creates a company-specific sustainability ranking, which is accompanied by a scorecard. Currently, the scorecard consists of four evaluation categories, and the scores are grouped into bronze, silver, gold, and platinum.

cesses, our decision making and our products. These ambitions are also reflected in our scores in rating and ranking and we aim to achieve the gold medal in the EcoVadis evaluation shortterm.



Sustainability efforts appreciated by the customer

Gerresheimer is committed to sustainability. This is also increasingly noticed and appreciated by our customers. The most recent example is Novo Nordisk. The insulin manufacturer posted a video on social media thanking its suppliers for their commitment around sustainability.

Otherwise, the company would not be able to achieve its own sustainability goals.

In the video, Novo Nordisk highlights the fact that at Gerresheimer we use electricity from solar, wind, hydropower and biomass to produce the components for insulin pens. We supply these pens to Novo Nordisk.

Novo Nordisk created the video to mark Climate Week in New York City. We are very pleased that our commitment is being seen and recognized. This is also an incentive to continue our activities in the field of sustainability at full speed.



Gerresheimer EcoLine: packaging medicines sustainably right from the start













With EcoLine, Gerresheimer shows at CPhI Worldwide in Milan (Italy) how you can develop plastic packaging solutions that are designed to be sustainable from the start. Material, weight, volume and recyclability play an important role in this.

More and more consumers are paying attention to environmentally friendly products and to the fact that they are packaged in an environmentally friendly way or at least in an environmentally compatible way. I think that's good, and I do the same myself," says Niels Düring, Global Executive Vice President Primary Packaging Plastic. "This is also confirmed by our customers who are looking for a plastic packaging solution for their pharmaceutical product in which the contents can be used and stored safely. Our EcoLine concept helps them find a solution that optimally combines quality and sustainability by ensuring tight and light solutions."

Our EcoLine concept includes the criteria of weight, volume, material and recyclability. It can be applied to all existing Gerresheimer product families made of plastics such as Duma, Triveni and to the dropper bottles as well as to the PET bottles.

Weight

How heavy does the individual packaging have to be to provide optimum protection for the contents? A lower tare weight saves transport and energy costs and consequently reduces CO₂ emissions.

Volume

What volumes are really required? The container should be sized to hold its contents but have as little void space as possible. This also has a direct influence on the material consumption, transport and storage costs for a product.

Material

Which plastic material can be used? Due to the overall increase in environmental awareness, consumers pay more attention today to environmentally friendly packaging. Where feasible, resource-saving, or recycled materials should be used. We offer both possibil-

Recyclability

Recyclability begins with material selection. The materials and natural resources that Gerresheimer uses in its production can be recycled. Likewise, we produce plastic containers from recycled materials. For example, PET bottles, which can be made from up to 100% recycled plastic. With BioPack, we offer a plastic made from sugar cane, a renewable raw material.

More information

Gerresheimer Primary Packaging Plastic

Gerresheimer specializes in the development and production of pharmaceutical primary and special packaging made of glass and plastic. In both areas, the company is pursuing ambitious targets in terms of sustainability, because in both development and production, sustainable criteria can ensure that less energy is consumed, and production is more resource efficient.



Digital simulation of the glass molding process

Lightweight, stable and resource-saving



sustainability

Gerresheimer has set itself the goal of applying sustainability criteria to 100 percent of new product developments by 2023. For example, glass simulation helps to achieve perfect, uniform glass distribution. It can improve strength and contribute to weight reduction and the avoidance of rejects. The innovative simulation software used by Gerresheimer for this purpose tunes the production parameters based on CFD (Computational Fluid Dynamics or numerical flow mechanics). In this way, potential for improvement can be identified at an early stage and the development time can be shortened.

"The production of the glass container starts with the design of the mold. The more precisely the mold is designed and manufactured, the better its quality in terms of glass distribution, visual appearance, strength and weight," says Philipp Amrhein, Manager New Product Development & Mould Design at Gerresheimer in Lohr (Germany). The weight of bottles, flacons, and jars in particular plays an important role in energy consumption and therefore in both production and transport logistics. Considering all chemical and physical

glass parameters, the molding production process and the design of the molds are optimized with the aid of digital simulation on the computer. The mold cooling is also optimally designed for the respective process by means of CFD simulation. This leads to stress reductions in the glass container and thus to an effectively improved quality of the entire production process, for example by avoiding high scrap rates.

