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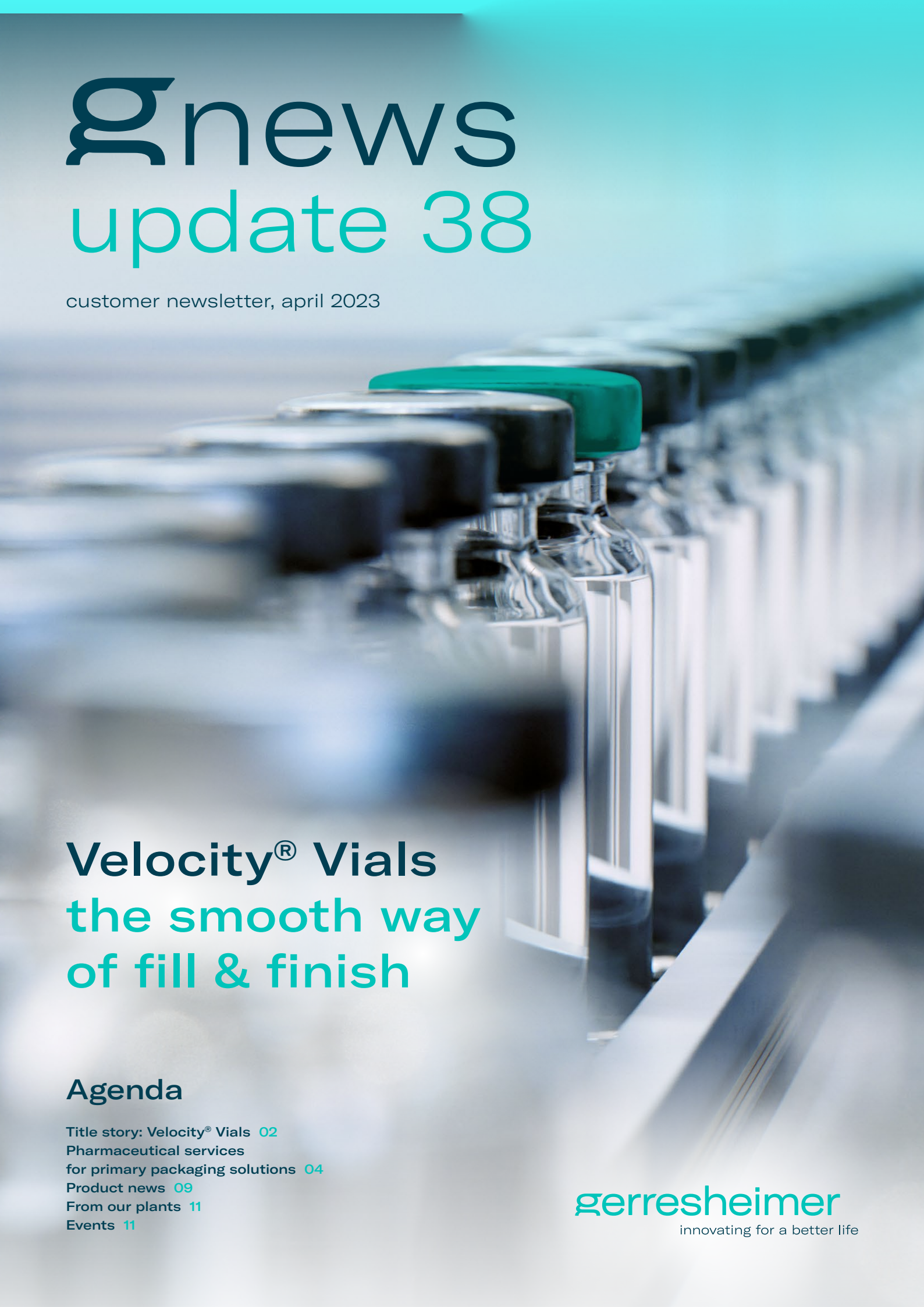


Velocity® Vials
the smooth way of fill & finish

Agenda

Title story: Velocity® Vials 02
Pharmaceutical services for primary packaging solutions 04
Product news 09
From our plants 11
Events 11

gerresheimer
innovating for a better life

Title story: Velocity® Vials

Make the fill & finish process up to 50% more efficient with vials with a Velocity® coating

A major problem in the fill & finish process of conventional borosilicate glass vials is the friction caused by glass-to-glass and glass-to-metal contacts. Frictional resistance reduces the transport speed of vials on the filling line and can cause vials to tip, scratch or break. Defective vials can cause production stops or – even more seriously – expensive recalls.

