

WHEN TRUST MATTERS

**YOUR PRODUCTS ARE VALUABLE
PUT THEM IN PROFESSIONAL HANDS**



R-PHARM
Germany GmbH

FULL SERVICE
CONTRACT
MANUFACTURING

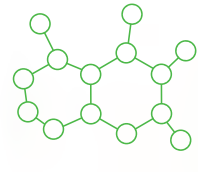


Rich in tradition yet state of the art, driven by the engagement of our employees you have found an exceptional production location for **pharmaceutical products** and **nutritional supplements**.

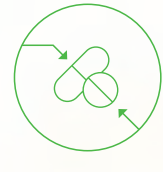
Using our unique service offer and expertise, R-Pharm Germany GmbH supports customers in achieving the results that count – quickly and cost effectively.



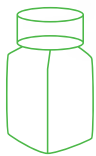
BIOTECH



DEVELOPMENT



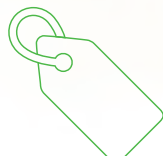
MANUFACTURING



PACKAGING



ANALYTICS



PRIVATE LABEL

THAT'S US !

**INDIVIDUAL SUPPORT
IS OUR ESSENTIAL KEY
TO SUCCESS**

BIOTECH



**VISION. FOCUS.
PERFECTION.**

We offer a state-of-the-art Bioprocess and Bioanalytical Development Center.

Fill & Finish operations are planned for vials and pre-filled syringes up to 1500m².

CHECK IT OUT



Single Use System based on equipment set-up for 1800 m².

TECHNOLOGY	SUITE 1	SUITE 2
Upstream	2x50, 200, 2x2000L bioreactors	2x50, 200, 2x2000L bioreactors
	Harvest skid	Harvest skid
Downstream	Chromatography system	
	2x TFF system	TFF system
	Viral Filtration skid	Viral filtration skid
Target product	B5L 1 Vaccines or MABs	MABs
Annual capacity	Up to 40 commercial batches	Up to 40 commercial batches



FORMULATION & DEVELOPMENT



As a CDMO, we offer the full range of contract and development manufacturing services. Your products are in good hands right from the beginning. Benefit from our experience, starting with the formulation and analytical development as well as the optimization of formulation concepts.

KEY FIGURES

- COMPLEXITY OF 600 SKUs
- 2,000 ORDERS ANNUALLY
- 150 YEARS OF EXPERIENCE IN MANUFACTURING
- PRODUCTS FOR MORE THAN 90 COUNTRIES
- 12,000 M² PRODUCTION AREA
- CAPACITY OF 4 BILLION UNITS

EXPERTISE. PASSION. CUSTOMIZED.

ACCURACY RIGHT FROM THE START

The state-of-the-art Product and Process Development Center enables product development as well as flexible and commercial small-scale manufacturing even for **high potent substances**.

OUR CAPABILITIES AND EXPERTISE

- Oncological solid forms
- Dry, wet and fluid bed granulation
- Modified release tablets, two-layer tablets
- Capsule filling with different components
- Clinical, pilot or small scale GMP manufacturing ranging from 0.5 kg up to 20 kg
- Scale up to commercial batch sizes



