



# Safe Handling of Radiopharmaceuticals

October 2018



## RoweMed AG

RoweMed AG – Medical 4 Life is a medium sized innovative MedTech company. Our focus is on developing and producing customized medical plastic systems, especially for the handling of sensitive pharmaceuticals.

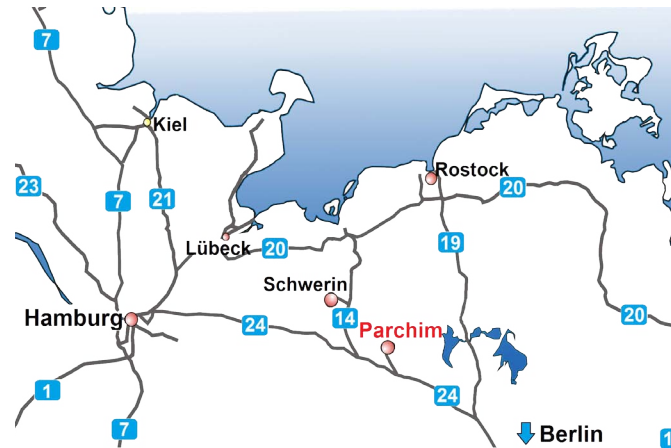
## Company Profile

For our customers we offer turnkey projects: R&D, MASS PRODUCTION, REGULATORY AFFAIRS. Our Quality Management System is certified according to DIN EN ISO 13485 and FDA 21 CFR Part 820. Our clean room production in Parchim (Germany) is certified according to ISO class 7 (particle class 10,000).

## RoweMed AG

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## **R & D**

The development of our systems is closely coordinated with the customer, from first sketch up to a market-ready product, including CAD construction, prototyping and product testing. We also offer serial production and full technical documentation. We guarantee the highest standard in order to fulfill the most demanding requirements for medtech, pharma and biotech industries.

## **Production**

We offer injection molding, assembling & packaging under one roof. In the cleanroom production facility (ISO class 7) in Parchim our employees carry out single-part, small series & automated mass production. In our facility all common welding & gluing technologies are implemented. Our production concept is based on high flexibility. The combination of automated manufacturing of components and individual processes allows a cost efficient and high quality production.

## **Regulatory Affairs**

RoweMed fulfills all regulatory requirements from authorities and notified bodies. We have more than 15 years experience in product approval of medical devices and disposables. In addition to our technical services we offer the complete technical documentation according to the requirements of the Council Directive 93/42/EEC and for the US market 21 CFR part 820.

# Products for drug production and preparation

- Mixing of drug solutions and suspensions
- Filling of patient vials
- Administration sets for critical pharmaceuticals



# Vent Filters Vent Needles

- Sterile venting of vessels, bioreactors or vials
- Retention of liquids, particles, germs, aerosols ( $> 0.1 \mu\text{m}$ )
- Hydrophobic filter (0,1  $\mu\text{m}$ , 3,0  $\mu\text{m}$ , ...)
- Connections: Luer, Luer-Lock, Barb