The solution: a friction-reducing and stabilizing outer coating for vials

A new generation of vials from Gerresheimer smoothly eliminates these problems. It features the Velocity® outside coating developed by Corning Inc., which speeds up the fill & finish process by reducing frictional resistance and minimizes defects in the glass. The fill & finish process becomes up to 50% more efficient with Velocity® vials.

Significant reduction of TCO

Velocity® vials speed up the fill & finish process and reduce machine downtime to a minimum. According to various studies, the increase in efficiency is between 20% and 50%.

Seamless integration

Velocity® vials are a drop-in solution to existing fill & finish lines, no changes are required. This results in an immediate reduction in pharmaceutical production costs.

No additional regulatory approval

There is no need for an additional post-marketing drug approval process because the internal surface that comes into contact with the drug is not altered. Velocity® coating technology is compliant with European and U.S. health authorities.

Less jams on the filling line

Velocity® exterior coating prevents vials from snagging and jamming in turn tables, depyro tunnels, tracks and trays.

Fewer damaged, scratched and tipped vials

Velocity® coating reduces mechanical stress on vials. Production interruptions are significantly minimized as there are hardly any defective or tipped vials in the filling line. This significantly reduces downtimes and improves the efficiency of fill & finish lines.

Improved quality

Less friction also means a reduced particle load and therefore an improved end product quality. Velocity® vials present a visually flawless appearance and meet the highest quality standards.

Immediately available

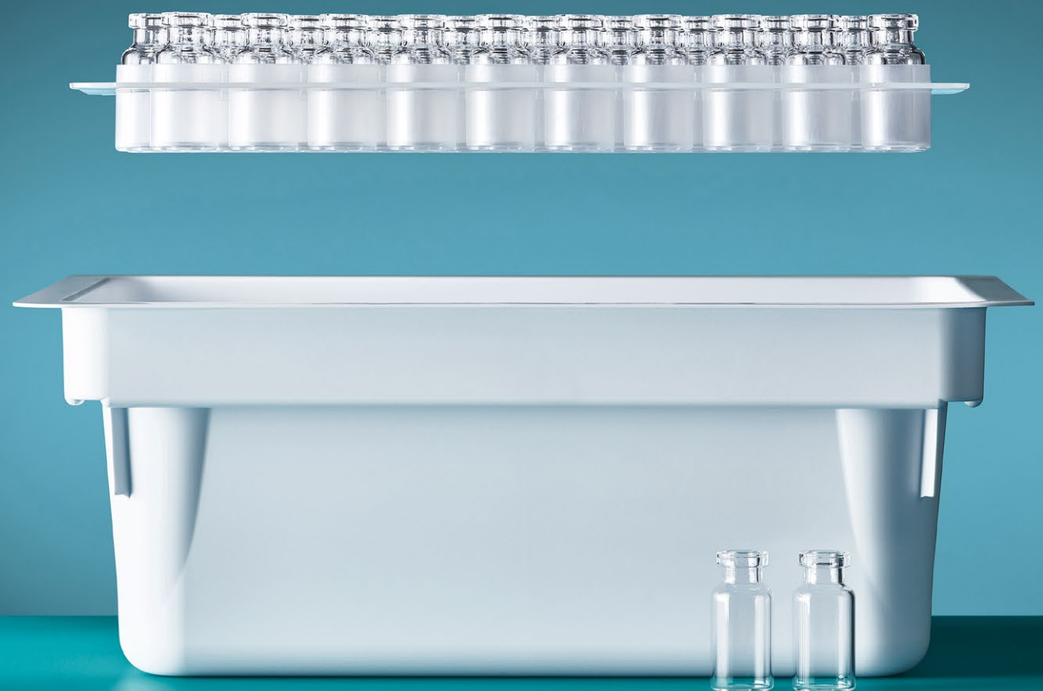
Velocity® vials are available immediately in all major sizes for the European and American markets. We are happy to provide samples so that you can see the benefits for yourself.

