



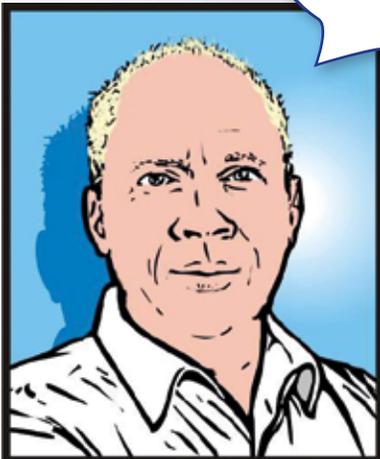
YOUR GERMAN SOURCE FOR ONCOLOGY PRODUCTS



Dr. Stephan Zinzen, Head of R&D

*"You are looking for a German supplier for the most important oncology products?"*

*"You need a flexible supply, sometimes even for small quantities?"*



Jürgen Lehberg, Commercial Director





## AQVIDA - YOUR GERMAN SOURCE FOR ONCOLOGY PRODUCTS

AqVida is a German pharmaceutical company based in Hamburg with manufacturing facilities in Dassow, Germany. We are specialized in oncology products and our team of experts offer:

- Generic Product Development
- High-End Production
- Efficient Registration Support
- Licensing of Dossiers and MAs
- Flexible and Competitive Supply

Our aim is to produce the world's best oncology products and make them available to patients or healthcare professionals around the world at reasonable and affordable prices.

Our products are registered in several EU countries and through our licensing partners we became an important supplier for oncology products to the German market.



Nadine Schröder,  
Head of Regulatory Affairs

*“You need quick  
market access and strong  
regulatory support?”*



## AQVIDA LABORATORY - QUALITY IS KEY

AqVida is dedicated to 100% German quality standards. This includes all processes, products and services for every client around the world. Our in-house laboratory provides the entire infrastructure, enabling our qualified team to conduct analytics and quality control according to our strict quality management processes.

### *GMP-certified processes*

AqVida's quality management system conforms to all German and EU legal requirements for the pharmaceutical industry, including AMG, AMWHV and EU-GMP – regularly certified by the German Health Authorities. We continuously improve standards, procedures and collectively exercise AqVida's „Quality is Key“ philosophy. This principle is maximizing product and health safety and is reflected in an uncompromising SOP system. Quality assurance accompanies the complete product cycle.

### *In-house capabilities include:*

- HPLC
- GC
- IR
- UV
- Water Content
- Gel-Electrophoresis
- IEF
- Western Blot
- Titration
- Sterility
- Microbiological Analytics

*“You expect your supplier to carry out regular audits of the complete supply chain to secure an outstanding quality of the products?”*



Bernd Temme, Head of QC and QA



## EU-GMP AND BEYOND. STRIVING FOR PERFECTION.

- Uncompromising SOP system
- Stringent Quality Standards
- Regulatory Affairs involvement through product life cycle ensures maximum quality of dossiers and documentation
- Regular audits and inspections of all suppliers

Pilot and production

### AUTOCLAVES & FREEZE DRYERS

- ⊕ Full GMP compliance
- ⊕ 21 CFR Part 11 conform
- ⊕ Customized solutions
- ⊕ Reliable and safe results




#### GERMAN ENGINEERING UNDER HIGH PRESSURE

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## AQVIDA ROBOTIC FILLING LINE – PRODUCING QUALITY IN ONCOLOGY INJECTABLES

Here at AqVida, innovation is part of our DNA. To improve product quality and production safety and to save cost and time, we envisioned a filling machine without format parts. By combining robotic arms and sensor technology, we conceptualized a new filling system to considerably minimize rejected vials during production. With the help of Steriline, we were able to create this new filling line, based on these concepts.

Fast robotic arms have been implemented in semi-conductor industry for decades, providing a highly reliable service in a very stringent clean room requirement. But there had never been a breakthrough in pharmaceutical industry for

robotic arms. Now AqVida is at the forefront of that breakthrough, and this new achievement was presented at ISPE conferences.

The new filling machine is installed inside isolators, so that the personal safety and the product quality are both ensured at highest level. The new machine is tailored to AqVida's process for oncology and sterile parenteral filling, offering maximum flexibility and efficiency. Due to zero loss during filling process and flexible batch sizes, AqVida filling line is suitable for commercial batches as well as for very targeted oncology medicines, development projects and clinical trials.





