

Customer-Specific Drug Delivery Systems, Medical and Diagnostic Products

We turn your visions
into products,
ready for market.



There are 5 Reasons and more to choose Gerresheimer as your partner for Customized Medical Solutions



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We are your solution provider
Our experts turn your visions into products, ready for market



Concept, product and process development



Industrialization



Contract manufacturing

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We are innovative Worldwide Technical Competence and Innovation Center

Our experts for glass, plastics and intelligent devices develop together with customers solutions including the primary packaging or electromechanical and digital capabilities.

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3

We are international Worldwide production and clean room capacities

Whether fully automatic large series production or manual and semi automatic small series production – we always produce your drug delivery device, diagnostic or medical product quick, cost-efficient and with top quality across three continents: Europe, America and Asia.

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We are broad-based Wide range of products for every need

Our broad range of products and solutions includes pharmaceutical packaging and products for the safe, simple administration of medicines: Insulin pens, inhalers, micro pumps, prefillable syringes, injection vials, ampoules, bottles and containers for liquid and solid medicines with closure and safety systems as well as diagnostics and medical products.

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We are sustainable EcoVadis Gold rating

In 2023 Gerresheimer has once again been awarded **Gold status** by the ratings agency **EcoVadis**. **EcoVadis** assesses the performance of businesses on environmental, labor and human rights, ethical, and sustainable procurement criteria.





Clean room production of ready-to-fill syringes in Bünde, Germany

Partners of the Pharmaceutical and Healthcare Industry

Gerresheimer AG

As one of the globally strongest solution partners for pharma, biotech, healthcare and cosmetics, Gerresheimer develops and manufactures primary packaging for drugs and cosmetics. Our intelligent drug delivery devices and platforms enable reliable administration of active medical ingredients. Gerresheimer produces close to its customers worldwide with around 11,000 employees and generated annual revenues in 2022 of EUR 1.82 bn.

Business Unit Medical Systems

Our Medical System business unit produces customized drug delivery systems, diagnostic and medical products, as well as primary packaging made from glass and plastics worldwide. For the global players of the pharmaceutical and medical technology industry, we produce inhaler, insulins pens, autoinjectors, injectables, read-to-fill glass and polymer syringes, cartridges, vials, laboratory disposables, point-of-care tests, as well as infusion sets, micro-infusion devices, surgical devices, solutions for blood treatment, catheters and much more.



A capsule dry powder inhaler for the customer Merxin



**Innovating
for a better life**



7 production facilities in Europe, North and South America, Asia



About 130,000 sqm (1,400,000 sqft) production area



About 67,000 sqm (720,000 sqft) clean room in accordance with ISO 14644-1 ISO classes 7, 8 and 9 or respectively GMP classes C and D



3,500 employees

Our Services



Concept, Product and Process Development



Industrialization



Contract Manufacturing

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Our experts turn your visions into products, ready for market.“



Our service portfolio

Products are born from ideas, mature solutions are the product of visions. As a full service provider, we handle all the phases of the value creation chain. Our process begins from the first idea development to the CE-labeled product ready for sale: concept development, concept studies and ratings with cost analysis, industrial design, product development, process and manufacturing equipment design to mold making, automation engineering, production of clinical samples, large and small batch production in the clean room under FDA / GMP conditions, manual, semi-automated and fully automated assembly as well as fully automatic function tests right through to product finishing, pharmaceutical assembly and filling, sterilization, packaging, and international distribution. Gerresheimer is your one-stop shop.

Flexible start and ending

Starting a project with Gerresheimer Medical Systems provides you with flexible options. We are your product development partner whether you want to implement a first product idea or you want to develop an existing project further.

We are your industrialization partner, if you want to optimize a completely developed product specifically for plastics and want to get it ready for mass production. In our **Technical Competence Centers (TCC)** you are in the best of hands.

We are your contract manufacturer for the production of the components in the injection molding process and any further needed processing in our international production facilities in Europe, Asia, as well as North and South America.



Support along the entire process chain:

From initial conception right through to the CE-labeled point-of-sale product.

Concept, Product and Process Development

You want to implement a first product idea or you want to develop an existing project further?

On behalf of leading pharmaceutical and medical technology companies we have been developing customer unique drug delivery systems, diagnostic and medical products for more than 55 years. Our interdisciplinary development teams in Bünde (Germany), Münster (Germany), Wackersdorf (Germany), Olten (Switzerland), Peachtree City (USA), and Plzen (Czech Republic) are composed of more than eighty specialists with a broad range of abilities. They look at product developments from the most varied perspectives: the specific requirements of the active ingredient, the needs and requirements of users and patients, functional technical and technological production requirements, as well as user-friendliness and design. This results in solutions that combine a high degree of functional security with easy handling and that are perfectly oriented to the specific requirements of active substance, patient, and user.

Your advantage:
Reduced development time, development costs, and project risk, because plastics optimization is already part of the development at Gerresheimer.

Our Services

- Development of all types of ideas and product concepts
- Industrial design
- Patent management
- Development of operational concepts as part of the usability engineering
- Analyze design concepts as part of usability studies
- Concept evaluation, feasibility studies
- Development of medical products, drug delivery devices, pharmaceutical primary packaging in accordance with regulations (such as MDR 2017 / 745, ISO 13485, ISO 15378, FDA 21 (CFR 820))
- Develop process for the manufacturing of the product
- Simulations and tests
- Design optimization
- Design for Manufacturing
- Create functional samples
- Supplier preselection, material selection
- Design of packaging

Equipment and Skills

- 20 software, electronic and hardware developing workplaces
- More than 25 state-of-the-art CAD-workplaces
- Simulation tools like Moldflow, FEA, statistic. TolAn (Cetol), CFD
- Own development laboratory and model shop for prototyping

Service Offering

As individual as your active ingredient, patient and user

GATE 1

Phase I: Concept Phase

In the first project phase, we develop ideas and product concepts for your new device. We understand market requirements, draft the industrial design, take over patent management, develop operational concepts as part of the usability engineering, consider critical sub-functions and develop models. In addition, we analyze design concept as part of usability studies and perform concept evaluations as well as feasibility studies.