Supplied in standard packaging

Velocity® vials are supplied in standardized trays and can be seamlessly integrated into existing filling processes.

EZ-fillsmart™

Making your life easier



Optimized TCO

- Reduced processing costs
- Reduced filling line breakage
- Faster line performance
- Reduced risks of market rejections and recalls
- Minimized investment costs for fill & finish lines by less equipment

Superior quality

- Significantly reduced particle load due to new polymer film seal
- Fully visible vials due to transparent seal
- Optimized nest design prevents glass-to-glass contact
- Increased patient safety

Advanced sustainability

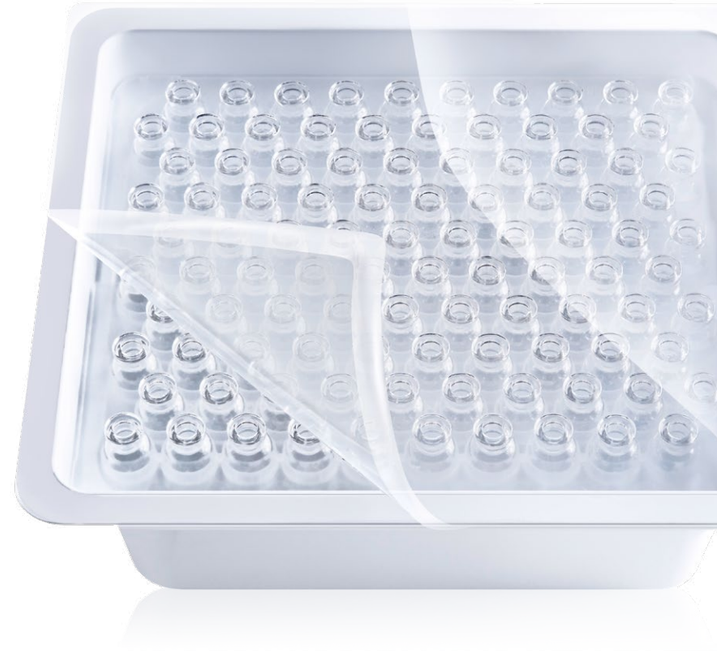
- Environmentally friendly new sterilization method
- Use of biopolymers and recycled plastic
- Less material and reduced packaging weight
- Vials manufactured with green energy
- Less scrap due to improved quality

Increased process efficiency

- Compatible with existing nest filling technologies
- Increased productivity through higher level of automation
- Platform suitable for all batch sizes

De-risking of fill and finish

- Machinability tested by leading machine vendors
- 3 inch tub for all vial sizes (and in the future also for cartridges)
- No supply chain risk through uniform standard of two leading suppliers
- Meets all worldwide regulatory requirements



The new EZ-fill Smart™ packaging platform comes in one size fits all vials in a nest & tub configuration and will also be available for cartridges in the future. A new transparent polymer film replaces the traditional Tyvek* lid and allows for convenient cosmetic view of the interior. Thanks to the new polymer film the particle load generated when opening the tub could be reduced by more than 90%. An impressive success that offers patients even more safety when taking and administering their medication. Along with the nest & tub configuration, EZ-fill Smart™ will also be available in tray configuration to support and accelerate the conversion from bulk to Gx® RTF vials that is already underway in the market.

“As an innovative and leading solution provider for the Pharma and Biotech industry, Gerresheimer responds to customer demand with a best-in-class solution. We are convinced that the new EZ-fill Smart™ platform is the next industry standard for Ready-to-Fill vials and in the future also for cartridges”, said Lukas Burkhardt, Member of the Executive Board of Gerresheimer AG. “The new platform will enable customers to optimize their processes, improve their quality and also their CO_2 footprint. In addition, our customers benefit from a significant reduction in the Total Cost of Ownership.”

*Tyvek is a registered trademark of the DuPont company.

Transforming primary packaging into digital twins

Proof of Concept (PoC) successfully provides primary packaging with a unique ID to access its own trustworthy digital twin

Secure access to data

Faster processes and savings

Data-informed decision-making

New business models thanks to process automation

Fight counterfeiting thanks to transparency

“We are convinced that our primary packaging will become the key to enable supply networks across organizations and lead to faster process operations and data-informed decision making,” said Daniel Diezi, Vice President Digitalization & New Business Models at Gerresheimer.

