gerresheimer
innovating for a better life

# Gx® Vials Platform

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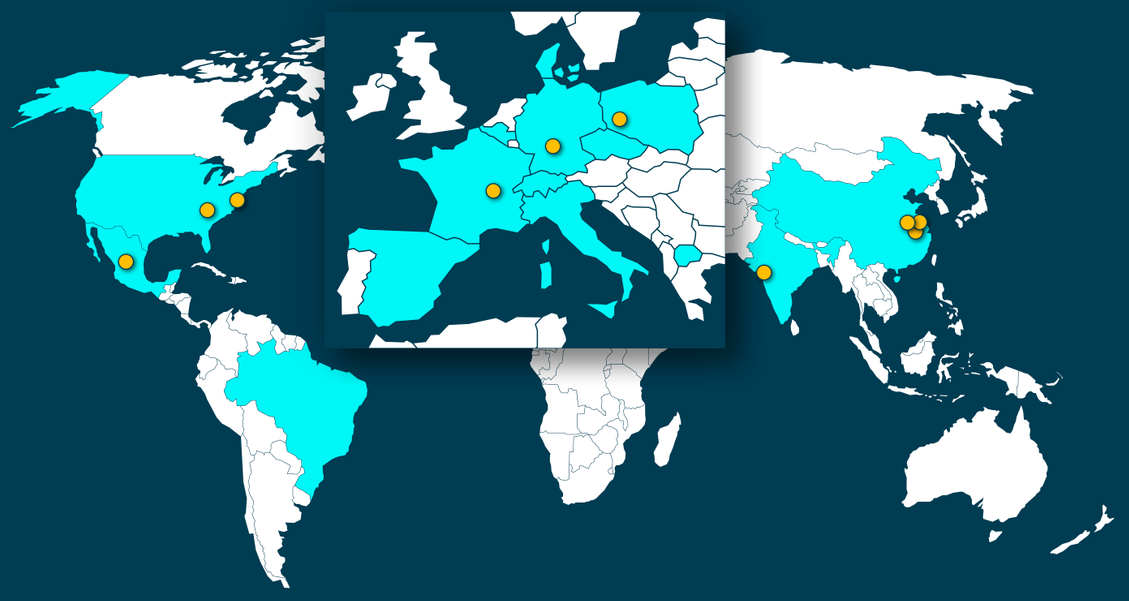

# No. 1 Vial Producer

We are the leading global manufacturer of high-quality vials. With more than 150 years of expertise we offer a broad range of pharmaceutical vials for different applications and three performance levels. Our vial portfolio also includes diagnostic vials (for ex. chromatography and screw thread vials) and special vials such as micro-vials and dual-chamber vials.

**Glass vials**
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# Five Great Reasons to Choose Gerresheimer as Preferred System and Solution Partner for Vials

## 1 Addressing industry pain points with innovation

Our top level vial product, the Gx® Elite vials were developed by translating common fill & finish pain points – breakage, sealing variability, and dimensional inconsistency – into measurable design and process parameters.

## 2 Next generation quality

Through a Quality by Design (QbD) approach, these parameters are tightly controlled and continuously monitored to deliver predictable, reproducible quality that simplifies validation, enhances process robustness, and de-risks drug product manufacturing.

## 3 Secure supply chain through global sourcing

We operate 10 vial production sites across Europe, the Anericas, and Asia to effectively mitigate risk.

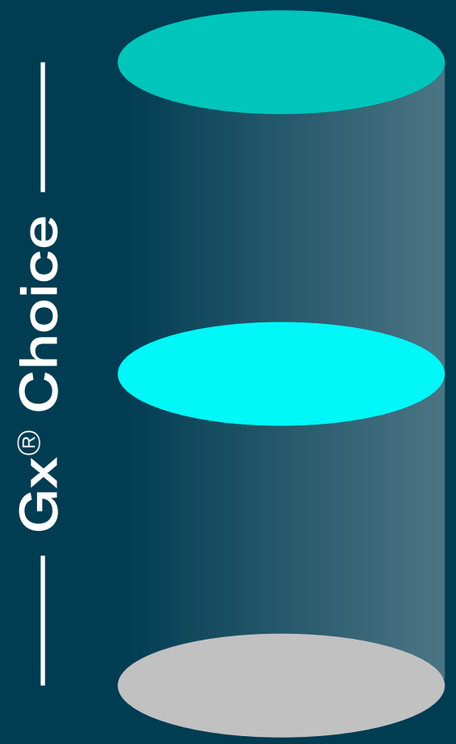
## 4 The right vial for your specific needs

Thanks to our three performance levels you can choose the vial level whose quality attributes are perfectly tailored to your situation.

