



## **Röchling Medical**

Products for Pharmaceuticals,  
Diagnostics and Life Sciences



Medical

# Röchling

## Competence in Plastics

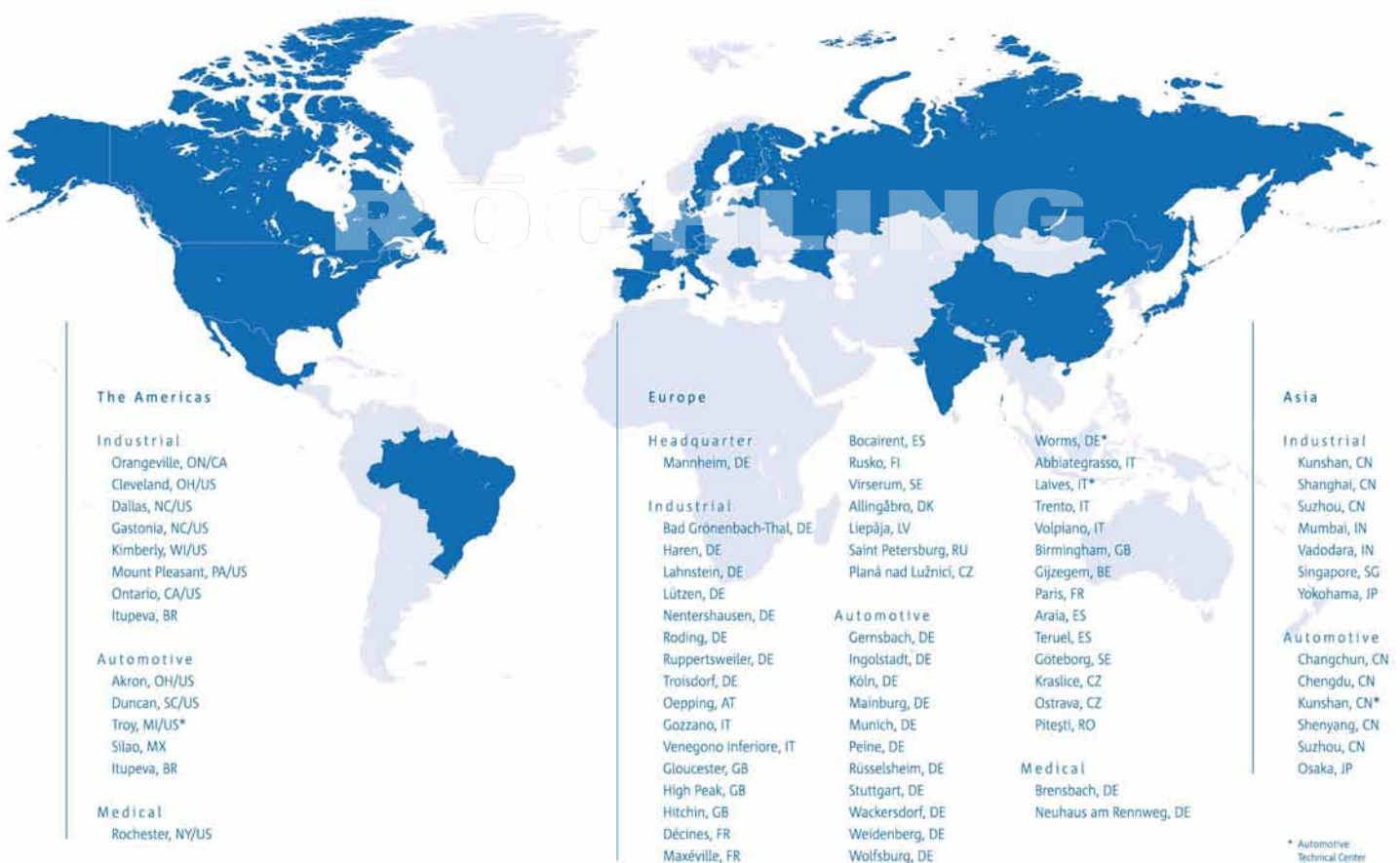
### Content

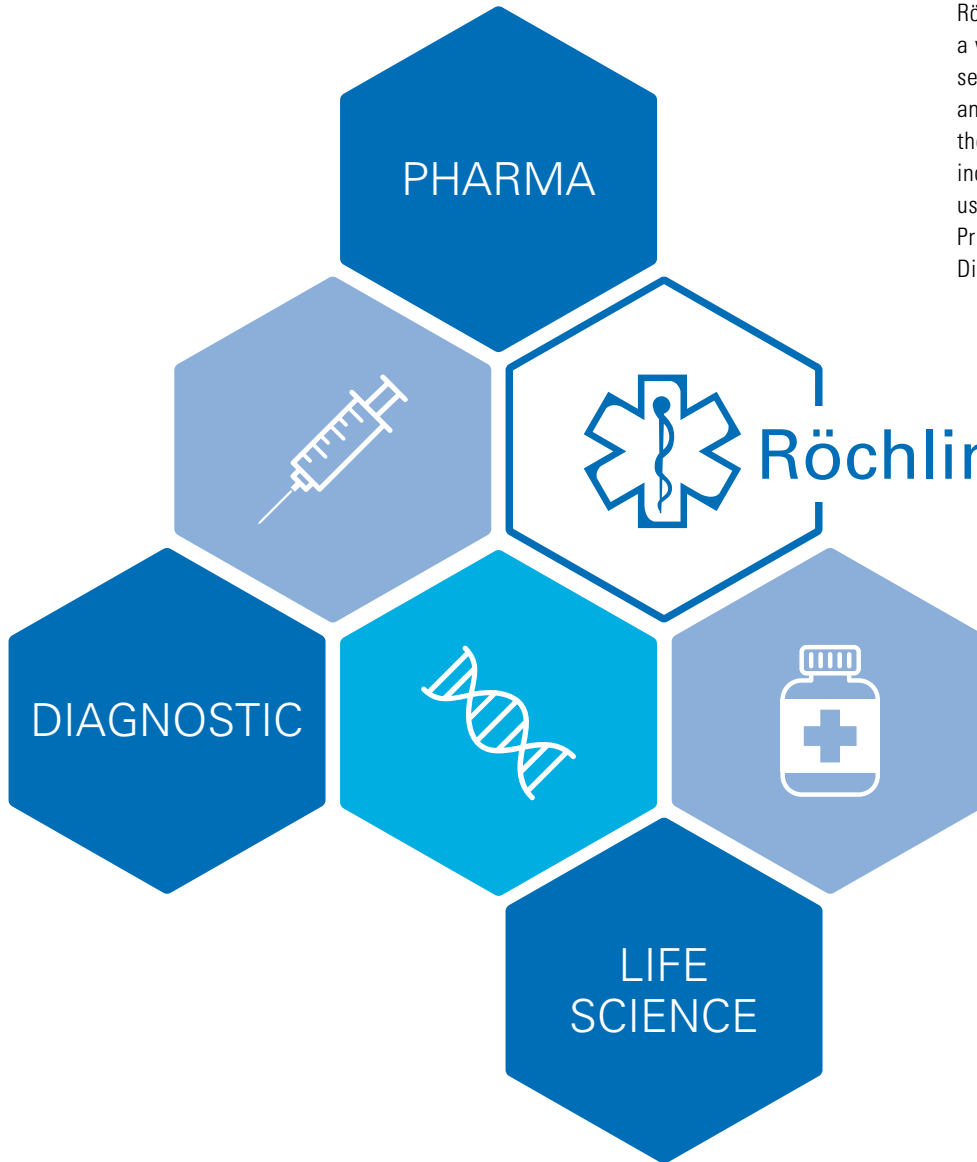
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The Röchling Group is a global plastics group. With some 8,800 on the workforce at 78 locations in 22 countries, Röchling today ranks internationally amongst the leading enterprises in the field of plastics processing.

With our Industrial, Automotive and Medical divisions, annual sales revenue from business in Europe, the Americas, and Asia amount to approximately EUR 1.7 billion.

### Röchling Group – Global presence: 78 locations in 22 countries





Röchling's Medical Division offers customers a wide range of contract manufacturing services in the field of plastics processing's and precision assemblies technologies for the Medical, Diagnostics & Pharmaceutical industry. These high quality products are used in innovative Drug Delivery Devices, Primary Packaging, Surgical Instruments and Diagnostics Disposables.