“At Merck, we develop innovative digital solutions to help companies exploit the exciting advantages of the Industrial Internet of Things (IIoT) and create digital twins they can really trust. We are proud to be a digital sparring partner to help Gerresheimer realize this by putting our patented digital technologies at their service,” said Thomas Endress, Executive Director of EMD Digital at Merck.

Unique ID is the key to unlocking data

With the jointly developed solution, our physical primary packaging is provided with a trusted “key”, enabling access to its digital twin. Primary packaging, such as syringes or vials, “travel” through the whole supply chain, from production to the point of care, connecting and collecting information that will be linked to their unique ID. They become the key to unlocking data coming from numerous digital ecosystems, enabling more efficient collaboration among various organizations in the supply network. The new solution implemented on our products uses blockchain-based platform and multi-patented authentication technologies developed by Merck to anchor physical objects securely in the digital world. In combination with Industry 4.0 standards, this makes it highly trustworthy and reliable. As a science and technology company that operates across different business sectors, Merck also develops forward-looking digital solutions for customers that can be applied in a wide variety of industries.

Access relevant features via Smartphone App

The joint PoC comprises physical syringes with a secure unique ID, a smartphone application, and access to the digital platform of Merck in order to unlock the digital twin features. The smartphone app is accessible to authorized stakeholders such as brand owners (marketing authorization holders) and quality assurance officers of the manufacturer. After authenticating the syringe and reading the unique ID, the authorized user can access features such as quality data on demand, root-cause analysis data, and customer complaint handling:

- Quality data on demand: retrieving the machine-readable certificate of analysis as well as cosmetic and dimensional inspection data
- Customer complaint handling: streamlined complaint handling from brand owner to manufacturer and dashboard-like overview
- Root cause analysis: product-related data such as specifications and aggregation across different packaging levels in combination with quality-related data make it possible to examine errors and spot potential sources for mistakes at the container level.

Onboarding further parties

In this particular case, as in pharmaceutical supply chains where many specialists contribute to overall success, we intend to onboard further parties to build additional seamless multiparty solutions and exploit the full potential of traceability from production to the point of care. As soon as additional parties, such as contract manufacturing organizations, logistics providers and regulatory bodies, adopt the solution, the potential for automated business logic grows for use cases such as automated machine-to-machine generation of certificates and its exchange across different parties.

More information

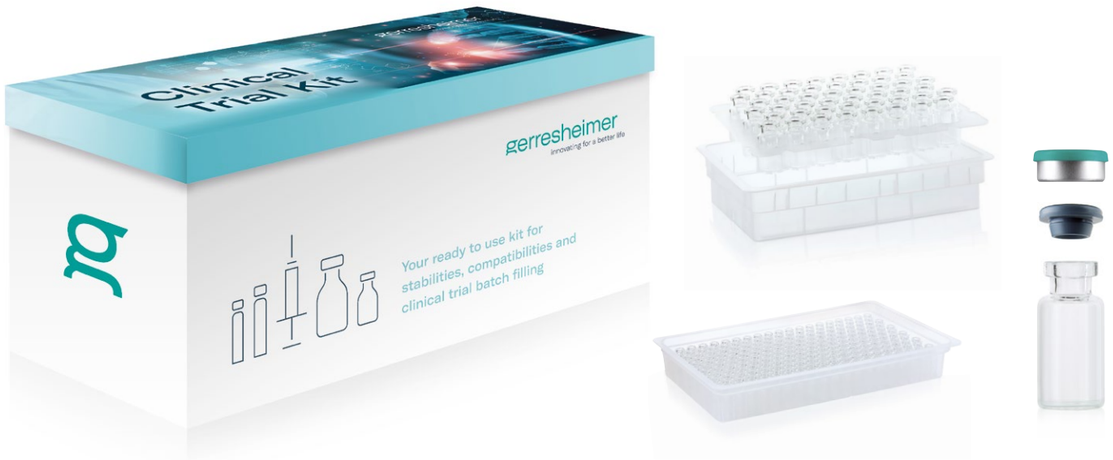
... about our solution for traceable primary packaging can be found here: www.gerresheimer.com/en/innovation/track-and-trace-solution.

