



CONTRACT PACKAGING



CONTRACT DEVELOPMENT



CONTRACT MANUFACTURING

MANUFACTURING  
PACKAGING  
FORMULATION DEVELOPMENT  
ANALYTICAL METHODS

ROTTENDORF PHARMA

# WE MASTER YOUR PRODUCT

No matter how  
tricky it is

Partner with a Top 20 Pharmaceutical  
CDMO with Superior Expertise  
in Solid Dosage Forms

EST.

1928

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



**ROTTENDORF**  
— PHARMA —

**FDA**



BULK  
MANUFACTURING

# CONTRACT MANUFACTURING

Highest level  
of technological  
expertise

## GMP MANUFACTURING FOR BATCHES UP TO 1,000 KG

Rottendorf Pharma GmbH serves clients worldwide with GMP manufacturing of solid dosage forms in facilities that are inspected by FDA, EMEA, ANVISA, and others. Our manufacturing facilities handle commercial batches up to 1,000 kg, and because our formulation pilot plant is FDA inspected and GMP compliant, we can manufacture smaller batches of 2 kg to approx. 150 kg for commercial distribution, clinical trials, or stability studies.

## A TRUSTED PARTNER

With more than 85 years of experience manufacturing solid dose forms, Rottendorf applies our expertise to optimize the production of your products. We have 40 formulation scientists and countless technicians and technical managers who call on their experience to ensure we provide the most cost-effective and efficient product transfer and manufacturing processes.



## FOCUS ON QUALITY

Each production stage is carried out in a separate room, including a dedicated production area for high-potency products. We use closed production systems and consistent ventilation to eliminate product contamination. Our goal is deviation-free manufacturing with on-time delivery.

## QUALITY CONTROL – THE INTEGRITY OF THE PRODUCT COUNTS

Rottendorf Pharma provides all the analytical capabilities you need for outsourced manufacture and development of solid oral dosage forms. To fulfill our commitment as a full-service contract development and manufacturing organization, Rottendorf supports a large analytical department staffed with experts to meet your needs for outsourced.

# TECHNOLOGY

## GRANULATION

### FLUID BED

- Glatt GPCG (100 – 300 kg)

### WET / VACUUM

- Diosna P10, P25, P60, P100, P250, P600 (5 – 300 kg)
- Diosna VAC 600

### DRY

- Gerteis Roller Compactor

## BLENDING

- Bohle tumbler mixer
  - (20 – 2,000 liters)
  - Max batch size 1,000 kg
- Lödige high-shear mixer
  - (20, 130, 300, 1,200 liters)
  - Max batch size 500 kg

## TABLETING / CAPSULE FILLING

### TABLETING

- Kilian Synthesis 500, T300, S250, Fette FE 55

### MULTI-LAYER / COATED TABLETS

- Kilian T400, S250 ZS-M

### CAPSULE FILLING

- Bosch GKF 1,400 and 1,500
- Bosch Checkweigher KKE 2500

## FILM COATING

- Dria coater (150 – 500 kg)
- Bohle BFC 400 & 600 coater
  - 250 – 750 kg (in one sub-lot)
  - Able to handle organic solvents

## SUGAR COATING

- Brucks coating pans 120 and 250
  - Batch sizes of 80 – 2,700 kg

## PELLETIZING

- Diosna P 600
  - Max batch size 615 liters
- Extruder NICA E 220
  - (Approx 50 – 100 kg/h)
- Spheronizer NICA S 700
  - 2 – 10 kg per spheronizer unit and cycle
- Aeromatic MP 4 / 5
  - Precision Coating

## HIGH POTENCY PRODUCTS

### GRANULATION

- Diosna 250

### TRAY DRYING

### BLENDING

- Bohle container system
  - Up to 2,000 liters

## QUALITY CONTROL

### DISSOLUTION TESTING DEVICES

- Erweka, Pharmatest
- Sotax
- Agilent (auto sampler)

### HPLC

- Waters

### H-CLASS

- Waters

### GC

- Agilent

→ For further information:  
[www.rottendorf.com](http://www.rottendorf.com)