## 5 Pharmaceutical integrity through standards and DMF Commitment

We ensure compliance with major pharmacopeial standards (Ph. Eur., USP, JP, and FEUM). Furthermore, we maintain a Drug Master File (DMF) type III.

# 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.

## For All Your Needs and Applications

To make it as easy as possible for you to find the right Gerresheimer product we have created a consistent structure with three performance levels for our vials, syringes, ampoules and cartridges.

The new classification is based on an understandable systematic with increasing performance from Gx® Value up to Gx® Elite and clearly defined quality requirements and attributes for each level.

Products at all performance levels passed through multi-stage, strict quality assurance processes and fulfill all regulatory requirements. On all three performance levels we offer several standard products in each product category: a broad range for all needs and applications.

Moreover, with Gx® Choice, we also offer you the opportunity to customize products and solutions according to your requirements. Whether you are optimizing for clinical efficiency, patient safety, or brand identity, Gx® Choice ensures your product is as unique as your application.

# Gx® Value Vial

Proven solutions in pharmaceutical quality.

Gx® Value Vials are functional products in proven pharmaceutical quality made of type I borosilicate glass. They guarantee an efficient and cost-effective fill & finish process at all times and comply with all regulatory requirements. We produce Gx® Value Vials worldwide locally for the respective markets and guarantuee a high level of supply availability.

Typical areas of application include heparins, generics and active ingredients of veterinary medicine.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment / proven compatibility

**State-of-the-art material**
Glass tubing from all major suppliers available

## Product Offerings

| | Gx® Value Level | Gx® Advance Level | Gx® Elite Level |
|---|---|---|---|
| **Dimensions** | Not applicable | Not applicable | CpKs ≥1.67 for CCI features |
| **Cosmetic appearance** | <500 Micron | <300 Micron | <100 Micron with tightest AQLs |
| **Strength gain** | No change | No change | Up to 4x |
| **Customizable** | N/A | N/A | Yes |
| **Coated** | No coating | Optional Baked-on Siliconization and Velocity® | Optional Baked-on Siliconization |

Velocity® is a registered trademark of Corning Incorporated.

# Gx® Advance Vial

Improved quality for higher efficiency in fill & finish.

Gx® Advance Vials offer the properties of the Gx® Value Vials plus additional benefits such as tighter dimensional tolerances, reduced glass-to-glass and glass-to-metal contact and reduced cosmetic defects. If more performance and even less risks are required for fill & finish, then the Gx® Advance Vials are the right choice.

Gx® Advance Vials are suitable for vaccines, small molecule drugs, or diabetes medications, for example.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment / proven compatibility

**State-of-the-art material**
Glass tubing from all major suppliers available

**Improved fill & finish efficiency**
Improved product quality leads to less defects on fill & finish lines with improved performance and reduced TCO

**Higher product quality**
Tighter AQLs, reduced glass-to-glass and glass-to-metal contact leads to reduced cosmetic defects.

**Advanced system variety**
Additional system features like surface treatment and elastomer components available

## Product Offerings

| | Gx® Value Level | Gx® Advance Level | Gx® Elite Level |
|---|---|---|---|
| **Dimensions** | Not applicable | Not applicable | CpKs ≥1.67 for CCI features |
| **Cosmetic appearance** | <500 Micron | <300 Micron | <100 Micron with tightest AQLs |
| **Strength gain** | No change | No change | Up to 4x |
| **Customizable** | N/A | N/A | Yes |
| **Coated** | No coating | Optional Baked-on Siliconization and Velocity® | Optional Baked-on Siliconization |

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# Velocity® Vial

Improved quality for higher efficiency in fill & finish.

Velocity® Vial are Gx® Advance Vials with Velocity® outer coating developed by Corning Inc., to speed up the fill & finish process by reducing frictional resistance and minimizing glass defects. The number of jams on the filling line is reduced, which means fewer vials are damaged, scratched, or tipped. The stabilizing outer coating reduces glass particulate by up to 90%.