### Sites – Medical Division

**Röchling Oertl Kunststofftechnik GmbH**

Höchster Str. 100  
64395 Brensbach  
Germany  
Phone: +49 6161 9308-0  
Email: [info@roechling-oertl.de](mailto:info@roechling-oertl.de)

**Röchling HPT Hochwertige Pharmatechnik GmbH & Co. KG**

Waldweg 16  
98724 Neuhaus am Rennweg  
Germany  
Phone: +49 3679 72606-0  
Email: [zentrale@roechling-hpt.com](mailto:zentrale@roechling-hpt.com)

**Röchling Advent Tool & Mold**

Holleder Technolgy Park, 999 Ridgeway Ave.  
14615 Rochester  
New York (NY)/United States  
Phone: +1 585 254-2000  
Email: [info@roechling-advent.us](mailto:info@roechling-advent.us)

# Röchling Medical

## Fields of Application

Products from Röchling Medical are used in Pharmaceuticals, Diagnostics and Life Sciences:



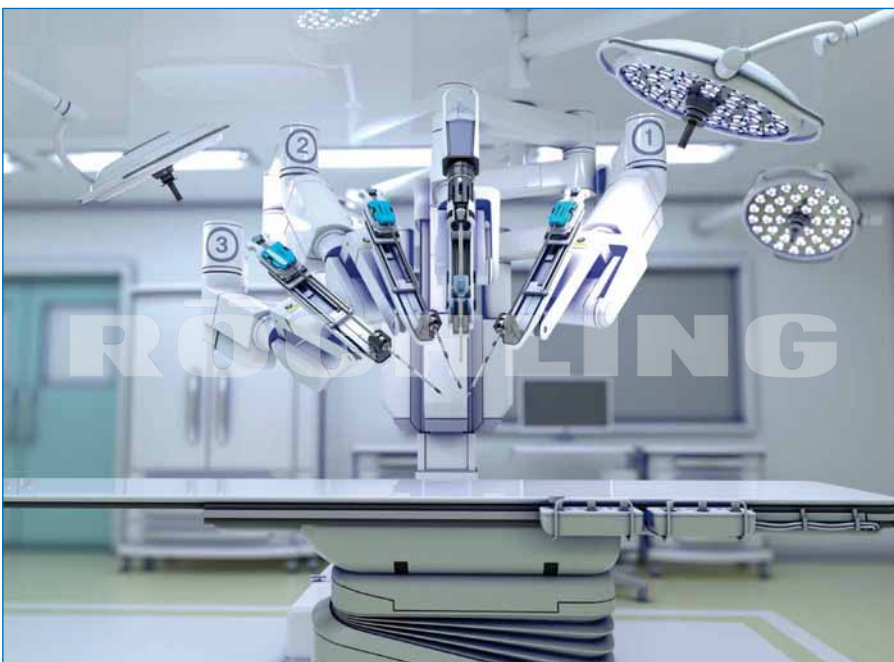
### Pharmaceutics

- Drug Delivery Systems
- Primary Packaging



### Diagnostics

- Pipettes, Tubes and Caps
- Dish, Racks and Lids
- Diagnostic Containers



### Life Sciences

- Cardiac Rhythm Management
- Cardiac Care
- Infusion Therapy
- Orthopedics
- Neurovascular Intervention
- Pain Management
- Vascular Surgery
- Gynecology
- Interventional Bronchoscopy
- Interventional Radiology
- Oncology
- Gastroenterology
- Dialysis

# Röchling Medical

## Product Development

### Realizing customer ideas

Röchling Medical has its own internal R&D department to aid it in realizing customer ideas and requests precisely, functionally and creatively. Röchling Medical's development department will assist you with everything from your inquiry to material selection, design creation and initial template production to the finished product – and even beyond. Röchling Medical places great importance on continuous research and constant further development. We work with national and international institutes and universities as part of our continuous search for new materials, procedures and innovations that can help our customers remain one step ahead of the competition at all times.