ROTTENDORF  
PHARMA

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# CONTRACT DEVELOPMENT

One-stop service  
in a best-in-class  
development  
center

## GMP, FDA COMPLIANT DEVELOPMENT CENTER

Rottendorf Pharma GmbH designs and develops solid dosage formulations from 2 kg to approx. 150 kg in a state-of-the-art Development Center that is both FDA inspected and GMP compliant – something not all CDMOs can offer. We have additional technologies for hot melt extrusion, hot melt granulation, micro-dosing, and the development and production of pellets. Special emphasis is placed on improved availability of poorly soluble APIs. Our large and unique staff of 40 formulation scientists turns years of experience into the best formulation designs for a wide range of solid dose forms:

- Blends and granulates
- Tablets: core, film- and sugar-coated, multi-layer, controlled- and delayed-release
- Pellets
- Hard-gelatin / HPMC capsules, micro-dosing capsules
- Hot melt extrudates, hot melt granulates





## FORMULATE WITH THE FINAL GOAL IN MIND

Our development expertise is grounded in the knowledge of commercial manufacturing operations and requirements. We formulate with the final goal in mind – delivering formulations that are ready to be easily and robustly manufactured at a commercial scale.



## A RANGE OF SERVICES

You can choose from individual or complete services, including process and formulation optimization, upscaling, clinical trial manufacturing, analytical method development, stability studies, and regulatory support.

→ For further information: [www.rottendorf.com](http://www.rottendorf.com)

# TECHNOLOGY

## GRANULATION

### FLUID BED

- Glatt GPCG 3 (1 – 5 kg)
- Glatt Midi (50 – 400 g)
- Aeromatic MP 3 / 4 (10 – 50 kg)

### WET

- Diosna P1, P4, P10, P25, P60 (0.2 – 25 kg)

### DRY

- Gerteis Roller Compactors

## BLENDING

- Bohle tumble mixer (0.5 – 400 liters)
  - Max batch size approximately 150 kg
- Lödige high-shear mixer (5, 10, 20, 130 liters)
  - Max batch size approximately 40 kg

## TABLETING

- Kilian T100, T200, S250 ZS-M

## CAPSULE FILLING

- Bosch GKF 400
- Bosch Checkweigher KKE 2500

## FILM COATING

- Bohle BFC 50 (10 – 33 liters)
- Bohle BFC 200 (150 – 250 kg)

## SUGAR COATING

- Brucks pans (5 – 60 kg)

## PELLETIZING

### EXTRUSION

- Nica Extruder E140 / Spheronizer S450
- Batches from 500 g upward

### LAYERING

- Glatt GPCG-3 Wurster (1 – 3 kg)
- Aeromatic MP 3/4 (10 – 50 kg)

## HOT MELT EXTRUSION

- Twin screw extruder; screw diameter 18 mm (Leistritz); Type ZSE 18-HPE
- Thermo Fisher Pharma 11 mm extruder

## HOT MELT GRANULATION

- Vacumix melting and mixing vessels
- Aeromatic MP 3 / 4 (10 – 40 kg)

## CLINICAL TRIAL MANUFACTURING

## CONTRACT PACKAGING

We meet a full range of solid dosage packaging requirements, using best-in-class equipment

### WIDE CHOICE OF PACKAGING OPTIONS

Rottendorf Pharma GmbH's state-of-the-art Packaging Site produces up to 260 million blister packs, 15 million plastic bottles and 10 million glass bottles of solid oral dosage forms per year, using standardized packaging processes, which are validated, monitored and regulated. Rottendorf's GMP facilities are inspected by FDA, EMEA, ANVISA and others to guarantee a global market supply. In addition, controlled climate conditions allow Rottendorf to deal with humidity-sensitive products to <35% relative humidity. Our focus is to provide our customers with a variety of packaging options.

