

Gx[®]Solutions

Advanced solutions for pharmaceutical
and biopharmaceutical primary packaging

Specialists for specialists



Gx[®] Solutions

A new generation of highly complex injectable drugs requires tailored primary packaging. For this task, Gerresheimer assembled an interdisciplinary team of industrial scientists, designers, product and process engineers, as well as product managers. The new Gx[®] Solutions unit develops new production technologies, processes, and components for pre-fillable syringes, vials, and cartridges. In this way, the next generation of pharmaceutical primary packaging with the highest quality standards with regard to active agent-packaging interaction is being created at Gerresheimer – for the next generation of highly sensitive, biotechnologically manufactured active agents. Customers profit from increased user-friendliness, application safety for patients and medical personnel, as well as optimization for filling lines.

The result:

Protection of sensitive content, secure administration, efficient production.

DEVELOPMENT KNOW HOW AND WORLDWIDE DEVELOPMENT CAPACITIES

Gx® Solutions can access the development know-how and the development capacities of our worldwide Technical Competence Centers in Europe, the USA, and Asia. Here you have development specialists at your side who are familiar with the challenges and procedures of drug development and of the related packaging material. We advise you on matters involving the right packaging material for your special active ingredient. More than 430 product designers, engineers, technicians, and skilled workers from the plastic and glass segments work hand in hand here. These include around 50 product developers. We work together with you closely, ideally already at an early development stage of the medication, because pharmacists and primary packaging materials manufacturers must look for innovative solutions right from the start, both with regard to the active agent and to the primary packaging material, because the latter is an integral component of every medication administered as a liquid – in this way we develop primary packaging that meets the specific requirements of your individual active agent.



SMALL SERIES PRODUCTION

Biotechnologically manufactured medications work in a much more targeted fashion, are oriented to a smaller number of patients, and are needed in much smaller quantities. In order to be able to quickly and flexibly address the needs of our customers, we have, independent of our production location for syringes in Bünde, established small series production with a clean room of the GMP classes C and D for pre-fillable syringes and cartridges of glass in our Technical Competence Center. Here we can quickly and flexibly produce clinical samples without complications for approval, prototypes for process and technology development, and small series.

Partner
for progress





GLOBAL REGULATORY EXPERTISE

The rise of biotech medications has changed the basic conditions. The batches are not only smaller, the quality regulations are also getting stricter all the time. However, not only biotechnologically manufactured medications change the regulatory requirements. The requirements with regard to user safety, for example, the avoidance of needle stick injuries, are getting stricter all the time. A team of product managers is at your side to advise you with their comprehensive knowledge about the market and the global regulatory requirements.

For best results

The biotechnologically manufactured active ingredients with highly complex, protein-based molecules should interact as little as possible with the packaging. At the same time, the products should be safely administered and economically produced. On this basis, Gx® Solutions continually develops new concepts for interior coating, cone forming, needle assembly, and many other aspects. This results in syringes with reduced free silicone oil, metal-free syringes, or syringes with reduced tungsten residue. The unit also develops especially break-proof primary packaging or solutions for patients with limited mobility.

The diversity of Gx[®] Solutions



Gx[®] RTF

Gx[®] Solutions offers solutions for all development stages of active agents. The starting foundation is thus provided by our pre-fillable syringes, vials, and cartridges. With more than 15 years of experience, Gerresheimer is widely regarded as a technology leader in the pre-fillable syringes segment. We deliver the Gx[®] RTF syringes washed, siliconized, equipped with a needle protection element or closure system, and sterilized. They are thus completely prepared for aseptic filling at the customer's facility.



PERFECT IN FILLING

SILICONE OIL-REDUCED Gx BAKED-ON RTF[®] SYRINGES

**Gx RTF[®] glass syringes plus baking process
patented in Europe and the USA**

Complete coating with the lowest possible quantities of silicone oil: We achieve this with the baked-on siliconization patented in Europe and the USA. Here a silicone oil emulsion is applied to the inside of the Gx RTF[®] glass syringes and subsequently affixed to the surface by heating.

The result: an extremely low load of free silicone oil droplets, reliable glide coating through the entire storage period, and stable breakaway and glide forces.

