WHEN TRUST MATTERS

YOUR PRODUCTS ARE VALUABLE PUT THEM IN PROFESSIONAL HANDS

R-PHARM
Germany GmbH

FULL SERVICE CONTRACT MANUFACTURING

WHO OFFERS THE FULL RANGE OF CONTRACT MANUFACTURING SERVICES AND GUARANTEES EFFICIENT COOPERATION?

THAT'S US !

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.

- FORMULATION & DEVELOPMENT
- SCALE UP, PRODUCT LAUNCH
- MANUFACTURING (OEB 1 – 5)
- PACKAGING
- ANALYTICS
- DISTRIBUTION

DEVELOPMENT MANUFACTURING PACKAGING ANALYTICS

INDIVIDUAL SUPPORT IS OUR ESSENTIAL KEY TO SUCCESS

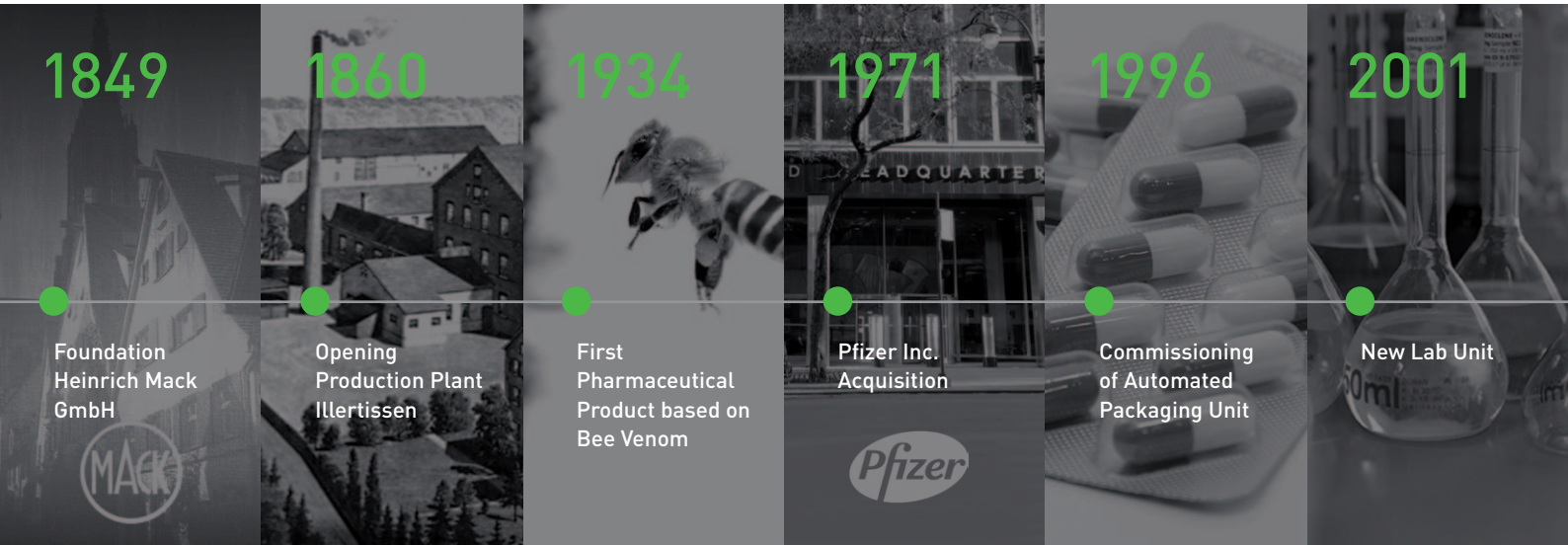
FORMULATION & DEVELOPMENT

We started with simple manufacturing and packaging, but, thanks to our increasing experience and continuous corporate growth, we offer the full range of contract and development manufacturing services (CDMO).

KEY FIGURES

- COMPLEXITY OF 1,500 SKUs
- 6,000 ORDERS ANNUALLY
- 150 YEARS OF EXPERIENCE IN MANUFACTURING
- PRODUCTS FOR MORE THAN 150 COUNTRIES
- 12,000 M² PRODUCTION AREA
- CAPACITY OF 4 BILLION UNITS

HISTORY



INNOVATION. FOCUS. PERFECTION.

FULL SERVICE PORTFOLIO

Our long-standing site in the south of Germany represents current state-of-the-art technology and covers a wide range of contract manufacturing services – starting with the formulation and analytical development of medicinal products and nutritional supplements as well as the optimization of formulation concepts.

The new facility PPDC (Product and Process Development Center) enables product development as well as flexible and commercial small-scale manufacturing even for high potent substances.

MANUFACTURING

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

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 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 fourteen packaging lines are available in multi-shift operation providing a capacity of 120 Mio. 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
- BOTTLE
- WALLET
- STICK PACK
- CUSTOMIZED PACKAGING SOLUTIONS

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.

With a well-established and intelligent IT infrastructure, we meet highest qualitative and technical standards 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

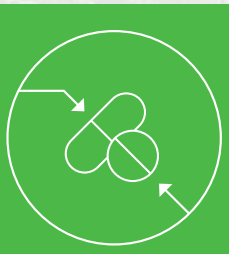
We advise and support the planning of stability studies including custom-made test plans and take over the entire sample management.

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

TAKE ADVANTAGE OF OUR BROAD SERVICE PORTFOLIO AND EXPERIENCE

DEVELOPMENT



MANUFACTURING

PACKAGING

ANALYTICS

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R-PHARM
Germany GmbH

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
- ANVISA
- Korean FDA
- Saudi Arabia
- PMDA Japan
- NAFDAC
- Turkish MOH
- and more
- Ministry of Trade and Industry of the Russian Federation

CERTIFICATIONS:

- ISO 14001 / OHSAS 18001 / 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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