- Implementation of Serialization and Aggregation
  - China coding
  - South Korea
  - EU
  - Brazil
- High-grade 2D code printing
  - French coding
- Two products in one blister
- Blister inline printing
- Consequent separation of primary and secondary packaging
- Tamper evident features
  - Security labeling
  - Hot melt closure
  - Induction sealing
  - Forth flap





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## TECHNOLOGY

### PACKAGING WITH THE FINAL GOAL IN MIND

Not only can Rottendorf package your products, we are experts at package formatting and design. We work closely with clients to determine the best, most cost-effective packaging. By designing with the final goal in mind, we create packaging that meets our customer's expectations.

**"Bulk Manufacturing and packaging process excellence groups have been implemented to ensure robust manufacturing and packaging processes."**

**LEA PAWLEWSKI -**  
Director Product Manufacturing

### BLISTER PACKAGING

#### MACHINERY

- IMA Giant
- IMA C90
- Uhlmann UPS 4 et
- Uhlmann UPS 3 mt
- Uhlmann UPS 2 et
- Noack N 920
- Noack N 921

#### FOIL PORTFOLIO

- PVC / PVDC
- Triplex
- Aclar
- PP
- Alu-Alu

### ALU-WRAP

#### MACHINERY

- Lafer Motion-C

#### FOIL PORTFOLIO

- Alu-Alu

### BOTTLE FILLING

#### MACHINERY

- Uhlmann IBC 120
- Pack Feeder

### POWDER FILLING

#### MACHINERY

- OPTIMA Linoline

### MODULAR EQUIPMENT

- Labeler / Printer ELS
- Labeler Bosch & Strobel
- Insert / Booklet Feeding System
- Bundling System Pester Pewo Pack 250
- Bundling System Skinetta ASK 3000
- Bundling System Skinetta ASK 450
- Bundling System Skinetta ASK 200
- Labeler Cipreski
- Labeler Tamper Evident
- Hot Melt Closure



## OUR STRUCTURE

### A unique company structure

#### INDEPENDENCE

PRESERVING THE AUTONOMY  
OF ROTTENDORF  
PHARMA

#### SECURITY

SECURING JOBS AT THE  
COMPANY  
HEADQUARTERS

#### FINANCIAL STABILITY

ALL PROFITS ARE  
REINVESTED INTO  
THE COMPANY

Rottendorf has a unique company structure that creates significant advantages for our customers. Andreas Rottendorf formed a structure to ensure long term sustainability and total independence of the company, creating significant advantages for our customers combined with a platform for charitable activities. There are four shareholders, the Rottendorf foundation and 3 minority shareholders with majority voting rights. All bound by the by-laws that Andreas Rottendorf put in place.

As a result of this, Rottendorf Pharma has true entrepreneurial freedom. This is an enormous competitive advantage for an international high-tech company.

#### ROTTENDORFS LONG TERM SUSTAINABLE STRUCTURE OFFERS:

- no growth and profit race  
no merger and acquisitions
- very little employee turn-over (no brain drain)
- fast and independent investment decisions
- ability to execute long term strategies
- totally independent no foreign influence
- financial stability  
all profits are reinvested into the company

## 4 SHAREHOLDERS

#### 3 MINORITY SHAREHOLDERS

96 % VOTES

0.6 % SHARES

#### ROTTENDORF FOUNDATION

4 % VOTES

99.4 % SHARES





## TPO (TOTAL PROCESS OWNERSHIP)

Strategy and company culture to minimize customer's oversight requirements

Rottendorf's Total Process Ownership (TPO) approach means to assume a high degree of ownership and responsibility over the manufacturing, packaging, formulation and analytical processes they use to bring the customer's pharmaceuticals to market. Clients can count on an exchange of ideas and recommendations to create integral solutions beyond the initial task description, and their timely and precise implementation.

Why merely "out-task" when you can truly "out-source" to a Top 20 Contract Development and Manufacturing Organization (CDMO) with decades of experience, deep pharmaceutical expertise, and robust and efficient processes?