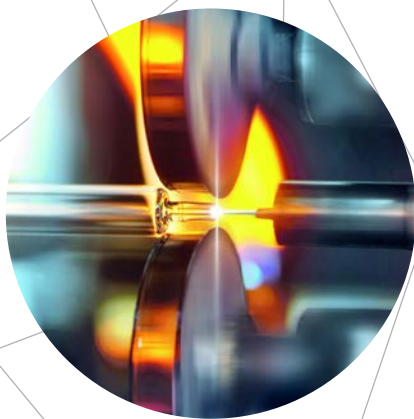


SIMPLE AND SAFE

PRE-FILLABLE Gx RTF® ClearJect® PLASTIC SYRINGES

The pre-fillable syringes made of the high-performance plastic COP are distinguished by a high degree of bio-compatibility, because the needle syringe is glue-free, all syringes are free of metal oxide residue, siliconization takes place with precisely controlled quantity of highly viscous and thus low-particle silicone oil. They convince with their rupture safety and glass-like transparency.

Economic plus: customers can supplement the COP syringe bodies with readily commercially available standard components.



METAL-FREE Gx RTF® SYRINGES

Gx RTF® glass syringes plus patented, metal-free technology for cone forming

Biotechnologically manufactured drugs can interact with tungsten residue from syringe production. Gerresheimer offers metal-free glass syringes for such cases. The pin used for cone forming doesn't consist of tungsten in this case, but instead of a special ceramic. External studies have proven that in this way we can produce syringes free of residue.

Your benefit: pre-fillable glass syringes that exclude the possibility of metal contamination.



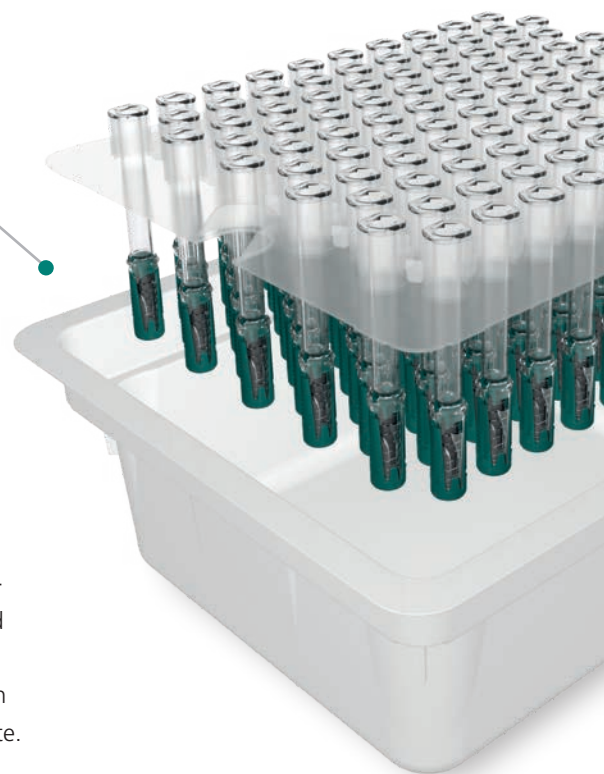


SAFETY SYRINGE Gx InnoSafe®

**Gx RTF® needle syringe plus integrated
and passive safety system**

The integrated passive safety system prevents needle stick injuries and reuse. When being used, the safety system is activated automatically and requires no additional action by the user. Pharmaceuticals customers can process the syringes without an additional assembly step on the existing lines in the nested state.

Your benefit: avoidance of needle stick injuries
without additional work steps.