GATE 2

Phase II: Design and Development Phase

In the subsequent project phases, we define product requirements, break down design and develop customers products in accordance with the regulations (for example MDR 2017 / 745, ISO 13485, ISO 15378, FDA 21 (CFR 820)).

We develop the process that is necessary to manufacture the product, analyze the processes for a potential patenting, conduct simulations and tests, and create functional samples.

Our service package also includes a preselection of suppliers and selection of materials.

GATE 3

Phase III: Pre-Production Development

This phase includes the design verification and the preparation for product validation. Our experts in mold design and automation engineering develop the molds for small batches and special-purpose machines. Mold and automation solutions are not only developed for mass production, but during the prototype and pre-production phase, which saves time. Quality planning develops the measuring equipment in the quality laboratory. If necessary, we manufacture development samples, clinical samples, or stability batches, as well as low volume commercial production in our small batch production with clean room in accordance with ISO 14644-1 ISO classes 7 and 8 or respectively GMP classes C and D.

The result of the concept phase is a preferred concept along with a thorough risk analysis and considered market requirements.



Design concept of a connected add-on device for flow measurement

The result of the design and development phase is a completely developed product with defined production processes and the design freeze.



Modular concept of a smart and wireless connected patch pump

The result of this phase is a verified product.



Two-cavity mold for a laboratory disposable

GATE 4

Phase IV: Mass Production Development

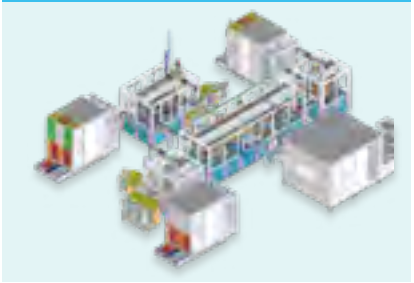
Phase IV involves the industrialization, the validation of production means, and preparations for the product introduction. Our experts from mold making and automation engineering design, develop and build the high-cavity injection molds and complex robots and systems used for mass production. We qualify the resources, project the global mold and specialty-machinery acquisitions and prepare the product master file.

GATE 5

Phase V: Mass Production

In this project phase, the product is introduced and the lifecycle management started.

The results of Phase IV are mass production means and a product validated for mass production.



Assembly line for an inhaler

The result of this phase is ongoing production of the standard parts and / or standard products.



Clean room production in the production facility in Pfreimd, Germany

Tailor-made service package

The development of a product undergoes several phases.

You decide how many you need our support for: from the start as of the product idea, the entry at an existing stage of development to the further development of an existing product.

At the end of the product development, you can decide on what the next steps are.

We offer you services that are as individual as your projects.

Multidose Dry Powder Inhaler produced for the customer AstraZeneca

Industrialization



Injection molding in clean room according to ISO 14644-1 ISO class 8

You would like to optimize a completely developed product specifically for plastics and want to get it ready for mass production?

Our Technical Competence Centers (TCC) are your specialists for industrialization with subsequent production. About 650 engineers, technicians and specialists from the most varied fields work hand-in-hand here on nearly 10,000 sqm (108,000 sqft).

The TCC is equipped with a sampling area, a qualification and validation department for molds and special-purpose machinery, its own quality lab, which contains a lab for material analysis, a measuring room for the creation of initial sample test reports and a functional testing lab with product-specific testing equipment, as well as mold making, mold optimization and special-purpose engineering.

The TCC is also capable of small series production with clean room according to ISO 14644-1 ISO class 7 and 8 and GMP class C and D. With simultaneous engineering, we cover the entire origination process from drug delivery systems, diagnostic and medical products as well as drug containment solutions to series production in our Sales and Engineering Centers in connection with the Technical Competence Centers.

Our Services

- Development and construction of small series and large scale molds and special-purpose machines
- Development and construction of the measuring equipment
- Sampling and process engineering
- Material-specific, physical and chemical analysis
- Optical and tactile measurements
- Functional measurements
- Qualification and validation of molds
- Production of development samples, clinical samples up to small batch production in accordance with ISO 14644-1 ISO classes 7, 8 and 9 or respectively GMP classes C and D

Our Technical Competence Centers

- **Technical Competence Center**
Wackersdorf (Germany)
- **Syringes Center of Excellence**
Bünde (Germany)
- **Technical Competence Center**
Münster (Germany)
- **Innovation Center**
Smart Devices / Micro Pumps
Olten (Switzerland)
- **Technical Competence Center**
Peachtree City (USA)
- **Technical Competence Center**
Dongguan (China)



Mold Making

Rotary table with four bottom tool halves for insert molding of a cannula with ABS for an infusion set

“
We construct the tools
for your success.”

Precision molds for clean room production

Gerresheimer's Medical Systems mold making department has a long tradition. As early as 1958, we started manufacturing sophisticated injection molds, mainly for clean room production. Our precision injection molding tools are designed to meet the high requirements of the pharmaceutical and healthcare industry relating to precision and size accuracy, surface quality, and high output quantities. They are characterized by a 100% repeat accuracy, durability and optimized temperature control for short cycle times.