Reduction of development time by up to 70 percent

What used to take lengthy empirical trials to achieve a stable production process is now done in a matter of minutes, at the push of a button so to speak, using computer-based simulation software. Subsequently, the

results are transferred via interfaces directly to the three-dimensional CAD software of the mold design department, and the mold processing machines use them directly to create the mold tools. It is also gratifying that the simulation software reduces development time by up to 70 percent.

Rapid detection of vulnerabilities

Based on the well-known finite element analysis (FEA), the stresses resulting from the product requirements are calculated on the glass containers. Based on these results, weak points can be avoided even before the finished article

Result of the process simulation – analysis of the glass wall thickness distribution

drawings of the product. In the mean-

time, computer-aided simulation of the

molding process and product requirements has become an indispensable

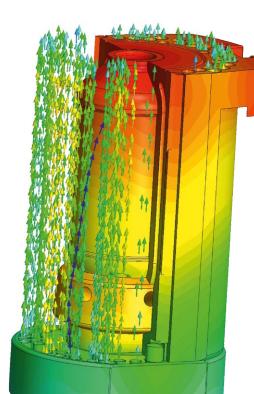
part of daily mold design and our con-

Environmental aspects considered from the outset

tinuous improvement process.

The global volume of packaging is constantly increasing and with it the negative impact on the environment. The transition to a circular economy is an important concern for us. We want to improve the environmental impact of our products throughout their entire life cycle - including production, transport, use and disposal. In many cases, the packaging solution is an integral part of the system, without which some medications would not be as userfriendly and safe. In this way, the we lay the foundation for a sustainable product right from the development process and aim to ensure that the environmental impact is considered from the outset.

Mold cooling design





Gerresheimer Lohr (Germany)

plans to use hybrid technology for greater sustainability in glass production

With modern and sustainable glass production technology, Gerresheimer's plants in Germany set exemplary standards for all of the company's plants in Europe, America and Asia, particularly in innovations for greater sustainability. With the use of hybrid technology, the Gerresheimer plant in Lohr plans to build a glass melting furnace for white glass in 2022 which will save significantly more CO₂ than conventional technology. The company has submitted a funding application to the German Federal Ministry for the Environment for this pioneering innovative project.

"This pioneering technology project serves to strengthen Germany as an industrial and glass location. With this innovative technology we will set new standards in terms of sustainability and avoidance of emissions," said Andreas Kohl, who as Global Senior Vice President Operations is responsible for worldwide container glass production and its technical development in the Group.

At the Lohr plant, Gerresheimer produces more than one billion glass containers annually for the pharma and food industries with two melting furnaces for clear and amber glass. "By using this sustainable furnace technology in conjunction with green energy for the glass melting process, we will significantly reduce CO₂ emissions in production by around 25,000 tons per year," says Jörg Buchmayer, Head of Production and Technology, who is responsible for the project. "We are using hybrid technology, which makes it possible to cover half of the required melting energy in the furnace with green electricity and the other half with natural gas."

Glass can be recycled an infinite number of times. However, high temperatures are required for glass melting. This costs energy and generates corresponding CO₂ emissions. For more than a decade, the Gerresheimer Group has been working on using no more energy than absolutely necessary for the sustainable production of its glass containers for the pharma, cosmetics and food industries.



At its Lohr plant, Gerresheimer produces more than one billion glass containers for the pharma and food industries every year. By using sustainable furnace technology and green energy for the glass melt, we aim to significantly reduce CO, emissions.

We also produce glass containers for numerous well-known branded products in the pharma and cosmetics world at its German sites in Essen and Tettau. As part of our global sustainability strategy, Gerresheimer has set itself the goal of reducing its CO, emissions by 50% by 2030 compared with 2019. The resource-saving production of glass plays a decisive role in this. The innovative technology planned for the plant in Lohr is pioneering in this respect.