GREATEST FLEXIBILITY

Gx RTF® VIALS

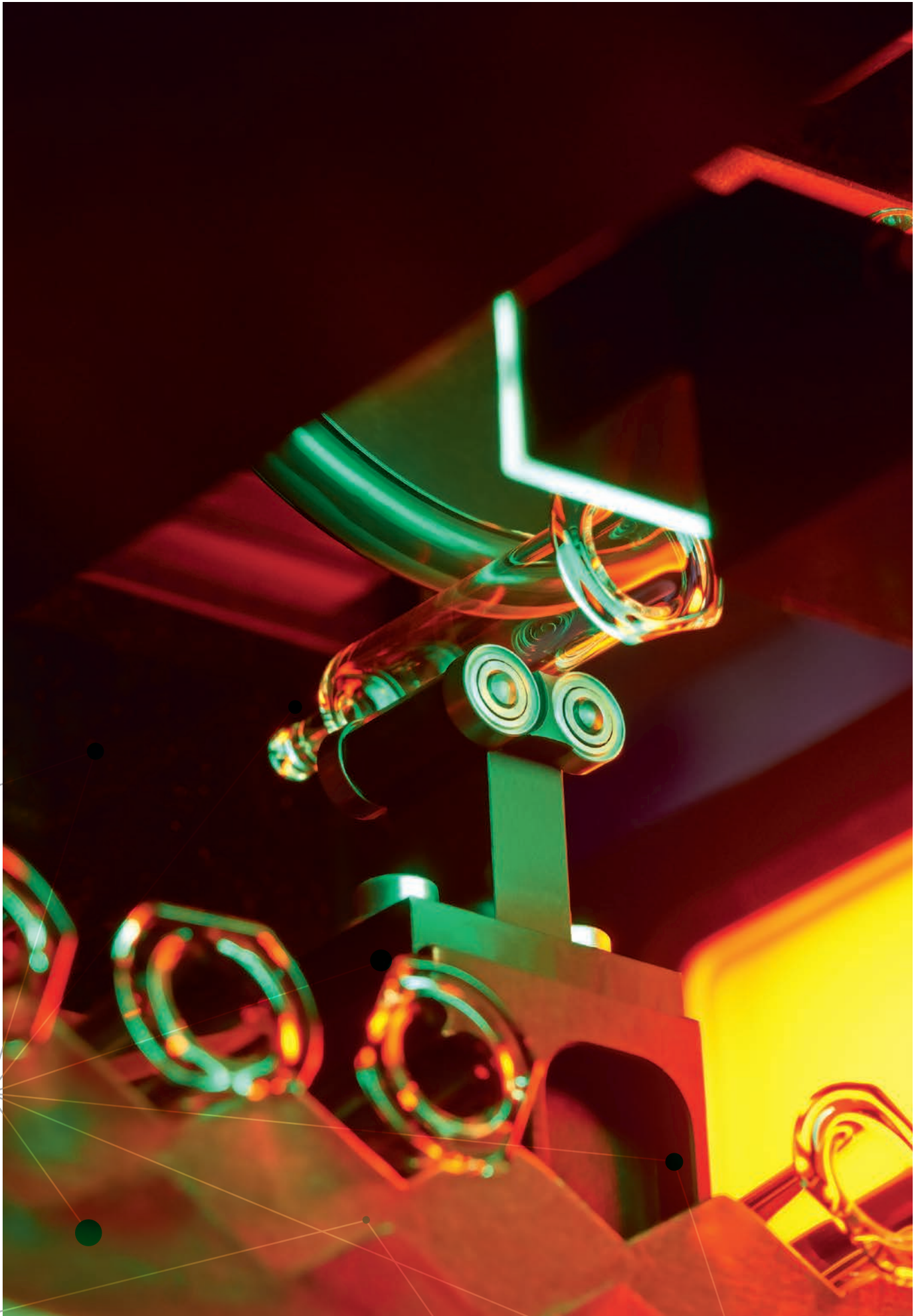
**Gerresheimer ready-to-use vials Gx® RTF plus
Ompi EZ-fill® packaging format**

Gx® RTF Vials are distinguished by a high degree of flexibility resulting from various packaging configurations from the development phase of new medications through small series to large series production. They fulfill the strictest requirements for quality and with regard to glass breakage, cosmetic defects, and particle contamination.

The pre-fillable vials are washed, packed in trays or nest and tub, and sterilized. The customer subsequently fills them without additional intermediate steps.



Your benefit: we deliver the Gx® RTF Vials in the Ompi EZ-fill® packaging format. This allows the processing of identically packaged, sterile injection vials from different manufacturers.



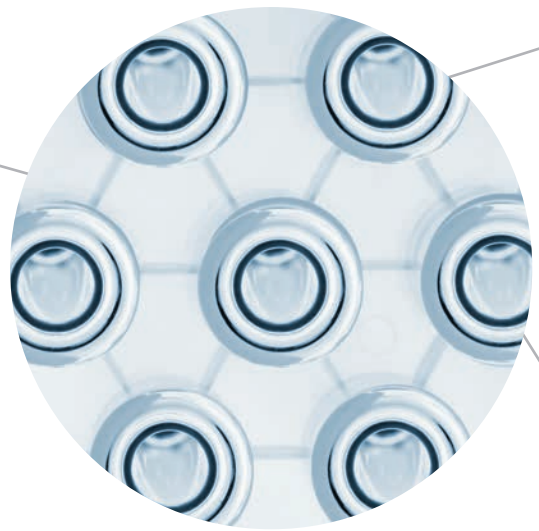
Quality is the foundation of our success

MONITORING ALONG THE VALUE CREATION CHAIN

Unique inspection systems for the highest product quality

Our primary goal is to meet the high quality requirements and needs of our customers. Our production systems for large and small series are equipped with a unique inspection system that was developed in our production site in Bünde. This enables a 100% visual inspection and 360 degree product testing of the entire syringe body. The cosmetic-visual inspections differentiate between cracks and scratches, particles, and air pockets. All data is documented via a CAQ system. Even minor defects of 25µm can be detected.

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