

**Rottendorf
Pharma GmbH**

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NUMBER OF EMPLOYEES
800+

DATE FOUNDED
1928

OUTSOURCING and Consulting Services



Rottendorf Pharma

Company Description

Rottendorf Pharma, a global Top 20 contract development and manufacturing organization (CDMO), has been formulating, manufacturing, and packaging solid oral dosage forms for pharmaceutical clients worldwide for more than 85 years. Its commitment to Total Process Ownership reduces clients' management oversight requirements and costs, while improving the supply chain and product quality. Clients choose Rottendorf for its broad-ranging expertise, global regulatory capabilities, commitment to quality, state-of-the-art equipment and facilities, and exceptional customer service.

Technical Services

Analytical development services: development, validation, and transfer of analytical methods; release analytics, ICH stability studies, and analytical support throughout the product manufacturing process.

Formulation development services: optimization, upscaling, regulatory affairs support, and development of granulates, blends, tablets, capsules, film and sugar coats, pellets, and hot-melt extrusion and granulates; also manufacturer of clinical-trial batches for all clinical phases.

Contract manufacturing services: Available for all solid dose forms, including high potency products. Product transfer, validation, qualification, procurement of APIs and excipients.

Packaging services: full range—blister packs, bottles, granulate filling, and Alu-wrap®; supply-chain services for procurement of packaging materials and distribution.

Facilities

Rottendorf has state-of-the-art development, manufacturing, and packaging facilities in Ennigerloh, Germany and Valenciennes, France. The Rottendorf Development Center provides best-in-class technical equipment in line with GMP and FDA standards. It produces batches from 2 kg to 150 kg. Manufacturing facilities produce batches up to 750 kg.

Major Products/Services

As a top 20 CDMO providing analytical development, formulation development, contract manufacturing, and packaging services to the global pharmaceutical market, Rottendorf Pharmaceuticals relies on a Total Process Ownership philosophy to serve our clients. This means we assume a much higher degree of ownership over the processes we use to bring your pharmaceuticals to market than a typical CDMO. At Rottendorf, you are not simply renting equipment or out-tasking. You are outsourcing critical components of your business to a trusted partner. We bring more than 85 years of experience, serving 200 clients and producing more than 600 products, to each project.

Markets Served

Rottendorf Pharma, serves the global pharmaceutical market—big, small, and virtual—with contract development, manufacturing, and packing services for solid oral dosage forms. All facilities are GMP compliant and inspected by regulatory agencies worldwide, including the FDA, EMA, ANVISA, and others. Rottendorf does not manufacture its own brands, and therefore is never in competition with its clients.