Our mold making department represents an efficient method of operation. We ensure a fast and smooth production of molds by a segmented structure in mold production and modification and changes division with test molds. Furthermore we work with replaceable mold inserts for short maintenance and repair times without additional adaptations. Data consistency from the design to all machines and workbenches as well as the direct link to quality assurance, ensure molds at the highest quality level. We manufacture molds for internal and external production.

Uncompromising quality assurance

The manufacture of our molds involves the use of the most modern die-sinking and wire eroding systems, precision grinding machines for all processes and micro-HSC milling machines. Uncompromising quality assurance is the highest priority in the entire production process. Precision molds are ultimately the prerequisite for excellent product quality. This is why only the latest measuring equipment, for example, CNC image processing measuring and CNC image processing measuring machines, are used in the internal measurement lab.

Most modern mold technologies

More than 65 specially trained employees produce low- and high-cavity injection molds (up to 128 cavities) with a precision in the micro-meter range, single and multi-component molds, indexing plate molds, hot-runner injection molds, molds for insert molding (encapsulation of needles and lancets) and stack molds.



Work preparation: CAD data



Mechanical manufacturing: high speed cutting

Sampling and Testing



Cavity pressure measurement in the Technical Competence Center in Wackersdorf, Germany

Sampling

The TCC sampling is our practice-oriented competence center for all injection molding processes. This is where we prove molds to check mold performance and there we measure, optimize and qualify molds. We sample molds and special machinery under near-series conditions and subject them to comprehensive application and processing tests to get them ready for large-scale production. The sampling and mold optimization process in the sampling area forms the basis of the entire component verification. Important stages during this process are, for example, the setup of stable parameter settings for injection molding. The basis for this is a fractional factorial DOE.

In addition, this is where the optical and dimensional component measurements take place in the certified measuring room, which is documented in a comprehensive sample test report. Machine and process-capability documentation and mold trials over defined periods of time (e.g. 4 or 24-hour runs) complete the pilot plant phase.

Quality Laboratory

Quality testing along the entire value creation chain

In the case of drug delivery systems, medical and diagnostic devices, safety is the priority. We therefore carry out extensive testing in the areas of materials, geometry and function during all phases of product origination. Gerresheimer has a measuring lab for the geometric measurement of components, assembly units and finished products, a lab for material analyses and a lab for functional testing with product-specific testing equipment.



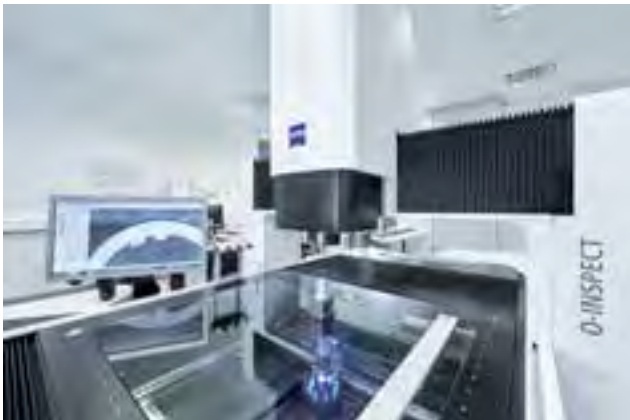
Computer tomograph for destruction-free measuring and testing



Measuring lab in the Technical Competence Center in Wackersdorf, Germany

Optical and tactile measurement technology and industrial computer tomography

A measurement laboratory with the most modern measuring equipment ensures that complex mold inserts and filigreed injection molding parts or assembly units can be measured extremely precisely. The complete component measurement is documented in an initial sample test report. The equipment includes various multi-sensor coordinate measuring machines for optical and tactile component measurements, universal coordinate-reading microscopes, as well as an industrial computer tomograph for the destruction-free measuring and testing of individual component or entire assemblies.



Multi-sensor coordinate measuring machine

Material-specific, physical and chemical analyses

Our material analysis lab is responsible for the incoming goods inspections and raw material approvals worldwide. In addition to the spectroscopic analysis (FTIR) and the established procedure for thermal analysis (MFR/MVR, DSC, TGA), our extensively equipped lab also offers the possibility of a physical-chemical analysis of viscosity, residual moisture and density, as well as an infrared spectrometer and a thin section microscope. The know-how for the development and execution of customer-specific methods round off our analysis portfolio.



Material analysis laboratory

Product-specific functional testing

In our functional testing lab, we develop and qualify test methods to guarantee compliance with product-specific requirements. We ensure more safety for patients with our comprehensive testing of the physical product characteristics, product-specific performance tests, and statistical data analysis during the product development.



Functional testing lab for measurements of the physical product properties and product-specific functional tests

Individual qualification packages

The pharmaceutical and medical product industry requires proof of process capability and the reproducible production of an injection mold. Quality assurance is an important point in the national and international laws and guidelines and signifies increased efforts and expenses for the qualification and validation of molds in the development and industrialization phase. In return, however, there is less wear on the mold and a higher parts' quality, resulting in less waste. Mold qualifications are, however, time and cost-intensive. This is why Gerresheimer offers you various mold qualification levels depending on the product, its area of application and regulatory requirement level.

Automation

Automation Plastics

Customer and part-specific automation solutions



Automation Glass

Glass forming, cannula assembly and RTF lines



High-performance automation solutions for the highly automated clean room production.“

Together with the development and the construction of the special-purpose machines associated with the molds, we offer our customers high-performance automation solutions. In the pharmaceutical and healthcare industries, automation coordinated precisely with the product, project and processes has a decisive influence on the quality and economic efficiency of production.

The technicians, mechanics, electricians, designers, qualification experts, and programmers from the Automation Engineering department are responsible for this task at our Technical Competence Center (TCC).