**Our team is always at your side, from the initial idea to the finished product and beyond!**

### We offer you development competencies for:

- CRC
- Container
- Drug Delivery Systems
- Life Science Device
- Packaging

### Development procedure:

- Understanding and documenting customer's and patient's needs
- Market analysis
- Selecting materials and processes
- Development of drawings and models
- Manufacturing of prototypes and pilot tools
- Product verification; approval of drawings and models
- Manufacturing of tools
- Qualification and Validation
- Production approval

### Competence

- Internal R & D department
- Technical customer service
- System supplier





## For the production of your medical devices we offer you a comprehensive range of technologies:

- Extrusion blow moulding
- Multi-layer extrusion blow moulding
- Injection blow moulding
- Injection stretch-blow moulding
- Injection moulding
- Assembling under clean room conditions
- Compression blow forming
- Co-Extrusion

## Mould Making

Röchling state-of-the-art in-house mould making capabilities are unparalleled within the Pharmaceutical, Diagnostics & Life Science Industry. Röchling employs some of the most skilled mould-designing artisans in the world – from Prototype Tools to Bridge Tools & Low & High Volume Production Tools – Röchling provides a full range of mould making – all **tailored to our client's needs**.

## Contract Manufacturing

Röchling is a full-service contract manufacturer with a proven track-record of serving the pharma & life science & pharma community. As a contract-manufacturing partner we offer our clients **flexibility, responsiveness, and traceability** – from start to finish. We want our clients to capitalize on our knowhow, infrastructure, and our ability to source from a global supply chain, striving to provide the most cost effective quality solutions that offer a competitive advantage to our clients.

## Supply Chain Management

The goal of Röchling Medical is to deliver exceptional results to our clients. This extends beyond our multiple facilities to the critical supply chains that support your programs. With this in mind, Röchling implemented key performance factors through a collaborative supply chain to **achieve the highest level of reliability, responsiveness, flexibility, lower costs, and better resource** management within our manufacturing processes.

## Sterilization

Röchling Medical manufactures, assembles, and packages your products under Class C + D / ISO 7 + 8 clean room conditions. If you have stricter requirements regarding the purity of your products (for example, if you require additional product sterilization), Röchling Medical is your systems supplier of choice. Our close partnerships with sterilization companies allows us to **offer all major sterilization processes**.

## Decoration

Röchling Medical's ability to innovate and incorporate new technologies enables our clients to benefit from cost and quality advantages. Röchling's extensive industry experience and innovative manufacturing processes **encompass all facets of production manufacturing** from injection moulding to final assembly and packaging, all performed with expertise and according to highest quality standards in clean room environments.

## Assembly

Röchling Medical has extensive experience in a **variety of different assembly systems** and the associated quality monitoring functions. A wide variety of assembly systems are used. Röchling Medical has a wide variety of assembly system models and functions, and can therefore cater to a wide range of customer demands. The assembly systems are both fully automated or semi-automated



**Competence**

- Production of medical devices under controlled conditions of clean room class C+D (GMP) / ISO 7+8
- Quality assurance and production processes according to guidelines of Good Manufacturing Practice (GMP)

# Röchling Medical

## Clean Room Technologies

### For highest requirements

The Röchling Medical locations are equipped with **clean rooms to meet the high requirements** for production environments in the pharmaceutical and medical sectors. Thanks to a wide variety of blow moulding and injection moulding processing technologies, and downstream assembly processes under clean room conditions, Röchling Medical is able to produce individual components and assemblies for the pharmaceutical and medical sectors, under **various clean room classes**.

All areas fulfil stringent requirements, are continuously monitored, and are regularly reviewed by internal and external auditors. Systematic training and education programmes ensure that our employees are always kept up to date, and the regulatory requirements are met. Monitoring is an essential element of quality assurance. In particular for demanding production processes, such as manufacture of products for the pharmaceutical and medical sectors, where compliance with operating parameters (including room pressure, particle concentrations, temperature etc.) must be continuously verified and documented in batch documentation.

