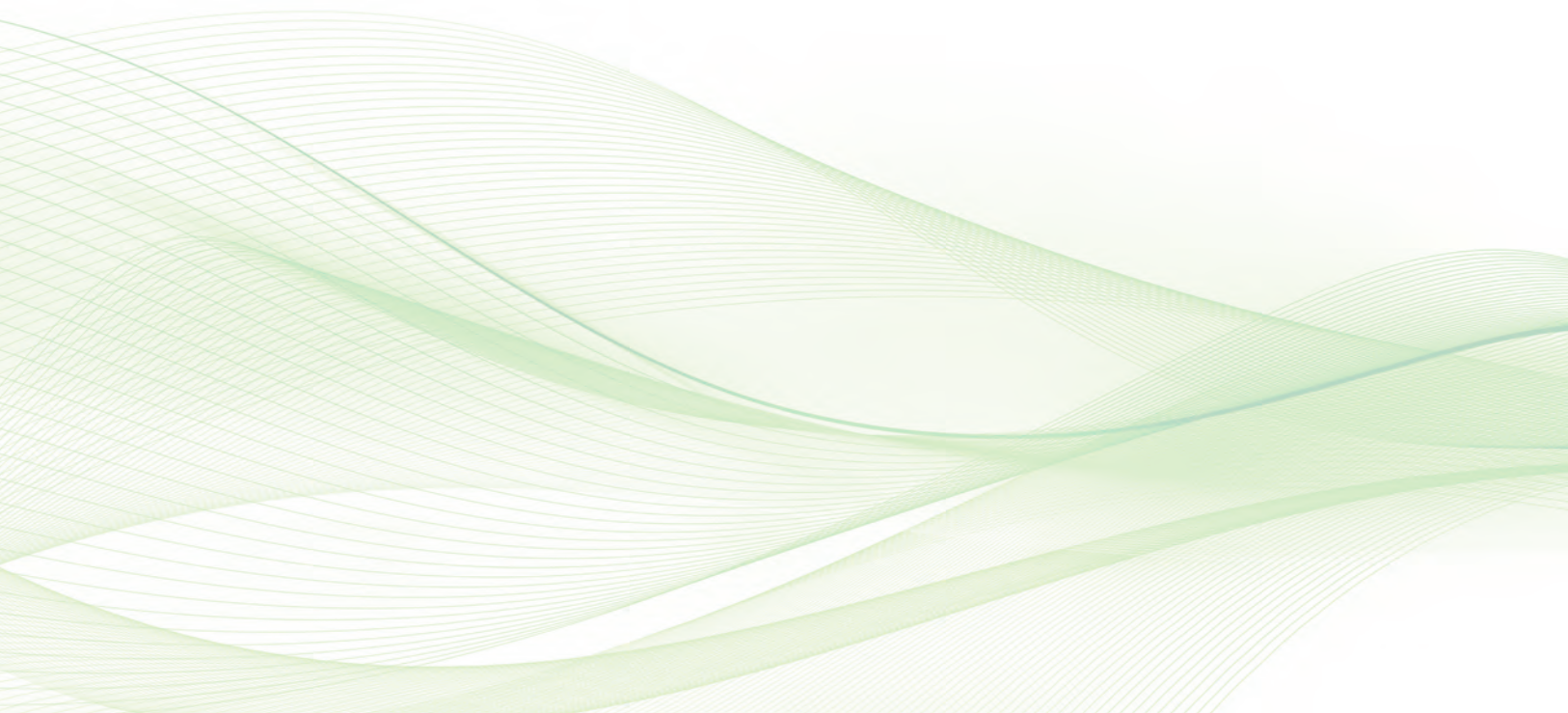




INNOVATIVE HEALTH TECHNOLOGIES

**ENHANCING
YOUR
PHARMACEUTICAL
BUSINESS**

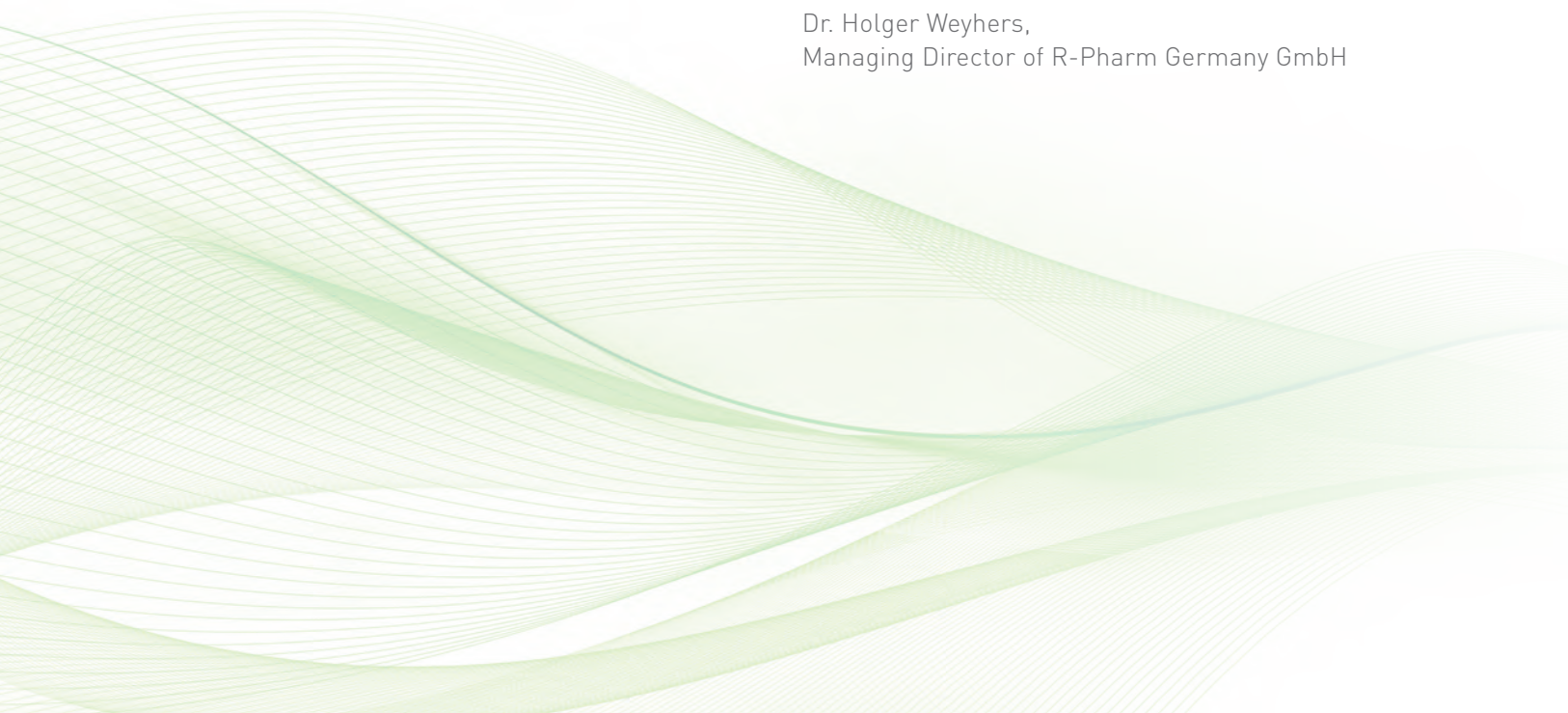




PHARMACEUTICAL PRODUCTION REQUIRES VISION AND INITIATIVE

“ We have been producing and packaging medicinal products for patients in 150 countries around the world for many years. Innovative technologies and a highly motivated and skilled team guarantee utmost reliability and set the highest standards in terms of quality and excellent value for money. ”

Dr. Holger Weyhers,
Managing Director of R-Pharm Germany GmbH





WHO WE ARE MORE THAN JUST MANUFACTURING



With its approximately 370 employees, our site is one of the most modern and innovative production facilities worldwide for manufacturing drugs with highly effective substances and for packaging pharmaceuticals.