The Velocity® Vial preserves the qualities of the Gx® Advance Vial but performs better on the filling line.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment

**State-of-the-art material**
Glass tubing from all major suppliers available

**Improved fill & finish efficiency**
The friction-reducing Velocity® coating makes the fill & finish process up to 50% more efficient, significantly reducing TCO

**Higher product quality**
Tighter AQLs, reduced glass-to-glass and glass-to-metal contact leads to fewer cosmetic defects. The Velocity® coating reduces the particle load, thereby improving the quality of the end product.

**Superior break resistance**
The Velocity® coating prevents transportation and fill & finish damage

**Advanced system variety**
Additional system features like surface treatment and elastomer components available

**No additional regulatory approval**
Full compliance with European and U.S. health authorities. The internal surface that comes into contact with the drug remains unaltered.

**Immediately available**
Velocity® Vials are available immediately in all major sizes for the European and American markets. Samples can be provided.

## Product Offerings

| | Gx® Value Level | Gx® Advance Level | Gx® Elite Level |
|---|---|---|---|
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| **Strength gain** | No change | No change | Up to 4x |
| **Customizable** | N/A | N/A | Yes |
| **Coated** | No coating | Optional Baked-on Siliconization and Velocity® | Optional Baked-on Siliconization |

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# Gx® Elite Vial

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

If the excellent quality of the Gx® Advance Vials does not yet meet your requirements, the Gx® Elite Vials are just right for you. Developed with Quality by Design (QbD) principles, Gx® Elite Vials exceed the market standard in every respect. Delivering superior optical clarity, precise dimensional consistency, and exceptional mechanical strength, these vials protect your drug products throughout their lifecycle, ensuring safety, reliability, and optimal performance at every stage.

Gx® Elite Vials are ideal for sensitive drugs and biologicals, mRNA vaccinations and gene therapy drugs, for example.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment / proven compatibility

**State-of-the-art material**
Glass tubing from all major suppliers available

**Improved fill & finish efficiency**
CPK≥1.67 for CCI features allows increased efficiency on fill & finish lines up to 25%

**Superior product quality**
Tighter AQLs (reduced vial-to-vial and vial-to-metal contact) lead to no visible defects, scratches or contamination.

**Advanced system variety**
Additional system features like surface treatment and elastomer components available

**Optimized TCO**
Improved performance on fill & finish lines leads to optimized TCO (lower running / lower overall costs for customers)

**Highest compatibility for sensitive drugs**
Extractables testing data, fulfils sophisticated pharmaceutical requirements

**Comprehensive data packages available**
System performance and compatibility data available including data for pharmaceutical requirements.

## Product Offerings

| | Gx® Value Level | Gx® Advance Level | Gx® Elite Level |
|---|---|---|---|
| **Dimensions** | Not applicable | Not applicable | CpKs ≥1.67 for CCI features |
| **Cosmetic appearance** | <500 Micron | <300 Micron | <100 Micron with tightest AQLs |
| **Strength gain** | No change | No change | Up to 4x |
| **Customizable** | N/A | N/A | Yes |
| **Coated** | No coating | Optional Baked-on Siliconization and Velocity® | Optional Baked-on Siliconization |

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# Gx® Elite RTF Vial

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

Gx® Elite RTF Vials are supplied in a Ready-to-Fill (RTF) packaging powered by the well-known EZ-fill platform. For you, this means no need for in-house washing and sterilization. This simplifies your production processes, reduces down-time and accelerates time-to-market.

Gx® Elite RTF Vials unite the industry's proven ready-to-fill packaging platform, EZ-fill, with the highest-quality Gx® Elite vials. Pre-sterilized and fully compatible with fill & finish lines, they streamline manufacturing, enhance drug protection, and boost efficiency – offering unmatched flexibility, reliability, and the lowest total cost of ownership across pharmaceutical production.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment / proven compatibility

**State-of-the-art material**
Glass tubing from all major suppliers available

**Enhanced operational efficiency**
Gx® Elite RTF Vials come pre-sterilized which simplifies the manufacturing process

**Superior product quality**
Tighter AQLs lead to no visible defects, scratches or contamination & minimum 2x – 4x more break resistance

**Advanced system variety**
Additional system features like surface treatment and elastomer components available

**Reduced TCO**
By reducing operational steps and ensuring higher manufacturing efficiency, the RTF packaging lowers the overall costs.