... about the digital solution by Merck to build digital trust in supply chains can be found here: www.merckgroup.com/en/research/research-and-development-highlights/blockchain.html.

... about digital printing: Sample boxes for printing unique IDs to tubular glass products are now available. Contact traceability@gerresheimer.com if you want to experience the advantages of digital printing.

New Clinical Trial Kit to accelerate drug development

Gerresheimer has developed a 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 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® RTF glass vials. Kits including Gx® Elite and Gx® RTF COP vials will follow soon.



"There are currently more than 3,000 injectable drug programs in pre-clinical and clinical phases. With our clinical trial kits and supportive services, we want to proactively support our customers by providing them with first-class primary packaging solutions," said Jean-Edouard Rabier, Sales Development Manager and Director Project Management/Pharmaceutical Services and member of the Gx® Biological Solutions Team.

Simplifying the clinical development of drugs

Our Clinical Trial Kit simplifies the clinical development of drugs by offering pre-tested and validated solutions that are readily usable for small batch sizes to replace commercial production. The major advantage of this concept is that companies can benefit from the exact same performance of the containers during commercialization as during research and development. This helps to shorten time-to-market and bring life-saving drugs to patients faster.

Sterile Gx® RTF Vials and a selected range of stoppers and closure options

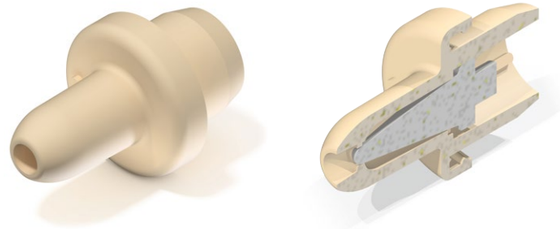
The kit provides a complete set of primary packaging container and containment solutions, especially selected for high-value drugs and/or most complex and demanding drugs. The Clinical Trial Kit complies with GMP requirements for the production of clinical batches. It is currently offered in six different configurations with nest and tub or tray for filling volumes 2R RTF, 6R RTF and 10R RTF. You may receive a tailored kit made from a range of stopper and closure options selected using expert advice. Each kit offers tried-and-tested product features, such as the integrity of the container system.

Additional integrated services

We accompany and support your drug development from basic analysis to fill & finish service, i.e., from the early phase through to life-cycle management. For this purpose, we have developed a network of partners to support you during the entire drug development journey. This includes expertise regarding regulatory implementation, development path and market approach, strategies for packaging and administration of drugs, as well as laboratory services. Analytical laboratory services include E&L studies (components and systems), material characterization according to ISO 10993-18:2020, biocompatibility studies according to the 10993 series, toxicological risk assessment and consulting services and BEP/BER writing services.

Formulation, fill & finish

Together with selected partners, we support you from the early pre-clinical phase to the start of clinical and commercial batch supplies. Regardless of whether you are CRO, CMO or CDMO, we know the right partners for a wide range of drugs including vaccines, mAbs, mRNA-based drugs and ATMPs.



DropControl – Gerresheimer's solution for new ophthalmic formulations

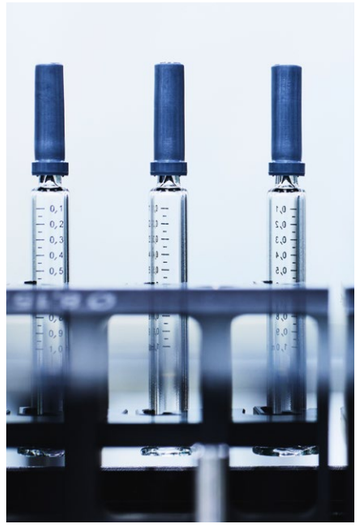
The new generation of eye drop solutions has modified properties compared to the former water-based eye-drop solutions to improve the pharmaceutical effectiveness. The function of the eye-dropper therefore required a modification to prevent uncontrolled dropping when the patient turns the eye-dropper to release the droplets. "With DropControl Gerresheimer offers a solution to enable the use of conventional eye dropper systems for the new eye drop solutions with very low viscosity", says Niels Düring, Global Executive Vice President at Gerresheimer Plastic Packaging.