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

As a reliable partner and contract manufacturer in the pharmaceutical industry, we offer excellent services and capabilities in terms of:

- Manufacturing services
- Packaging services
- Analytical services
- Projects

Currently we master the complexity of 1,500 Stock Keeping Units in 6,000 orders annually at a consistently high service level of over 99%.

You can expect the best from an exceptional location, an ultra-modern plant and our sophisticated products, that have won multiple awards.

Our aim is to deliver real benefits – to our customers and to human health.

We take our responsibility seriously. Therefore quality and quality assurance are our top priorities and a matter of trust. Our exemplary quality system ensures reliable and safe service. The premise of our actions: Only products that we feel comfortable to recommend to our parents, children, friends or neighbours, are those that reach the market.

APPROVED BY AUTHORITIES

US FDA / EMA / ANVISA / Korean FDA / Canadian BOH / PMDA Japan / NAFDAC / Turkish MOH / Saudi Arabia

CERTIFICATIONS

ISO 14001 / OHSAS 18001 / ISO 50001

REFERENCES

ISPE Category Winner Process Innovation & Overall Facility of the Year Winner 2008
Packaging HCPC Columbus Awards Winner 2011
10 Pfizer Customer Service Award for best consistent performance in series



TRADITION GUARANTEES THE FUTURE

The roots of our company go back a long way with Heinrich Mack GmbH having been founded in 1849. Since then the company has constantly been striving for innovation.

A BRIEF HISTORY OF SUCCESS

- 1849: Founding of Heinrich Mack GmbH in Ulm
- 1860: Founding of production plant in Illertissen
- 1934: Start of drug production based on bee venom
- 1971: Takeover by Pfizer Inc. NY
- 1996: Expansion of packaging plant (Building A8 is built)
- 1999: Specialization of solid preparations
- 2003: FDA First Certification
- 2007: Center of Excellence - Containment Production
- 2008: NEWCON Facility of the Year Award
- 2008: Serialization
- 2009: Automated Palletization
- 2009: Center of Excellence – Wallet packaging
- 2011: Certification “Green Manufacturing”
- 2014: R-Pharm acquires the Illertissen site

CORE VALUES – OUR FOUNDATION FOR SUSTAINABILITY AND COMPETITIVENESS



R-PHARM GERMANY GMBH IS COMMITTED TO FOLLOWING FOUR CORE VALUES:



WE LIVE AND BREATHE “GREEN AWARENESS” AND COMPLIANCE EVERY DAY

The success of our business is largely due to the drive of all our employees at R-Pharm, who are committed to upholding high standards of business integrity, honesty and transparency in all their business dealings.

Consequently, we believe that our corporate culture and corporate social responsibility is a matter of course, a pleasure not a chore.

Therefore, we have developed and implemented measures to support our goals regarding:

- Occupational safety
- Environmental protection and energy efficiency
- Health protection
- Corporate social responsibility
- Personnel development



WITH R-PHARM GERMANY GMBH YOU ARE WELL EQUIPPED FOR THE FUTURE

Our long-standing manufacturing site in Illertissen represents current state-of-the-art technology for production and packaging of medicinal products for human use:

COMMERCIAL MANUFACTURING

- Conventional manufacturing
- High Containment manufacturing

PACKAGING

- Blister packaging
- Wallet packaging
- Serialization & Aggregation
- Repackaging/Manual processing

WE ALSO PROVIDE ADDITIONAL SERVICES RELATED TO:

- Scale up
- Product launch
- Market approvals
- Distribution
- Analytics
- Stability studies
- EU Gate testing and release
- QP release
- and much more...