Most modern means of production for the pharmaceutical and healthcare industry

The 120 member team supports product development with automation competency, develops automation solutions, specifies, designs, builds, procures, and qualifies glass forming, cannula assembly and RTF lines as well as customer and part-specific assembly lines, testing robots (pressure, flow rate, optical features, force deflection systems), rotary table systems, linear systems, robots to insert and remove parts, packaging systems, pre-production equipment as well as pharmaceutical assembly systems.

All the production systems produced by us meet GAMP (Good Automated Manufacturing Practice) requirements as well as FDA 21 CFR Part 11 and are designed for the production in clean rooms in accordance with ISO 14644-1 ISO classes 7 and 8 or GMP classes C and D. They are globally standardized at a high quality level. Being an international manufacturer, we also monitor and assist the start-up of our production equipment on the customer's site.

One contact for all project systems

We purchase from experienced suppliers in the market and also build systems ourselves in our in-house special-purpose machinery manufacture. Our in-house qualification department is responsible for qualifying all project systems. For you this means, whether purchased or built by ourselves: you have only one contact for all systems of the project.

Automation – integral element of product development

Automation is an integral component of our product and process development. Our know-how is used throughout the concept and design phase. We do not wait until mass production to develop automation solutions, but develop them in the prototype and pre-production phase to save time. The knowledge gained here can also be passed on to other automatic systems manufacturers when an external solution is planned for series production.

Small Batch Production

with large-scale production standards

Small batch production glass in clean room GMP class C

Prior to series production, pharmaceutical and medical products 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. Our Technical Competence Center offers you its own production systems for this task, on which the quick and uncomplicated production of development samples, clinical samples or small series is possible at any point of the project. The production area of our small batch production for glass and plastics is approximately 2,750 sqm (29,600 sqft).

A clean room class 7 and 8 in accordance with DIN EN ISO 14644-1 with about 2,170 sqm (23,500 sqft) for injection molding and assembly of plastic parts and a clean room GMP class C and D for pharmaceutical glass products with about 360 sqm (3,900 sqft) are available as well. The equipment includes injection molding machines with a clamping force of 65-420 tons, glass forming lines, RTF and cannula assembly lines as well as a line for baked-on siliconization. Project-specific assembly units and specific measuring technologies complete the equipment.



Development samples, clinical samples up to small batch production at any project stage.“

Small batch production Plastics

Injection Molding



Injection molding in clean room according to ISO 14644-1 ISO class 7 and 8

Assembly



Assembly in clean room according to ISO 14644-1 ISO class 7 and 8

Packaging & Quality Control



Small batch production Glass

Glass Forming



Glass forming in controlled area

Needle Assembly



Needle assembly in clean room according to ISO 14644-1 ISO class 8

RTF Processing



RTF processing in clean room according to ISO 14644-1 ISO class 7

Contract Manufacturing



We are your contract manufacturing partner for the production of components and products in the injection molding process and any further needed processing.“

Seven days a week, day and night

We are producing medical plastic systems with millions of parts nonstop with fully automated production and assembly facilities worldwide – always quick, cost-efficient and with top quality. Prior to the start of production, the setup of the systems is simulated in order to set up the sequence of individual production steps economically and efficiently – short routes for production are the goal.

Worldwide production and clean room capacities

As a global player we think and act international. Therefore, we offer our customers about 130,000 sqm (1.4 million sqft) of production area, of this about 67,000 sqm (720 thousand sqft) of clean room area in accordance with ISO 14644-1 ISO classes 7, 8 and 9 or respectively GMP classes C and D in Europe, North and South America and Asia. Whether you need a fully automated mass production or semi-automated and manual low volume commercial production of complex and technically sophisticated products: we offer you the best production options worldwide.

Our strength: experience

The production of high-quality drug delivery systems, medical, and diagnostic products requires an adequate production environment. With over 45 years of experience in clean room production according to ISO 14644-1 ISO classes 7, 8 and 9, and coverage of the entire value creation chain in the clean room, we are your specialist for clean room production.

Uniform Manufacturing Execution System (MES)

Top performance in production is no longer possible today without high-performance data processing. We therefore control and monitor production throughout the company with an internationally uniform Manufacturing Execution System (MES). Automated quality tests that are coupled with the production process and seamlessly documented traceability ensure that all products meet the required quality standards.

Worldwide Production Sites



Peachtree City
USA (near Atlanta)



Dongguan City
China (near Hongkong)



Indaiatuba
Brazil (near São Paulo)



Bünde
Germany



Pfreimd
Germany



Horšovský Týn
Czech Republic



Skopje
North Macedonia



New AGV (Automated Guided Vehicle) system in our production site in Pfreimd, Germany

Production

Full services for full customer satisfaction

The full service of Gerresheimer Medical Systems encompasses much more than 100% quality injection molding. It includes many different post-production processing methods – from completion and assembly of modules to optical, haptic and functional finishing through to filling, sealing and packaging of ready-to-use systems.

We even take care of high-quality parts that need to be purchased. Our core competence is in fully automatic large series production and in the manual and semi-automatic small series production of complex and technically sophisticated systems consisting of many individual plastic and purchased parts.



Fully automatic insertion of a spring into an autoinjector in the clean room according to ISO 14644-1 ISO class 8 in Pfreimd, Germany



Injection molding and assembly of inhaler in the ISO 14644-1 ISO class 8 clean room in Dongguan City, China

Injection Molding

Latest injection molding technologies

Sustainable pharmaceutical, diagnostic and medical products unite a plus in functionality and design quality with optimized production costs – a performance that is only possible through innovative production technologies. This is why Gerresheimer offers modern injection molding technologies such as multi-component injection molding (2-K, 3-K), insert molding, turning stack mold technology, water injection and internal gas pressure, sandwich technology, injection embossing, in-mold decoration, thin wall injection molding, and micro injection molding.