HISTORY

1849 Foundation Heinrich Mack GmbH

1860 Opening Production Plant Illertissen

1934 First Pharmaceutical Product based on Bee Venom

1971 Pfizer Inc. Acquisition

1996 Commissioning of Automated Packaging Unit

2003 First FDA Certification

2008 Center of Excellence Containment Production

2009 Center of Excellence Wallet Packaging

2010 Serialization and Aggregation (Track & Trace)

2014 R-Pharm Acquisition

2017 Opening PPDC (Product and Process Development Center)

2021 New BioTech Facility

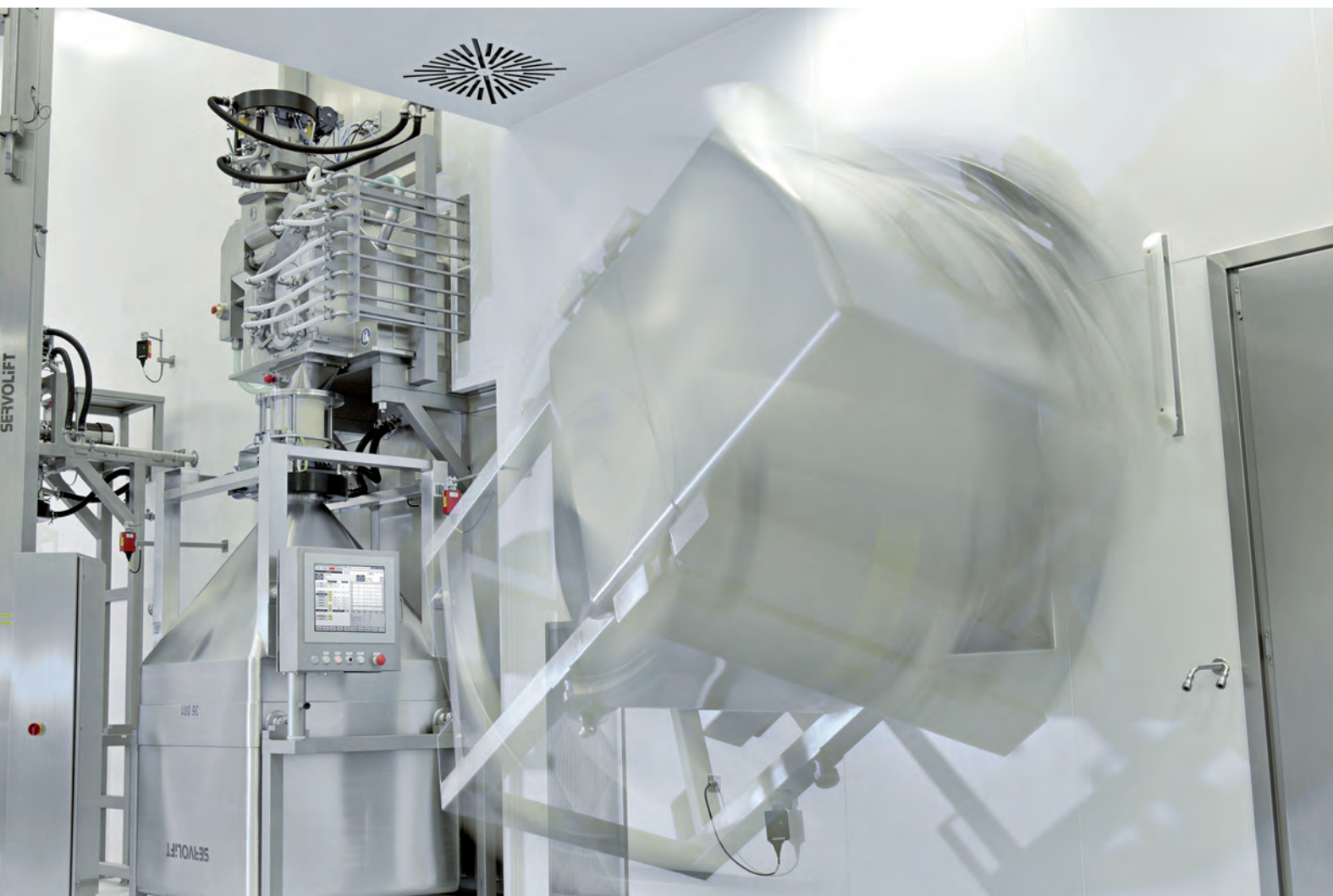
MANUFACTURING



R-Pharm Germany GmbH covers a wide range of manufacturing possibilities for solid dosage forms of **pharmaceutical products** and **food supplements**. Both experience the same diligence and quality standards.

Additionally, we offer the development of OEB 1-3 products and food supplements in a separate building. For OEB 4-5 products we offer four production units

- small batches in FLEXCON from 5-40 kg.
- medium batches in the ICON and SPEEDCON 20-300 kg.
- large batches in the NEWCON up to 700 kg.



QUALITY. COMPETENCE. STANDARDS.

CONVENTIONAL MANUFACTURING

For methods in the range **OEB 1 to 3**, we have a highly flexible production facility at your disposal with 12,000 m², spread above three levels.

We offer a capacity to manufacture 4 billion units of **various solid dosage forms** under GMP and HACCP compliant conditions in top quality.

Flexibility is our strength: therefore, we constantly invest in new technologies and processes.

HIGH POTENT MANUFACTURING

We offer several segregated production units to manufacture **OEB 4/5** products with different batch sizes – starting with 0.5 to 20 kg, up to 700 kg.

The „NEWCON“ (New Containment Facility)

The production unit sets standards in terms of process robustness and process safety. The application of a **fully automated** process flow of several batches in parallel allows **cost-effective containment** solutions.

The PPDC (Product and Process Development Center) expands our service portfolio in the area of high potent manufacturing for **manual** and **flexible** small-scale orders.

PACKAGING



Our team and **14 packaging lines** are available in multi-shift operation providing a capacity of **105 million sales units**. We offer innovative packaging solutions and allow a quick and secure commercialization of your product. More than **eight decades of experience** in packaging of pharmaceutical and nutritional products enable our customers' growth and success.



FLEXIBILITY. EXPERIENCE. SOLUTIONS.

SOLID DOSAGE FORMS

With our **broad range of packaging solutions** for small to large-scale order sizes we specifically and flexibly meet the needs of our customers. Whatever packaging requirements your product calls for, our segregated primary and secondary packaging area allow us to meet various product requirements and to pack even **high potent** formulations in a very efficient and secure way.