With DropControl the patient can apply the eye-drops as usual. The outer shape is unchanged, we just developed an insert which prevents the uncontrolled release of droplets. It is suitable for all Gerresheimer's A, E and F dropper bottle systems in 5, 10, 15 and 30 ml.

Siliconization for moulded glass packaging

We have established a siliconization process of the inner glass surface for volumes from 5 to 500 ml for clear and amber containers of hydrolytic classes I, II and III. Siliconization creates a hydrophobic silicone film that improves residual emptying of the filled medicine. This enables almost one hundred percent utilisation of the filling volume and optimal dosing of the medication. The silicone coating also forms a protective barrier between the medicine and the glass surface, ensuring that the medicine is additionally protected over its life cycle. This will help you to maximize the value of your pharmaceutical product and keep your patients safe.

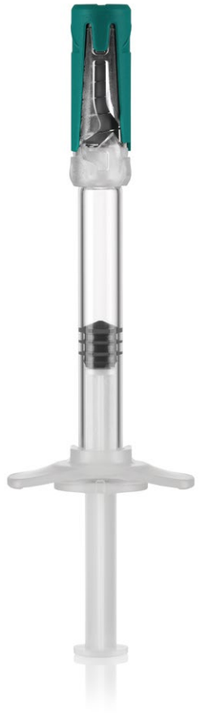
Improved sterilization of Gx RTF® syringes



With our sterile Gx RTF® syringes, we are regarded as the technology leader with more than 20 years of production experience. We wash, siliconize, assemble with needle shield or tip cap and sterilize Gx RTF® syringes with ethylene oxide (EtO), which means that they are delivered completely prepared for aseptic filling. Together with our service provider, a global leader in outsourced sterilization services, we are working on an innovative solution that will reduce the use of ethylene oxide by around 45% and thus reduce fugitive emissions of ethylene oxide.

The benefits of reduced ethylene oxide use at a glance:

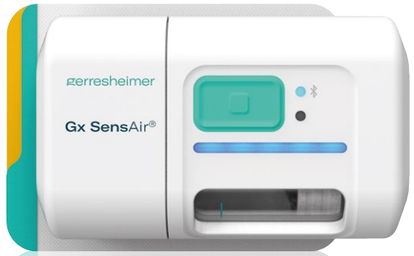
- Continued safe use of ethylene oxide as the most widely used sterilization method for primary glass packaging.
- Maintaining specified residual ethylene oxide while reducing fugitive emissions and excess residuals
- Reduction of required aeration times and thus resulting in improved customer supply chain efficiencies
- Reduction of the CO_2 footprint



Gx InnoSafe® syringe with passive needle protection system

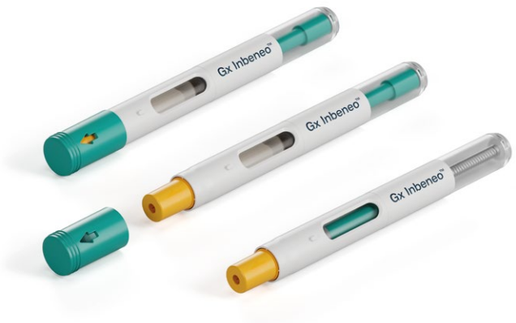
Nurses are among the occupational groups with the most frequent cuts and puncture wounds. This can lead to infection with dangerous pathogens such as hepatitis B and C viruses or HIV. The Gx InnoSafe® safety syringe is the first syringe with an integrated passive safety system. The function of this solution is to prevent accidental injury to an already used syringe by an unintentional needle stick, because the needle is fixed in a sleeve immediately after use. In addition to these unique safety features, a special feature of the Gx InnoSafe® syringe 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.

Innovative Gx SensAir® platform for highly viscous biologics



With Gx SensAir®, Gerresheimer presents an innovative platform for on-body delivery of drugs with 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 Gx SensAir® On-Body Drug Delivery Device enables patients to start medication in a self-determined manner in familiar surroundings, for example at home. The Gx 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, Gx SensAir® enables optimized delivery of biologics.

Gx Inbeneo® – first Gerresheimer autoinjector



Our new autoinjector Gx Inbeneo® offers new opportunities in the treatment of various diseases. It is suitable for subcutaneous injection with up to 3ml volume. The patient-friendly, robust cartridge-based autoinjector will serve as a flexible 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.