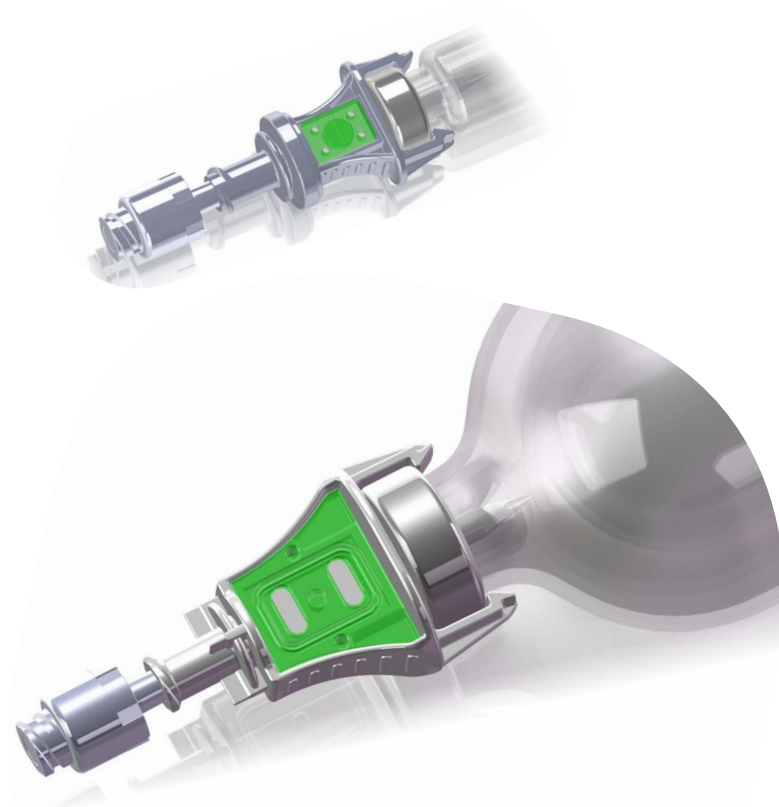
# Sampling Needles

- Withdrawal of drugs and samplings from vessels, bioreactors or vials
- Materials:
  - PEEK
  - Polyethylen
  - Steel
- Different lengths
- Connections:  
Luer, Luer-Lock, Tube



# Bottle Spikes

- Hydrophobic ventilation filter (0,1  $\mu\text{m}$ , 3,0  $\mu\text{m}$ , ...)
- Hydrophilic particle filter (0.2  $\mu\text{m}$ , 5.0  $\mu\text{m}$ , ...)
- Repeated withdrawal and aspiration of solutions, drugs and toxic substances
- Available:
  - different safety valves (needle free)
  - one way valve
  - snap-fit hooks
- Safe vial connections for bottle caps 13 mm, 20 mm or 32 mm
- Luer-Lock connection



# Injection Filters

- For sterile drug preparation
- Avoiding particle contamination
- Diameter:  
3 mm, 18 mm, 25 mm, ...
- Hydrophilic particle filter  
(0.2  $\mu\text{m}$ , 5.0  $\mu\text{m}$ , ...)
- Connections:  
Luer, Luer-Lock, Tube, Barb





# Injection Filters

- Customized filtration systems
- Special requirements
- High hygienic standards
- Handling of hazardous chemicals and aerosols

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# Tubings / Lines

- Materials:
  - Polyethylene (PE)
  - PTFE
  - PEEK
  - Polyurethane (PUR)
- Different lengths
- Straight, spiral or dual-spiral
- Luer-Lock connections



# Reaction Vials

- Material:
  - Cyclic Olefin Copolymer (COC)
  - Glass
- Resistant to acids and most organic solvents
- Complete emptying through optimum housing design
- Heat stability
- Bottle caps 13 mm, 20 mm or 32 mm



# Bottles, Vials Vessels

- Materials:
  - Polyethylene
  - Glass
- Resistant to acids and most organic solvents
- Round and flat designs
- Filling volume <10 ml to 150 ml
- Bottle caps 13 mm, 20 mm or 32 mm

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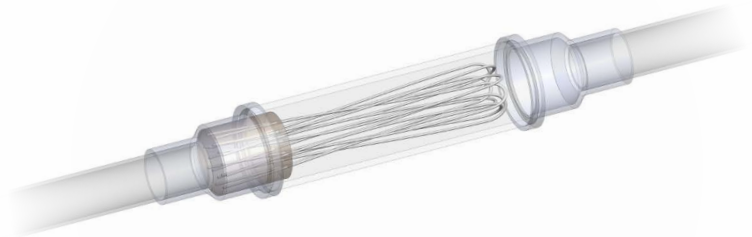
# Bag Spikes

- Supply and withdrawal from bags or bottles
- Available with check valves to prevent leakages
- Luer-Lock connections



# Hollow Fibre Filter

- Large filter surface with high flow and good operation performance
- For ultra and micro filtration
- Available in High Flux (3 – 4 nm), Endotoxin (10 nm) or Plasma (0.2 – 0.5  $\mu\text{m}$ )



# Customized Sets

- Individual complex configurations
- According special customer's requirements