### Clean room conditions

Röchling Medical currently has over 6,500 m<sup>2</sup> of clean room space, which is used both for injection moulding and assembly processes. Röchling Medical can currently manufacture products for the pharmaceutical and medical sectors under the following clean room conditions:

- ISO 7+8
- GMP C+D
- Clean room / controlled area



## Controlled and reproducible conditions at all times

Thanks to our consistent application of our quality management system certified to pharmaceutical requirements, which is closely linked to compliance with good manufacturing practice (GMP) guidelines, we guarantee that processes occur under controlled and reproducible conditions at all times. Röchling Medical has a **large number of certifications** related to everything from quality management to environmental safety to specific products, and is constantly working on new developments and corresponding certifications. Manufacturing products for the pharmaceuticals, life sciences and diagnostics industry entails **strict standards**, which regards environmental conditions. That is why our production takes place in a controlled environment.

## Certification according to

- ISO 15378 – GMP ISO 8317 for child-resistant packaging
- ISO 13485 – medical devices Drug Master Files (for selected products)
- ISO 14001 – environment GMP-Higher requirements
- ISO 50001 – energy (customer preferences)
- ISO 8317 for child-resistant packaging
- Drug Master Files (for selected products)
- GMP-Higher requirements (customer preferences)



## We offer you:

- Automated in-process-controls
- Traceability of components down to raw material
- Closed material flow
- Inspection by cameras

# Röchling Medical


## Good Manufacturing Practice (GMP-Plus)

Röchling Medical has developed “GMP-Plus” in order to offer our customers even more service and security, above and beyond GMP guidelines. GMP-Plus is a protected in-house brand that takes **cleanliness to a whole new level**, for even more added value!

GMP stands for Good Manufacturing Practice for medicinal products, and represents a set of national and international rules that govern, among other things, requirements for hygiene, premises, equipment, documentation and inspections. **Quality assurance plays a central role** in the manufacture of pharmaceutical products, since deviations in quality can have a direct impact on user health. For this reason, our employees undergo regular training regarding GMP guidelines.

### What does GMP-Plus mean for our customers?

- On request we can provide guaranteed complete freedom from DNA residues or pyrogens, offer production under Class B Clean Room conditions if certain prerequisites are in place, or manufacture products 100% free of any human contact whatsoever.
- We can also carry out customer-specific tests, increase documentation levels or perform more in-depth validations.
- Protection against product piracy is becoming a subject of increasing focus within the pharmaceutical industry as well. European Parliament Directives 2001/83/EC and 2001/62/EU (to be implemented by 2017) and requirements of the FDA include measures to prevent counterfeit medications from infiltrating the legal supply chain. These guidelines were supplemented by Delegated Regulation (EU) 2016/161, passed by the Commission of October 2, 2015. We actively address the subject of counterfeit protection and are the right contact partners for you in this regard.



We will work with you to find the perfect solution, because your product is worth it!

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# Röchling Medical

## NPI System

### New Product Innovation

Röchling Medical is **experienced partner** for the design, development and manufacturing of high quality medical and pharmaceutical products. We have established a cutting edge New Product Innovation (NPI) process **to ensure a high quality and on time delivery** for product development and industrialization activities.

The NPI system includes procedures, processes, guidelines, work instructions and templates for all new product innovation and new product introduction activities and includes all the related project management and steering task. The process includes embedded milestone / gate stage to de-risk the projects.

#### The highlights of the NPI System are:

- Flexible and scalable procedures, best fit for purpose solutions to cover simple and complex projects (3 different complexity tracks)
- Different starting points with key action points and defined input & output per phase
- Milestone / gate stage approach to de-risk the projects deliveries and the related investments
- Robust and cGMP / FDA / ISO 13485 conform validation procedure
- Certified according to ISO 15378, which defines the high requirements for the production of pharmaceutical packaging
- Based on proven program management practice



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**Röchling Oertl Kunststofftechnik GmbH**

Höchster Str. 100  
64395 Brensbach  
Germany  
Phone: +49 6161 9308-0  
Email: [info@roechling-oertl.de](mailto:info@roechling-oertl.de)

**Röchling HPT Hochwertige Pharmatechnik GmbH & Co. KG**

Waldweg 16  
98724 Neuhaus am Rennweg, Germany  
Phone: +49 3679 72606-0  
Email: [zentrale@roechling-hpt.com](mailto:zentrale@roechling-hpt.com)

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Holleder Technolgy Park, 999 Ridgeway Ave.  
14615 Rochester  
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Phone: +1 585 254-2000  
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