Micro injection molding

Miniaturization is one of the most important technological trends. More and more functions are integrated in medical devices, which means that the components have to become smaller and smaller and the precision requirements higher and higher. In order to meet these challenges, we use the latest injection molding technologies in our production such as micro injection molding.



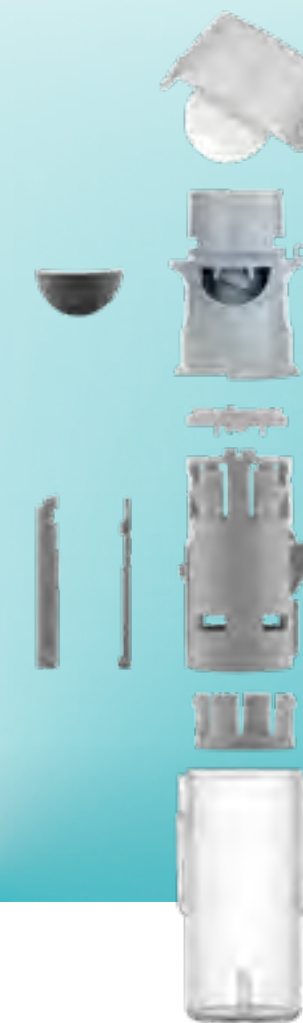
Micro injection molded parts of an infusion pump



Micro injection molding system in a clean room in accordance with ISO 14644-1 ISO class 8



High-volume line for the assembly of the Respimat® reusable inhaler housing module in a clean room ISO class 8 in Pfreimd, Germany



Finishing

Sophisticated product finishing

Naturally, we also carry out the surface decoration of all components in accordance with your individual ideas. We complete finished products, for example, through printing, laser marking, metallizing, lacquering, sleeving, and many other decorating methods. Large-scale product finishing is subjected to the same quality requirements applied to the production of individual component assemblies: upon request, we integrate camera systems into the decoration line to ensure the immaculate quality and precise positioning of printed images and labels. This way, we can be sure that your desired design is implemented with high quality and cost efficiency.



Laser marking of a plastic part for an insulin pen

Product-specific production steps

On behalf of our customers, we assume responsibility for product-specific manufacturing steps like, for example, the filling of the dilution solution required for point-of-care tests or the loading of point-of-care test housings with the test strips under climate, temperature and air humidity conditions specifically configured for this process. In the case of inhaler, we ensure the reliable functioning of the modules in that we improve gliding properties through the dispensing of Vaseline with individually adjustable dispensing valves in the assembly system. For an applicator, we apply Teflon on the contact surface for the placement of a permanent implant.



Vaseline metering to improve gliding properties

Assembly

Sophisticated joining and bonding technologies

For the production of drug delivery systems, medical and diagnostic products, in addition to clean room production, we use sophisticated joining processes like the laser welding of plastic and metal parts, ultrasonic and vibration welding, as well as thermoforming and cold calking. We possess the know-how for the gluing of sophisticated plastic and metal parts or tubes. For an infusion set, for example, we glue a tube with a coupling part and then harden the glue with UV light. A subsequent 100% check of whether the glue has been correctly dispensed, and an additional test to determine whether the tube also still provides the correct volumetric flow after gluing is carried out directly in the fully automatic system.



Gluing of tube and coupling part with subsequent flow inspection

The most cost-efficient assembly solution for every product

For the assembly of plastic parts, assembly units and complete devices we offer you both modern, fully automatic assembly technologies and semi-automatic or manual assembly, which are primarily more affordable for smaller series. Our assembly lines ensure that the products have the best surface quality due to surface-preserving assembly and a visual inspection for damages on visible parts within the assembly system. A 100% in-process control of the assembly steps, the parameters that are critical for quality as well as the assembly, and product functions is performed with the help of several different camera systems and control stations in the assembly system. Gap-free documentation of the assembly processes ensures the traceability of all batches.



Manual assembly of an inhaler in Dongguan City, China



Assembly line in our production site in Pfreimd, Germany

Assembly

Assembly of electronics

As an expert in combining plastics with metal, we can also, if desired, take over the electronics assembly. We integrate electronic counters in the drug delivery devices for the dosing, atomization actuators, and various sensors. We provide disposable laboratory articles with RFID chips, because the traceability of tests and providing of information of the analysis devices being tested, are gaining increasing importance. For the assembly of electronics, we create our own clean rooms, which are also equipped with a special ESD protective floor for preventing static charge.

Special camera tests in the assembly unit ensure the correctly positioned insertion of circuit boards, the damage-free positioning and snap-fitting of punch parts and the correct position of switches. A gap-free in-line function test at the assembly system rounds off our range of services.



Lab disposable with RFID chip for the tracing of tests

Sterilization, Packaging, and Global Logistics

Product-specific packaging options

Gerresheimer offers you many different packaging options such as packaging in blisters, in a transport tray (disposal or reusable), air-tight aluminum bag (moisture protection), sterile packaging, in disposable and reusable packaging, in a Tyvek bag (ethylene oxide and gamma-sterilizable, steam-sterilizable up to 125°) or in a special clean room bag. With the packaging, too, we pay attention to fulfilling the strict requirements of the pharmaceuticals and medical technology industries for quality and cleanliness.

Our systems ensure that the product is carefully placed in special transport trays. The use of specially washed trays thereby adjusts the number of particles to the prescribed specification. Like production and assembly, packaging at Gerresheimer can also take place in the clean room.