**Highest compatibility for sensitive drugs**
Extractables testing data, fulfils sophisticated pharmaceutical requirements

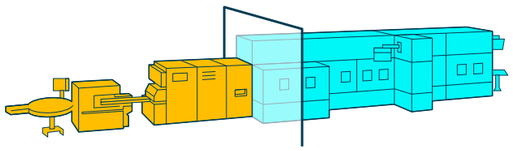
**Comprehensive data packages available**
System performance and compatibility data available including data for pharmaceutical requirements.

**Proven sterilization method**
Sterilized with Ethylene Oxide (EtO) gas

**Increased flexibility with standardized packaging in EZ-fill format**
Available in nest & tub or tray

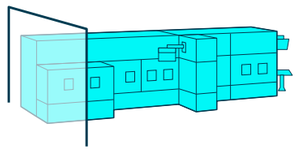
**De-risking of fill & finish**
The RTF packaging minimizes the risk of vial damage or breakage ensuring the integrity of the drug product.

## Comparison Bulk vs. RTF Manufacturing



### Bulk Line Processing

**Complex Processing**
- Washing by WFI (70°C+)
- Heat tunnel for sterilization (up to 350°C)
- Additional failure modes
- Additional qualification and validation



### RTF Line Processing

**Efficient Processing**
- Focus only on fill & finish process: no washing, no heat tunnel
- High-quality packaging directly entering filling line
- Lower space requirements and operations due to reduced footprint
- Reduced overhead qualification and validation activities

# Gx Elite
# EZ-fill Smart® Vial

Gx Elite EZ-fill Smart® Vials combine the power of the Gx® Elite Vials with the perfection of the EZ-fill Smart® packaging platform, developed by Gerresheimer to deliver the best of both worlds. The new EZ-fill Smart® packaging is an evolution of the standard EZ-fill platform and comes in a one-size-fits-all-vials nest & tub configuration. The new design brings further advancements that drive appreciable customer benefits. It leverages increased automation throughout the manufacturing process to increase quality by reducing human errors.

The EZ-fill Smart® packaging comes as a highly standardized platform for streamlined and flexible pharma operations with highest product quality and reduced particle contamination risks, all while ensuring top-tier vial consistency and quality.

## Product Benefits

**Internationally standardized product**
Full compliance to ISO standards to address pharma quality

**Local-for-local supply**
Secured supply chain by global availability with short lead times

**Proven functionality**
Seamless integration into all existing fill & finish equipment / proven compatibility

**State-of-the-art material**
Glass tubing from all major suppliers available

**Improved fill & finish efficiency**
CPK≥1.67 for CCI features allows increased efficiency on fill & finish lines up to 25%

**Superior product quality**
Tighter AQLs lead to no visible defects, scratches or contamination

**Advanced system variety**
Additional system features like surface treatment and elastomer components available

**Reduced TCO**
Reduced cost and investment driven by smaller machine footprint due to centralized processing of washing/depyrogenization

**Highest compatibility for sensitive drugs**
Extractables testing data, fulfils sophisticated pharmaceutical requirements

**Comprehensive data packages available**
System performance and compatibility data available including data for pharmaceutical requirements.

**Alternative sterilization option**
Introduction of VHP as safe, sensitive and environmentally friendly method for sterilization matching with FDA expectations

**De-risking of fill & finish**
Risk-free processing and seamless integration into standard fill & finish lines from all major machine vendors; no glass-to-glass and reduced glass-to-metal contact

**Low particles – improved quality**
>90% particle reduction creating a new gold standard for the benefit of the patient

**Supply chain security**
Risk mitigation through like-for-like standard of two leading global manufacturer

**Sustainability: Reduced $CO_2$ footprint**
Investigating PCF reductions through the use of biopolymers or re-usable material

## New Tub Design

## Future-Ready VHP Sterilization

VHP

- Sterilization method leaning towards current FDA expectations, with less toxic impact by sterilization
- Zero risk of harmful by-product output from sterilization is released into the environment
- Different sterilization methods available for customer to decide how to “phase” the switch from Ethylene Oxide gas (EtO) to Vapo Hydrogen Peroxide (VHP) sterilization
- No need to modify current validated test methods at customer site; in line with guidelines given by regulatory bodies

# Gx® Elite COP Vial

Our Gx® Elite COP Vials come as Gx® Elite Vials with a single layer structure based on COP (Cyclic Olefin Polymer). They combine the best properties of glass and plastic packaging which has been proven for various pharma applications of liquid medicines. Its unique safety features are crucial for solutions of biologic, toxic or high potency drugs.