EXPERTISE. INNOVATION. STATE-OF-THE-ART TECHNOLOGY

Our Illertissen production site has been servicing the pharmaceutical industry ever since it has been founded in 1860. Therefore, we offer a strong expertise in manufacturing and cover a wide range of production possibilities within Conventional Manufacturing and High Containment Manufacturing.

CONVENTIONAL MANUFACTURING

You are looking for production services for various solid dosage forms in the best quality? We combine proven methodologies with state-of-the-art technologies to deliver solida production in the range OEB 1 to 3, such as

- film coated tablets
- hard capsules
- powders
- granules
- pellets

With 12,000 m² on three levels with cutting edge equipment and technology our flexible production facility offers a capacity of 5 billion tablets and capsules – including facilities for handling non-aqueous solutions (explosion proof).

- Milling , mixing and sieving processes
- Dry and wet granulation
- Pelletizing, capsule filling, tableting
- Coating

IN THE LIMELIGHT

HIGH CONTAINMENT MANUFACTURING – DELIVERING EXCELLENCE

We know, there is an increasing demand for higher potency levels regarding pharmaceutical ingredients (API). High containment manufacturing is a specialised area and requires top-notch facilities, technology, production processes, quality control and expertise to ensure safe operation through all phases.

OUR CENTREPIECE:

With the commissioning of the Newcon Facility in 2007, Illertissen has set a major milestone in terms of automation, process robustness and process safety. The production unit awarded as Facility of the Year by ISPE and certified by the FDA still sets standards in the application of Quality by Design (QbD), Process Analytical Technology (PAT) and Lean Principles. Without human intervention in production, an intelligent IT infrastructure guarantees a fully automated process flow of several batches in parallel (Automation Layer Concept).

We offer several segregated production units for different batch sizes of 80 kg - 700 kg to manufacture OEB 4/5 products.

- Milling, mixing and sieving processes
- Dry granulation
- Pelletizing
- Capsule filling
- Tableting
- Coating



EFFECTIVE PACKAGING IS THE KEY TO SUCCESS AND A MATTER OF TRUST

The R-Pharm Germany GmbH site in Illertissen has over eight decades of experience in packaging of pharmaceutical products.

Whatever packaging requirements your pharmaceutical product calls for, we are able to specifically and flexibly meet the needs of our customer with our broad range of packaging solutions for small to large-scale order sizes:

- Blister Packaging
- Bottle Packaging
- Wallet Packaging
- Serialization & Aggregation
- Repackaging /Manual Processing

With currently 13 packaging lines in a multi-shift operation and a capacity of approximately 120 million sales units, we continue to drive innovations and accelerate time-to-market – enabling our customers' growth and success.

We comply with present and future regulatory requirements concerning serialization/aggregation for guaranteed protection against forgery. Though our current product portfolio of 1,500 stock keeping units (SKUs) for 150 countries worldwide, we are able to master a high degree of complexity at a constant service level of 99 %.

In order to provide this level of service, we follow a rigorous performance measurement system.



IN THE LIMELIGHT WALLET PACKAGING



Safety and patient compliance are one of the most important criteria regarding packaging. Especially this option in terms of childproof packaging provides outstanding possibilities for differentiation from the competition while increasing patient safety and loyalty.

The extra available surface area is suitable particularly for displaying therapy, titration and patient information and for adding brochures and promotional materials. Wallet packaging has proven to be successful with our customers, especially as medical and clinical samples as well as OTC.

SERIALIZATION AND AGGREGATION

The effective protection against counterfeiting through product coding, serialization and aggregation of drugs (primary, secondary, and tertiary packaging) has become a regulatory requirement in various markets. Compliance with these quality requirements is essential to ensure customer safety, brand protection of products and more transparent supply chain processes.



The ability to fulfil these criteria in accordingly regulated countries is crucial in terms of access to markets.



We cover all currently known market requirements including those of subsequent years with our innovative and qualified system integrations:

Through intelligent and customer-oriented packaging line concepts we meet the highest technical and organizational standards at all levels of coding, serialization and aggregation.