Packaging including original seal and sterilization

Upon request, we can also sterilize your product in collaboration with our partner. We package an infusion set in a blister pack, for example, seal it with a Tyvek film and print the film. These finished individual packages are placed in boxes of ten, and the package insert and separating strips added.

A robot applies the label on the front and the back and secures the final packaging with a tamper-evident closure. Then, the completely packaged products are sterilized with ethylene oxide (ETO). The gas-permeable Tyvek film makes it possible for the ETO to permeate the packaging and to subsequently release the gas again.

Certified Quality

We want to become better all the time, for our customers and for human health.

Qualification and validation for international markets

The Gerresheimer business unit Medical Systems uses a globally standardized quality management system that is based on the ISO 9001, EN ISO 13485 and EN ISO 15378 standards and is site-specifically certified. The requirements for an environmental management system according to ISO 14001, occupational safety management system according to ISO 45001 and energy management system according to ISO 50001 are also implemented and certified on a site-specific basis.

In addition, we comply with the relevant FDA guidelines, GxP and normative product requirements (such as the labeling of medical products). This also means that, in addition to the validated production processes, our buildings and clean rooms as well as the warehousing are qualified and validated in accordance with clearly defined quality criteria. For specific products, we meet additional requirement or standards in our various facilities.

Certificate of accreditation as overseas manufacturer

In cooperation with our customers, the Gerresheimer production locations Pfreimd (Germany) and Dongguan City (China) have been accredited as manufacturers for medical products for the Japanese market. The certificates for accreditation as „Overseas Manufacturer“ in Japan are valid for five years.





Top international positions in the production of medical devices

Successful inspections by the FDA as well as notified body inspections have confirmed that Gerresheimer Medical Systems operates a fully 21 CFR 820 and respective ISO standard compliant quality management system (QMS) and thus maintains one of the top international positions in the production of medical devices in terms of performance and quality. The inspections cover the entire value creation chain of production in our facilities.

Assistance with the registration of product files

We assume responsibility for both the qualification according to GMP and FDA guidelines and the creation and submission of the documentation for medical devices and pharmaceutical primary packaging materials (for example, DMF type III, EU File).

Validation along the entire value creation chain

Our validation approach follows the classic V model and comprises all the phases from DQ to PQ. Each individual production process is validated to ensure that the sum of all steps leads to the desired, reliable production sequence. The tests determined by our quality planners in the Technical Competence Center (TCC), specified in the test plan, and verified during the validation, are carried out as part of the product development process in collaboration with the production from incoming goods and process testing to the approval testing.

Quality Management System

Our Quality Management is based on a sound corrective and preventive action (CAPA) system combined with systematic problem solving according to the Kepner Tregoe methodology. A binding change / control process ensures that changes do not have a negative effect on the qualification status of equipment or the validated status of a process. To handle complaints and deviations, define corrective and preventive actions, and their follow up, we use an electronic workflow management system, i.e. SAP QIM, which fully meets the requirements of 21 CFR part 11. Comprehensive documentation is prepared for all quality assurance measures, which are also included in the respective customer certificates.

Continuous improvement by the Gerresheimer Management System (GMS)

We want to become better all the time, for our customers and for human health. Our key for this is GMS: Gerresheimer Management System. The Gerresheimer Management System forms the basis for the continuous improvement of all business processes in the Gerresheimer Group. GMS includes and describes the most important methods, processes, and regulations of a facility in a systematic and standardized form, thereby creating transparent, binding standards.

Our criteria for success in terms of customer satisfaction are the goals of the GMS: top-quality products and services, minimum cost, adherence to delivery times, product and process innovation, elimination of waste, continuous improvement, acquisition, development, and preservation of competency and consistent inclusion of all employees.

Our Products



We find the right solution for every customer.“

Gerresheimer Medical Systems produces innovative and groundbreaking products in the segments primary packaging made of glass and plastics, drug delivery devices as customized or proprietary solutions as well as customized diagnostic and medical products. We are market leader for certain medical devices as inhalers and pens and with an annual production capacity of more than 5 billion vials we are also market leader for glass injection vials.

Our plastic experts work hand in hand with our glass specialists and coordinate the tolerances of primary packaging and plastic parts closely with one another. In this way we ensure that for example injection forces are optimized and that cartridge and syringe are positioned optimally in the plastic device.

Primary Packaging

Made of Glass and Plastics



Vials



Cartridges



Syringes



Drug Delivery Devices

Customized Solutions



Inhaler



Pen systems



Autoinjectors

Proprietary Solutions



On-body drug delivery devices



Single-use autoinjector

Customized Diagnostic Products



Laboratory disposables



Point-of-care tests



Customized Medical Products



Cartridges



Flow sensor for respirators



Infusion sets

Primary Packaging



Gx[®] glass syringes

- Bulk and “ready-to-fill” format
- Filling volumes of 0.5 ml to 5.0 ml
- Luer cone, Luer lock systems and needle syringes
- Integrated cannulas in the most varied formats
- Round and cut finger flange
- Various options for siliconization (spray and baked-on siliconization)
- Innovative components (closure systems, plunger stoppers, plunger rods, backstops)
- Optional: syringes with reduced tungsten content, low subvisible particle load
- Most varied possibilities for printing
- Individual solutions upon request

Prefillable polymer syringes for sensitive ingredients

Our product range for polymer syringes comprises syringes in “ready-to-fill” format of 1.0 ml long and 2.25 ml, Luer as well as needle syringes.