Successful FDA inspection

Gerresheimer Peachtree City, GA (USA)

Vero Biotech's first tankless inhaled nitric oxide delivery system

The Gerresheimer subsidiary in Peachtree City, GA (USA), was named an approved "Contract Manufacturer for VERO Biotech's GENOSYL Delivery System (DS), drug substance intermediate" for the disposable cassette of the company's third generation of the first tankless inhaled nitric oxide delivery system. As part of the product's approval on the American market, the entire manufacturing strategy was examined by the United States Food and Drug Administration.

This inspection was a key step for the approval of the third generation GENOSYL Delivery System (DS). The approval presents an important new development in the clinical use of inhaled nitric oxide, and the pent-up demand for this third generation innovation demonstrates its increasing value to the acute care community.

Unlike tank-based systems, GENOSYL DS generates and delivers iNO at the bedside using a small disposable cassette. This eliminates the need for hospitals to manage large, cumbersome tanks and helps to simplify clinical workflow. The recently approved third generation GENOSYL DS also includes an innovative dual-cassette design and secondary adaptive sensor technology to further optimize patient care.

300 years of Gerresheimer Essen

Today's Gerresheimer Essen GmbH (Germany) has been in existence since 1723, its origins going back to the "Royal Privileged Glass Manufactory" founded 300 years ago.

The product portfolio of Gerresheimer essen today consists of flint and amber glass of glass types II and III. Primary packaging for the pharma industry in particular is produced at the plant, for example for cough & cold remedies, penicillin, antibiotics or also infusion and injection medications. Gerresheimer Essen is also a specialist for spirit miniatures and produces bottles and jars for the cosmetics industry.

Through the use of innovative technologies and continuous investment in development and progress, Gerresheimer has been able to maintain its leading position in the market. As early as 1976, the plant was one of the first glassworks ever to have ISO Class 8 cleanroom technology. Today, Gerresheimer Essen has integrated robot-based automation solutions into production to achieve greater flexibility, productivity as well as relief for staff. Focused on quality, innovation and customer satisfaction, Gerresheimer Essen is committed to remaining a leading supplier of glass products in the years to come.

Trade Fairs

Injectable Drug Delivery
May 10–11, 2023
London, United Kingdom
Copthorne Tara Hotel

DDF Summit
May 31 – June 02, 2023
Berlin, Germany

Bio Boston
June 05–08, 2023
Boston, MA (USA)
Boston Convention & Exhibition Center
Hall 4 | booth 234

Connect in Pharma
June 14–15, 2023
Geneva, Switzerland
Palexpo | booth E15

CPHI China
June 19–21, 2023
Shanghai, China

CPHI South East Asia
July 12–14, 2023
QSNCC Bangkok, Thailand
Hall 3 | booth P30

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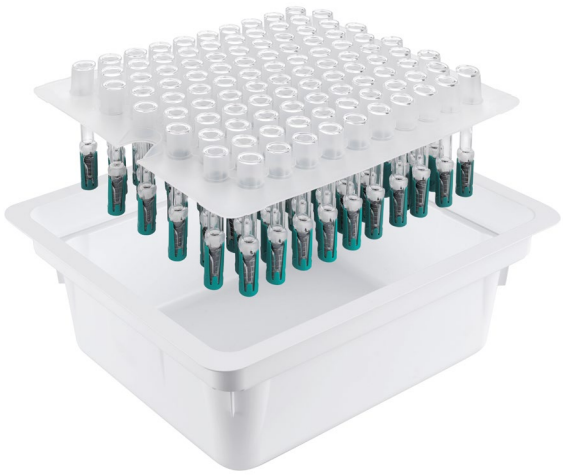
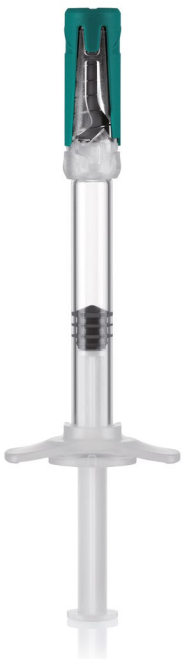
Protection against needlestick injuries





Gx InnoSafe®

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

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