WE STRIVE FOR THE HIGHEST STANDARDS IN QUALITY

Quality is more than a standard in Illertissen, whether for in-house production or as a contract manufacturer. Ensuring quality and safety for all stakeholders such as customers, employers, patients, healthcare professionals, regulation authorities or other internal and external customers is our utmost priority. This is safeguarded by:

- Operational excellence principles
- Robust processes
- Continuous monitoring and analytical quality control tests
- Continuous education of employees

ANALYTICAL SERVICES

Whether you are seeking support regarding development, optimization or quality control of your products – our quality control division with its 40 qualified laboratory staff members and cutting edge equipment is at your side.

- Analysis and approval of pharmaceutical active ingredients and excipients in accordance with the pharmacopoeial monograph or customer specifications
- Analysis and approval for packaging or distribution of oral solid drugs from our own contract production according to the registration documents
- Analysis of narcotics
- State-of-the-art method optimization for HPLC / UPLC methods for content- or purity determination as well as release methods (USP Dissolution Method I or II; manually, semi-automatic and fully automatic)
- Method development and validation of all dosage forms according to ICH guidelines or customer specifications
- Lab-to-Lab-transfer [method transfer] / ISPE guidelines, including planning and reporting - including method optimization in the context of transfers upon request
- Analysis of highly effective substances in our safety lab

IN THE LIMELIGHT

STABILITY STUDIES

Stability studies are a substantial element in terms of developing pharmaceutical products and are crucial for product marketing approval.

Consultation, planning, testing and storing – we offer our customers complete and holistic support as well as capacious stability testing and storage facilities.

SERVICES:

- Advice and support in the planning of stability studies
- Creation of stability plans
- Execution of stability studies according to ICH guidelines (on-going, follow-up)
- Conducting in-use stability
- Conducting photo-stability
- Conducting stress tests (indicating stability)
- Complete data- and sample management including schedule management and sample shipping

Your stability samples can be stored in the most varied 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

Naturally, all documentation / data reporting is completed in accordance with current GMP guidelines and can be put at your disposal for registration procedures.



UNDERSTANDING CUSTOMERS' NEEDS

PRODUCT & PROCESS DEVELOPMENT CENTER (PPDC)

We recognize the importance of meeting the constantly shifting needs of pharmaceutical manufacturing and packaging. Therefore, our Product and Process Development Center (PPDC) will be a Center of Excellence for process transfer and clinical manufacturing of highly active substances in solid dosage forms:

- Galenical development
- Production of small-scale batches
- Manufacturing of dosage forms for clinical studies

PLANNED TECHNOLOGIES

- Roller compactor
- Bin blender
- Sieve mill
- Fluid bed granulator
- High share mixer
- Tablet press
- Capsule filler
- Drum coater
- Blistering machine

SEGREGATION CONCEPT AND CONTAINMENT

According to EU and US regulatory documents, segregation is based on a implemented Quality Risk Management process which includes a potency and toxicological evaluation. To increase product safety, the PPDC is comprised of dedicated manufacturing suites, which allow a spatial product separation.

The manufacturing suites serve as containment, respectively. Each suite features a personnel and a material lock, as well as an independent air handler unit.



ASEPTIC FILL & FINISHING

In future we will be able to provide the entire biopharmaceutical contract manufacturing chain for vials and syringes.

With intelligent and customer-oriented concepts we will have the capability and capacity to fill and finish liquid and lyophilized products of small to large volume order dimensions.

Therefore we fulfil highest technical and organizational standards in a validated GMP environment.

We guarantee a highest level of staff and product security via isolator technology and professional services and procedures.

Our services:

- Formulation and product preparation
- Aseptic filling
- Lyophilization of vials
- Visual inspection
- Packaging
- Analytics & Release



INNOVATIVE HEALTH TECHNOLOGIES

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