The Gx RTF[®] ClearJect[®] syringes are designed for a safe and secure use in combination with commercially known and available standard components like cannulas and elastomers. Polymer syringes provide low reactivity and show no interaction towards the drug. The inert material ensures that the drug effectiveness is not influenced throughout the storage and injection process. Reduced residual volume is achieved by low tolerances due to the injection molding process. Our Gx RTF[®] ClearJect[®] needle syringes are also suitable for use in auto-injectors thanks to their robustness and precision.



Gx[®] glass cartridges

For more than 60 years now we have been producing high quality cartridges that fulfill the requirements of modern filling systems on state-of-the-art production lines. Our program encompasses cartridges made of type I glass in the size of 3.0 ml (further formats on request).



Gx[®] RTF vials

Gerresheimer is the leading global manufacturer of high-quality glass vials. We offer a comprehensive range of vials from 0.6 to 100 ml in different designs, with or without blowback (European and American version) according to industry standards or to your individual specifications. State-of-the-art production process and in-line camera inspection systems ensure high-performance in filling lines and lyophilization processes. Our polymer vials are made of COP (Cyclic Olefin Polymer) and are available in the sizes of 2, 5, 10, 50 and 100ml. They offer improved barrier properties for sensitive liquid medications.



Customized Drug Delivery Systems



Inhaler

In close cooperation with leading pharmaceutical companies, Gerresheimer Medical Systems has been globally developing and producing powder inhaler, capsule inhaler, and nebulizer for the treatment of respiratory diseases such as Asthma, COPD (Chronic Obstructive Pulmonary Disease), and cystic fibrosis for more than 20 years. With our annual production of over 100 million inhalers, we are a leading specialist in the area of customer-specific drug delivery devices for inhalation therapy. Our complete service also includes the appraisal of drug delivery systems and the evaluation of systems together with their entire documentation (e.g. device master file) as the basis for the approval of the product.



Pen injectors for insulin

Autoinjector and syringe components

Reusable pen injectors and disposable pens

In the product segment of pen injectors for insulin and other hormones, our core competencies are both high-quality, reusable pen injectors, as well as cost-effectively produced disposable pens – including the glass cartridge. We produce more than 350 million disposable pens annually. Our highly automated assembly processes and pad printing systems directly coupled with the injection molding machine, ensure the most cost-effective production.

With regard to the production of high-quality, reusable insulin pens, their acceptance in the day-to-day life of patients, also depends on an attractive design, we use the entire portfolio of our technological know-how: the laser welding of metal parts, laser welding and laser labeling of plastic parts, and lacquering processes meet the highest technical and visual quality requirements.

Injection systems

Whether you need components for needle-free injection systems, safety syringes, tamper-proof closures or autoinjectors, in Gerresheimer Medical Systems you have found an experienced partner. We actively address dermatological questions such as penetration behavior and pain development and use this knowledge for the development and production of sophisticated injection systems.

Proprietary Solutions

Delivery Devices for Subcutaneous Administration of Drugs

We developed a novel micro volumetric rotary piston pump which forms the heart of our micro-infusion pump devices. Our products are adaptable for different therapies and flexible to primary packaging (type, size, fill volume).



On-body drug delivery devices

On-Body Drug Delivery Devices (large molecules)

The Gx SensAir® drug delivery device is ready to be customized! This patched-on device delivers large molecules (biologics) subcutaneously and is designed for therapies which periodically require a certain total quantity of a formulated drug. Typical applications include proteins such as monoclonal antibodies.

On-Body Drug Delivery Devices (small molecules)

The on-body drug delivery device for the subcutaneous administration of small-molecule drugs is available for volumes up to 3 ml. It is patched onto the body. Typical applications are bolus and basal regimens over several hours.

Belt worn On-Body Drug Delivery Devices (small molecules)

This belt-worn on-body drug delivery device for small-molecule drugs has been developed for our pharma partner EVER Pharma. The wearable device is used by Parkinson's disease patients for the administration of apomorphine to treat this long-term degenerative disorder of the central nervous system. This device is customizable to be used with suitable other drugs for other diseases.

“

From concept to delivery of the final product – One-Stop-Shop Gerresheimer.“

Gerresheimer offers besides OEM products innovative platform solutions that accelerate the cost-efficient development of medical devices. Our platforms consist of **on-body infusers** that enable the subcutaneous delivery of various forms of liquid medicines and a **new generation of a cartridge-based autoinjector** for single dose application.



Gx Inbeneo® Autoinjector for Biopharmaceuticals

We have created the Gx Inbeneo® autoinjector to facilitate effective delivery of biologic drugs as well as aiding autonomous patient usage.

The Gx Inbeneo® platform is modular, making it easily customizable to a wide range of drug formulations. This versatility, combined with our extensive experience in primary packaging, device development, manufacturing, and regulatory compliance, reduces the timeframe for clinical trial readiness and market launch.

Single use autoinjector for subcutaneous application

- Pre-pressurized, cartridge-based system
- No contact between the needle and the drug during storage (dry needle system)
- Possibility of accommodating cartridges with baked-on silicone

Platform technology

- Customizable subcutaneous needle 25, 27 and 29G
- Customizable spring force 30 to 70 N
- Customizable for 1.5 and 3 ml ISO cartridges

Patient-centric approach

- No release button, push-on-skin activation
- Partially transparent casing for visualization of injection progress in real time
- Concealed needle before and after the injection

Simplicity of design

- Cartridge based, pre-pressurized system

Customized Diagnostic Products



Laboratory disposables to prepare, process, and analyze samples

Laboratory disposables tailored to your needs

Whether disposables for sample preparation, reagent vessels and tips for sample processing or cuvettes and micro well plates for sample analyses – we develop and produce disposables for the entire sample run in laboratories. Consistently high quality and identical reproduction are absolutely necessary for laboratory disposables made from plastics, because the slightest deviation can, for example, impair the results of visual and chemical analysis processes in cuvettes.