## AQVIDA ROBOTIC FILLING LINE – INNOVATIVE, FLEXIBLE AND EFFICIENT



Dwight You, Head of Production

- „Zero“ format parts
- „Zero“ loss of product liquid
- filling of cytotoxic molecules and antibody drug conjugates (ADCs)
- Filling range : 1 ml – 100 ml vials
- Bulk batch size: 10 liters – 300 liters

*“You believe that technological  
advance should improve the  
safety of products?”*

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ASEPTIC PROCESSING

[www.remoin.com](http://www.remoin.com)

**Distillatori d'acqua**  
Multi effect Still



**Distillatori d'acqua**  
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**Distillatore Termocompressione**  
Distiller Thermocompression



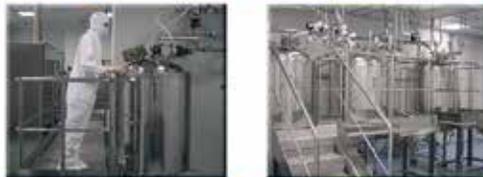
**Generatori di Vapore Puro**  
Pure Steam Generator

**Impianto Osmosi**  
Reverse Osmosis



**Piping Sanitari 3A**  
Sanitary Piping 3A

**Dissolutori/Preparatori**  
Preparation Tanks



**Solui Preparazione**  
Solution Preparation

**Torbo Emulsori**  
Turbo-Emulsifiers



**Sistemi CIP**  
Clean in Place - Systems

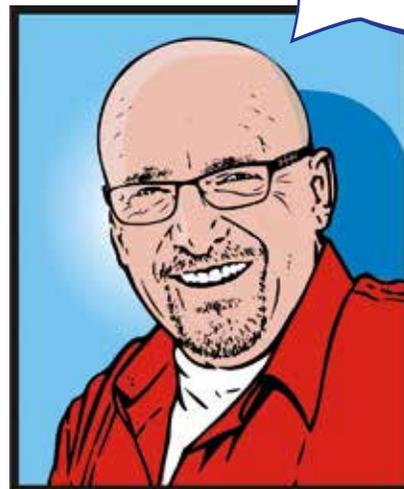


## THE AQVIDA COMPOUNDING SYSTEM

AqVida, together with the partner Remoin, an Italian specialist in compounding systems and WFI systems, built an ultra modern compounding system that is tailored to AqVida's production process.

The system consists of mobile compounding tanks and isolator with a special split valve system, which provides a closed system for compounding operation. This system prevents contamination to the product liquid, while minimizing the exposure of operators to the cytotoxic APIs.

*"You think that only a strong technical backbone can guarantee a steady and safe production?"*



Joachim Bär, Head of Engineering Department

[www.remoin.com](http://www.remoin.com)  
Pharmaceutical System Plants

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Strada Vicinale Majorana, 29  
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[info@remoin.it](mailto:info@remoin.it)



- Compounding system with isolator technology
- Cytotoxic APIs are transferred to tanks via special split valve to increase the quality of the product and safety for operators
- Automated CIP and SIP cycles provide validated processes
- Mobile tanks give flexibilities to batch sizes and production operations  
Tanks can be added and dedicated for certain products

**RGT**  
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## AQVIDA – A GLOBAL COMMITMENT HIGH QUALITY ONCOLOGY TREATMENT FOR THE WORLD

AqVida is the reliable German source for oncology products – for partners, pharmacists, doctors and patients. However, a high quality product is only the first step to a high quality treatment. That is why we:

- Organize congresses and speeches
- Sponsor visits to congresses for international know-how exchange
- Support training programs for international healthcare specialists
- Carry out post marketing studies
- **AQVIDA INNOVATION** - AqVida is developing a mobile container for sterile compounding to establish German hygiene standards all over the world

Our task is only completed if all cancer patients have access to high quality products and treatments at affordable and reasonable prices.



Wolfgang Heinze, CEO

*“Did some of my colleagues guess what you are looking for? If yes I have good news: You have found your partner in oncology!”*

*“Welcome to the Pharmatastic world of AqVida!”*



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