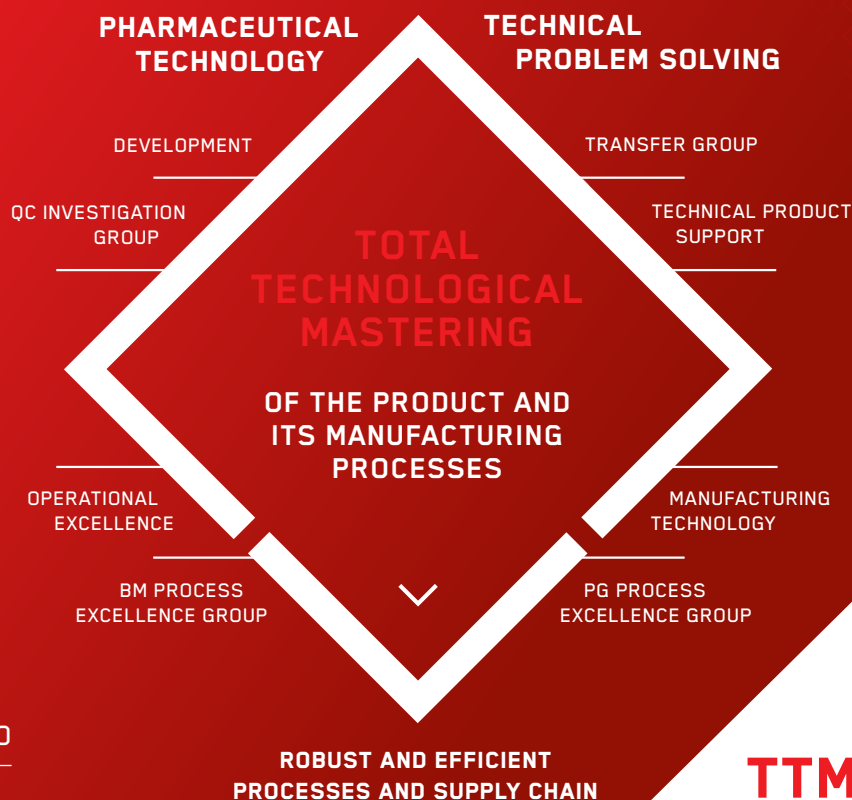
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### TOTAL PROCESS OWNERSHIP MEANS FOR ROTTENDORF:

- assuming customer's position
- understanding the underlying process
- and adopting customer's final goal
- creating integral solution beyond the initial task description



EVERY OUTSOURCED TASK IS EMBEDDED IN AN UNDERLYING  
PROCESS AND IS SUPPORTING A FINAL GOAL



>600

PRODUCTS  
MASTERED  
SO FAR

10

**TTM**

## TTM (TOTAL TECHNOLOGICAL MASTERING)

No matter how tricky  
your product is  
– we master it –

### TOTAL TECHNOLOGICAL MASTERING MEANS FOR ROTTENDORF:

- to fully understand the galenical design of the product and its critical parameters during transfer
- providing the technical expertise to solve product design based problems
- identifying process improvement potential and corresponding solutions
- successful technical trouble shooting of all product and manufacturing issues

Therefore eliminating customers  
needs to provide expertise on product  
technology and technical operations

Rottendorf Pharma is 100% dedicated to the manufacturing, packaging and formulation development of solid dosage forms. Thanks to performing a lot of pioneering work and to constantly solving complex and difficult tasks together with our clients, Rottendorf has become a partner at eye level for our customers.

Clients profit from Rottendorf's Total Technological Mastering (TTM) approach which eliminates the customer's needs to provide expertise on product technology and technical operations. Rottendorf's team consists of extremely well-trained employees who accompany the product, for instance from the up-scaling stage to the creation and definition of the production process and right up to the machine level. Thus, we have the expertise from development right up to production.



## SUPPLY CHAIN MANAGEMENT

Best-in-class on time delivery creating a robust and efficient supply chain

Supply Chain Management is the key element within the product supply pillar because it functions as the connecting and synchronising element between Bulk Manufacturing, Quality Control and Packaging. Our Rottendorf Supply Chain Management group operates based on a holistic advanced 3-stage planning process from rough cut planning down to detailed daily planning throughout the business. Through this highly integrated process best in class on Time Delivery is ensured. The communication with our customers always takes place in a proactive and customer-oriented manner.