With the help of a safe selection of materials and high-cavity molds that are designed for a clean room production, we create the conditions necessary to produce these sensitive products in perfect quality. As an expert for the combination of plastics and metal, we also assume responsibility for the assembly of electronics, for example, the assembly of RFID chips, because the traceability of tests and the provision of information for the analysis device through the test to be carried out is increasing in importance.

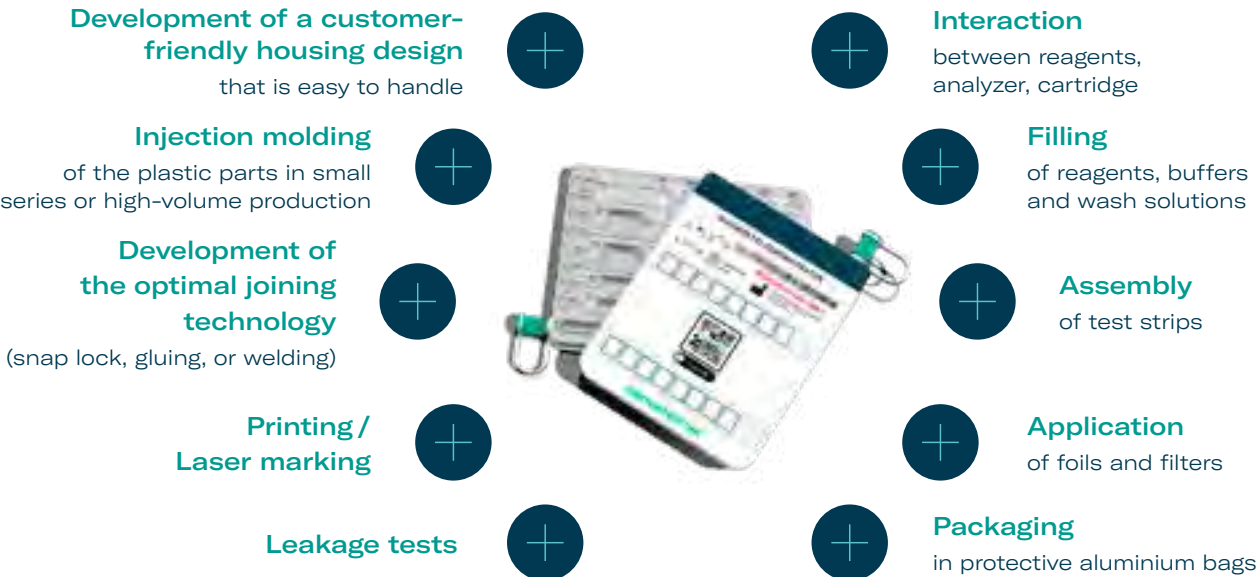
User-friendly and safe point-of-care tests

20 years of experience in the production of point-of-care tests make us the ideal partner. Whether COVID19-tests, drug detection, pregnancy tests, detection of emergency parameters or allergy tests, whether use in the doctor's office or in the analysis

device in the lab: We develop and produce your complete PCR-test including loading of the point-of-care tests with test strips and filling of the quick test with the necessary dilution solution.



Point-of-care tests to be used in doctor's office or in the analysis device in the laboratory



Customized Medical Products



CentriMag blood pump
Special gluing techniques for a burr-free, blood-friendly surface



Flow sensor for respirators
connection between patient and artificial respiration machine



Cartridge
of a tankless inhalation system for nitric oxide



Infusion set
with flexible Teflon cannula and detachable insulin pump



Infusion set
with flexible Teflon cannula and fixed insulin pump

The tailored production solution for medical products

Irrespective of the number of units and the requirements of the medical product, we offer our customers a tailored production solution. In addition to the fully automated mass production of medical products, we also offer the manual and semi-automated small batch production of complex, technically sophisticated injection molded products. In our small batch production, we have our own production facilities (injection molding machines, project-specific assembly systems such as joining robots, gluing devices, or ultrasound welding systems) as well as a clean room according to ISO 14644-1 ISO classes 7 and 8 or respectively GMP classes C and D are available.

As a full-service provider, Gerresheimer Medical Systems assumes responsibility for all levels of the value creation chain including all project-specific production steps like the installation of the entire electronics into the end devices and organizing the various purchase parts. In this process we make use of strategic partners subject to regular quality audits and that fulfill our strict requirements 100%.

Our experts for the design and development of medical devices attach importance to project-specific requirements like, for example, special gluing techniques for a burr-free, blood-friendly surface, the connection of metal and plastics. We take care of the device packaging development, the handling of needles and much more.

Infusion sets

In diabetes patients who obtain insulin from a pump, an infusion set connects the insulin pump with the body. Together with a leading diagnostic company, Gerresheimer developed a solution for this that consists of an air-permeable, skin-friendly band-aid and a needle housing with guide needle and cannula. In order to meet the different needs of patients, the set is available in versions with a flexible Teflon cannula for high wear comfort or an extra-thin steel cannula that is pain-free, as well as with a fixed or detachable insulin pump. Particularly innovative is the design of the needle and cannula in the Teflon cannula product version. A tube made from very soft fluoride ethylene propylene (Teflon FEP) is reformed into a soft cannula, pulled over the needle and then coated.

Another challenge is the gluing of the set's sophisticated plastic and metal parts. The fully automated production system checks all parts as to whether the glue is correctly dosed and was hardened with UV light and whether the tube provides the correct flow even after the gluing process. Gerresheimer was responsible for all the project steps from the design concept and the development, the user tests of development samples, the mold and plant construction, as well as the procurement of all purchased parts to mass production.



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