- BLISTER
- WALLET
- VIALS
- CUSTOMIZED PACKAGING SOLUTIONS
- BOTTLE
- FOLDING BOX
- SYRINGES

SERIALIZATION AND AGGREGATION

The effective protection against counterfeiting (Track & Trace) is essential to ensure customer safety, brand protection and a transparent supply chain.

We serialize and aggregate according to our **customer needs**: integrated, combined or manual – on all serialization and aggregation steps for all market standards and **regulatory requirements**.

A well-established and intelligent IT infrastructure offers smart and convenient **customer onboardings** at all levels of data and event communication.



ANALYTICS



Quality is more than a standard - our aim is to ensure quality systematically within the process and to embed **supreme standards** as a contribution for process excellence. Naturally, all documentation & data reporting is done in accordance with current **GMP** guidelines.



AGILITY. KNOW-HOW. RELIABILITY.

QUALITY CONTROL & RELEASE

Our Quality Control Division with 40 qualified laboratory staff members supports you in the development, optimization and quality control of your products:

- Analysis and release of pharmaceutical active ingredients, excipients and medicinal products
- State-of-the-art method optimization
- Method development and validation of all dosage forms
- Lab-to-Lab-transfer (method transfer)
- Analysis of highly active substances in our safety lab

For companies beyond the European economic area we offer to perform analysis (EU-Gate Testing) to support the EU-batch release.

STABILITY STUDIES

We advise and support the planning of stability studies including custom-made test plans and take over the entire sample management.

Your stability samples will be stored under various climatic conditions in modern climate chambers with continuous monitoring:

- Climatic zone I / II: 25°C/60% r.h.
- Climatic zone III / IVa: 30°C/65% r.h.
- Climatic zone IVb: 30°C/75% r.h.
- Accelerated: 40°C/75% r.h.
- References: 5°C



PRIVAT LABEL



The basis for your successful product is an idea that works. As an experienced and reliable partner for **food supplements** and nutritional products, we offer numerous standard products for a wide variety of indications, but also conceptual developments for highly innovative labels in the healthcare segment. **Let us inspire you!**



CREATIVITY. NETWORK. EXPERIENCE.

ONE-STOP-SHOP

Whether superfoods or classic recipes: health supplements are anything but short-term lifestyle trends. We provide and develop exactly the products that meets your expectations. From the cost-effective procurement of raw materials and packaging materials, through reliable and safe production and storage, to the logistic of your product **made in Germany**.

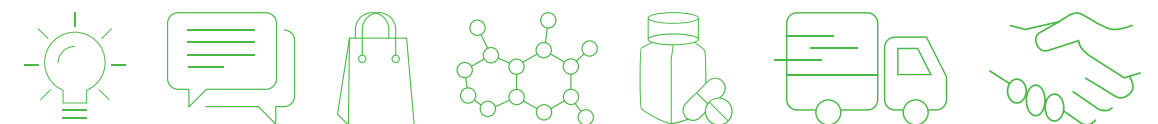


FIRST-CLASS-QUALITY

An implemented HACCP concept guarantees reliable safety in the production, processing and distribution of dietary supplements. ISO 9001:2008 and IFS are among our standard certifications.

OUR KNOW HOW IS YOUR ADVANTAGE

Benefit from our contacts and close cooperation with certificated suppliers. Our knowledge of recipes and technological processes as well as existing robus supply chain processes will reduce your time to market. An implemented **HACCP concept** guarantees reliable safety in the production, processing and distribution of dietary supplements. **ISO 9001:2008** and **IFS** are among our standard certifications.



ACTING SUSTAINABLE

The corporate culture at the Illertissen site always aims at living up to its **responsibility** towards our employees and the environment. We live and breathe „Green Awareness“ and **compliance** every day! Therefore, an integrated management system for occupational safety, environmental protection and health care is in place in Illertissen since many years.

HIGHEST FOCUS ON QUALITY

We take our **responsibility** seriously. Therefore **quality** and quality assurance are our top priorities – a matter of trust. Our exemplary quality system ensures reliable and safe services.

CONTACT US



OUR UNIQUENESS

APPROVED BY AUTHORITIES:

- US FDA
- EMA
- Ministry of Trade and Industry of the Russian Federation
- Korean FDA
- Saudi Arabia
- CETHS UE Belarus
- Canadian BOH
- WHO

CERTIFICATIONS:

- ISO 14001 / OHSAS 18001 / ISO 45001 / ISO 50001

REFERENCES:

- ISPE Category Winner Process Innovation & Overall Facility of the Year Winner 2008 (“Newcon”)
- Packaging HCPC Columbus Awards Winner 2011
- 10 Pfizer Customer Service Awards for best consistent performance

IT'S A MATTER OF TRUST!

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WHEN TRUST MATTERS



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