Gx® Elite COP Vials are available in 2, 5, 10, 20, and 50ml.

## Product Benefits

**Improved efficiency**
High break resistance, tight dimensional tolerance

**Compatibility to wide pH range**
No delamination

**Proven functionality**
Several products launched on the market

**Protein compatibility**
Low adsorption

**Low residual volume**
Hydrophobic surface

**Highest compatibility for sensitive drugs**
Minimum extractables, high chemical resistance

**Internationally standardized product**
Design based on ISO standards

**Optimized TCO**
Improved performance on fill & finish lines leads to optimized TCO (Total Cost of Ownership

**Suitable for deep cold storage**
CCIT data for different stoppers

**Ready-To-Use**
Validated gamma irradiation, limited impact on polymer

# Components, Add-ons and Services

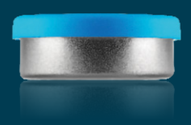
Thanks to the three performance levels Gx® Value, Gx® Advance and Gx® Elite, you can find the right solution for your needs quickly and easily. In addition, we provide our products as a complete system with a great variety of components, add-ons and services that guarantee a perfect match with our standard products within the three performance levels.

## Components and Accessories

We offer you suitable caps & closures for our vials. All components offered meet the highest requirements in terms of safety and user-friendliness. Depending on the application and the fill & finish process, they vary in sizes, and design.

In our new Clinical Trial Kit, you can find a selection of caps and closures that perfectly complement our Gx® Elite RTF Vials, enabling you to create your specific all-in-one, ready-to-use solution for small and clinical batches. For more information please visit our US shop at www.gerresheimer.shop.

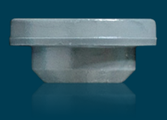
Aluminum seal
13 mm



Aluminum seal
20 mm

Aluminum seal
20 mm

Serum
rubber stopper
13 mm



Serum
rubber stopper
20 mm

Serum
rubber stopper
20 mm

## Add-ons

We offer Baked-on Siliconization, which is a specialized process involving the application of a silicone coating onto the inner glass surface, where the coating is baked at high temperatures to ensure adhesion and durability. This method is applied to reduce fogging and optimize emptying.

## Container-level Traceability

The Gerresheimer traceability system enables complete traceability of our products throughout the value chain: from primary packaging to secondary packaging, and from drug filling and serialization up to the final application at the PoC. Therefore traceability helps to increase patient safety and fight counterfeiting. Data can be linked to individual products, analyzed and evaluated via our powerful digital infrastructure.

## Accredited Lab Services

Our analytical services help you to determine the perfect glass packaging solution for your drug molecules. Whether material and mechanical testing, non-conformance identification, delamination or elemental extractables testing – we are pleased to support you with our dedicated lab capabilities.

# About Gerresheimer

Gerresheimer is an innovative systems and solutions provider and a global partner for the pharma, biotech and cosmetic industries. The Group offers a comprehensive portfolio of drug containment solutions including closures and accessories, as well as drug delivery systems, medical devices and solutions for the health industry. The product range includes digital solutions for therapy support, medication pumps, syringes, pens, auto-injectors and inhalers as well as vials, cartridges, ampoules, tablet containers, infusion, dropper and syrup bottles and more. Gerresheimer ensures the safe delivery and reliable administration of drugs to the patient. Gerresheimer supports its customers with comprehensive services along the value chain and in addressing the growing demand for enhanced sustainability. With over 40 production sites in 16 countries in Europe, America and Asia, Gerresheimer has a global presence and produces locally for regional markets. Together with Bormioli Pharma, the Group generated revenues of around EUR 2.4bn in 2024 and currently employs around 13,600 people. Gerresheimer AG is listed in the MDAX on the Frankfurt Stock Exchange (ISIN: DE000A0LD6E6).

www.gerresheimer.com