In 2020 Gerresheimer Zaragoza initiated a replacement plan for the existing 25 years old cooling-system for molds and machines. Aligned with our sustainability goals, the focus was not just the one-to-one replacement but a

Gerresheimer Zaragoza (Spain):

New eco-friendly cooling system and certificate for sustainability

change in the concept, evolving towards a system that reduces the impact on the environment. The aim is to significantly reduce the water consumption through the replacement of the existent equipment with new air-condensation chillers.

The project is divided in different phases during the coming years. We expect to reduce the water consumption by 20% already this year.

Besides water consumption the topic of energy consumption was always high on the agenda of Gerresheimer Zaragoza. Meanwhile, all the energy Gerresheimer Zaragoza consumes, comes from 100% renewable energy sources. Therefore the plant has been certified by the CNMC (Comisión Nacional de los Mercados y la Competencia) and received the sustainable energy certificate for 2021.

Gerresheimer in Pfreimd (Germany):

Expansion of the clean room area for a major project



Gerresheimer production location Pfreimd with new connecting building

Gerresheimer has expanded the production area at one of its larger locations. The new building in Pfreimd (Germany) offers 1,800 square meters of clean room area of ISO class 8. This construction measure will result in a continuous connection of all clean room areas, so that all loading and unloading procedures in intralogistics are dispensed with. The new building will be used for setting up additional assembly lines, and the building can be used universally thanks to a flexible usage concept.

Following the expansion of small batch production at the Wackersdorf location in Germany and the erection of a new production location in Skopje (North Macedonia), Gerresheimer has also expanded the production capacity at the Pfreimd location with a new building. The new area is required for the major order of a leading pharmaceuticals company. Construction already started in October 2020, and meanwhile the new building is completed. With an additional 1,800 square meters, the entire clean room area is expanded to around 20,000 square meters. In Pfreimd, Gerresheimer Medical Systems manufactures products like lab disposables, pen systems, infusion sets, lancing devices, pumps, autoinjectors, inhalers, and catheters for worldwide pharmaceuticals, diagnostics, and medical technology companies.

The new building makes it possible to already increase the number of assembly lines at the location to 29 this year. The new, fully automatic lines correspond to the most modern standards, are equipped with Industry 4.0 data analysis systems, and will be connected to an automated guided vehicle system (AGVS). The building itself is conceived of on the basis of our sustainability strategy and contributes to saving CO₂ through energy efficiency, as well as heat recovery. The new building is also pre-equipped for the erection of a photovoltaic system, the use of which is currently being tested. "The new connecting building offers our customers clear advantages for the production of sophisticated pharmaceutical and medical technology products," explains Oliver Burgel, Global Executive Vice President Operations, Procurement, HR & Quality, Member of the Management Board, Gerresheimer Regensburg GmbH. "With its highly modern technology, the building is at the same time an important building block for assuring the future of our production facility in Pfreimd." Thanks to the continuing automation, many attractive workplaces for well-trained specialists will be created in areas like mechatronics, electronics, or IT, among others.



Gerresheimer **Boleslawiec (Poland)** is now ISO 45001 certified

Our Polish plant Gerresheimer Boleslawiec has been certified in compliance with ISO 45001 and thus made a big step on the way to safe workplaces. ISO 45001 is an international standard that specifies requirements for an occupational health & safety (OHS) management system. It provides a framework for organizations to manage risks and opportunities to help prevent worker illnesses and injuries.

Furthermore, at the same audit Gerresheimer Boleslawiec maintained the existing ISO certifications 9001, 15378 and 14001.



Gerresheimer Kosamba (India) the construction of the new plant continues to progress

The construction of our new 4.000 m² Primary Packaging Plastics plant in Kosamba has moved into the second phase. 40% of the building is completed and the second floor's slab shuttering and tie beam work are in progress.



Events

CPHI Worldwide November 09-11, 2021

Milano, Italy Hall 6, Booth 6J10

Pharmtech & Ingredients November 23–26, 2021

Moscow, Russia

CPhI India November 24–26, 2021

New Delhi, India Expo Centre, Greater Noida, Delhi

MD&M East December 07–09, 2021

New York, USA

CPhl China December 16–18, 2021

Shanghai, China

Medtec China December 20–22, 2021

Shanghai, China



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Improved strength – minimum 2x-4x standard Type I glass

- Same glass chemistry as Type I
- Cosmetically flawless
- Dimensionally superior
- Delamination resistant



innovating for a better life