We understand the market demands and requirements of our customers and match the applicable supply chain strategy against. This maximizes the customer's benefits while minimizing the oversight requirements. Within the daily business we are aware of the detailed status of our orders and the customer's requirements at any point in time. We continuously identify potential for improvement in the planning processes and proactively make suggestions for their implementation. By continuously developing our processes, planning models and our staff, we always provide our customers with the best service possible.



**OVERALL: CONTINUOUS PRODUCT SUPPLY PROCESS IMPROVEMENT THROUGH SYNCHRONIZED CONTROL LOOP**

- **PRODUCTION:** Adherence to planned process time –  
Online monitoring of shop floor and QC performance
- **SUPPLY CHAIN:** Advanced planning Process –  
Advanced synchronized 3-stage planning processes embedded into holistic customer involved capacity planning approach
- **PRODUCT QUALITY:** Deviation free manufacturing –  
enables Right First Time

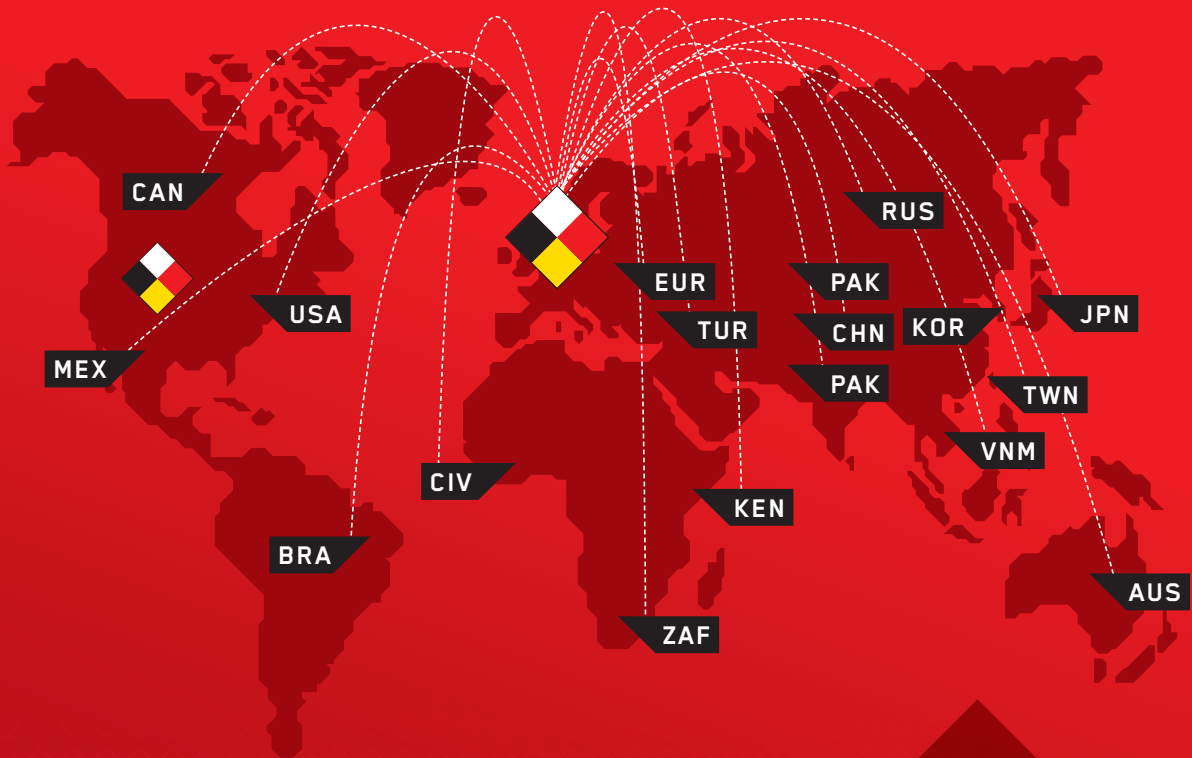
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CONSISTENT MANUFACTURING PROMISES  
ON TIME DELIVERY





# OUR MARKETS – Our Locations



## CONTACT US

Contact us to discover the benefits of our best-practice enterprise communications so that you can become more successful in the market.

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