

# CSR STATUS REPORT 2020



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# About Rottendorf Pharma

Rottendorf Pharma GmbH, headquartered in Ennigerloh, North Rhine-Westphalia, Germany, and with around 1,200 employees, is one of the leading contract manufacturers and developers of oral solid dosage forms for the international pharmaceutical industry and has been operating successfully in this market for more than 90 years. The Company's production facility is located in Ennigerloh, while it also has a distribution site in Bozeman, Montana, USA.

As a full-service contract development and manufacturing organization (CDMO), Rottendorf Pharma offers the complete range of services for solid oral dosage forms, from development and production to analytics and packaging. With its innovative TOTAL PROCESS OWNERSHIP (TPO) and TOTAL TECHNOLOGICAL MASTERING (TTM) service models, Rottendorf supports its clients as a full-service partner and eases the burden of their responsibilities by providing expertise on product technology and technical






processes. This reduces the client's resource requirements and overall outsourcing costs while optimizing their supply chain and product quality. The Company's clients include large, small, virtual and global pharmaceutical and biotechnology companies.

Pharma companies strategically outsource their manufacturing to focus on research, sales and marketing, utilize the expertise of highly proficient contract manufacturers such as Rottendorf Pharma and, in some cases, reduce capital commitments, for example. Other factors influencing these decisions include a pharmaceutical company's individual capacity utilization, their expertise in incorporating knowledge of pharmaceutical developments into the production process, and their strategic direction when it comes to mapping process steps based on their own capacities.

In addition to the production and analytics of oral solid dosage forms, Rottendorf Pharma's core business also involves packaging products manufactured by the client. In its development business, Rottendorf carries out formulation and process development of the final dosage form on behalf of the client in accordance with quality standards, using the active ingredients defined by the client. This division also supplies clients with compounds for their clinical studies and provides technological support for products until they are transferred to routine production.

The target audience for these products and services are start-up companies, clients requiring development services during clinical phases and commercial experimental production, and clients looking for a highly qualified CDMO for their development work.

The acquisition of new clients, management of existing clients, expansion of packaging, labor, bulk manufacturing and the USA business all fall under the Company's economic considerations. Rottendorf Pharma's specific goals here are as follows:

- To further build on its market positioning as a CDMO full-service provider in the area of oral solid dosage forms in its strategic target markets of the EU and North America
  - To sustainably increase revenue by 5% to 10% annually during the 2020–2025 planning period
  - To develop a model to systematically measure client satisfaction by 2023
  - To intensify its business relationships with long-standing existing clients
  - To continually and structurally ensure operational quality results and KPIs
  - To accelerate the production of clinical batches to a maximum of two months from scheduling to production
  - To successfully implement planned investments for 2021–2025 while taking market changes into account
  - To develop additional business models in the area of solid dosage forms
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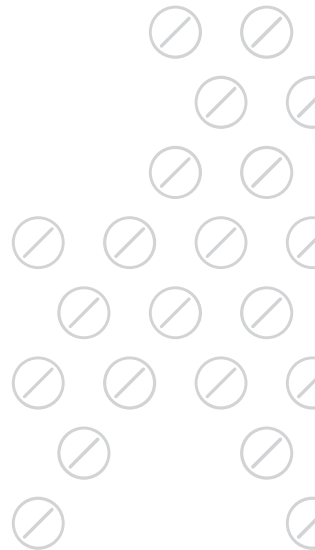




SUSTAINABILITY AT ROTTENDORF PHARMA

# Sustainable by tradition

Safe production conditions, strict quality management and high occupational safety and environmental protection standards have been self-evident of course for Rottendorf Pharma for more than 90 years. The unique corporate structure created by founder Andreas Rottendorf ensures the Company's long-term sustainability and independence while at the same time providing a basis for the Rottendorf Foundation's wide-ranging charitable activities.



As a development partner and producer of medicines and nutritional supplements for the global market, Rottendorf Pharma makes a contribution to global healthcare. The Company's role as a manufacturer of orphan drugs and a single supplier for medicines also ensures reliable market supply.

To ensure that it can develop sustainability aspects holistically in the future and systematically integrate them into its corporate strategy, Rottendorf Pharma has made sustainability work an integral part of its corporate governance activities.

As part of these efforts, the Company comprehensively analyzes and continually optimizes its own value creation structures to ensure it can incorporate all aspects of sustainability into its operational and strategic business processes. To underline these ambitions, Rottendorf Pharma has joined the United Nations Global Compact and has thus committed to its ten principles in the areas of human rights, labor standards, environmental and climate protection and corruption prevention.

For some time now, Rottendorf Pharma has had its own EHS (Environment, Health and Safety) department to monitor and support the Company's sustainability performance. This department is also responsible for designing and introducing suitable procedures for environmental and health protection as well as occupational safety.

The Company set up a sustainability team that reports directly to the Executive Board in order to intensify its strategic sustainability work in particular. Its aim is to develop a roadmap that enables Rottendorf Pharma to manufacture products for its clients that meet not only the highest quality standards but also the highest environmental and social standards.

To further strengthen its corporate, leadership and working culture and expand its management strategy, Rottendorf Pharma has set itself the following goals:

- To finalize and communicate the new Company Culture Compass by Q3 2022
- To enhance performance by focusing on client needs as part of matrix-oriented corporate governance

## SUSTAINABLE PROCUREMENT

Due to the Company's activities as a manufacturing service provider, the procurement of active ingredients usually means that the client provides or stipulates the source to be used. Rottendorf Pharma's direct influence on this part of the procurement process is extremely limited. When selecting suppliers for the procurement of its own raw materials and active ingredients, Rottendorf Pharma believes it is increasingly important to take social and environmental sustainability aspects into account in addition to carrying out thorough mandatory inspections of the suppliers' quality systems and processes. With this in mind, the Company has introduced a software solution designed to manage risks holistically along the entire value chain, and has defined and recorded minimum environmental requirements for suppliers.

To promote biodiversity, Rottendorf Pharma has set itself the goal:

- To carry out one project a year to increase biodiversity and create natural habitats from 2021 onwards

## SOCIAL RESPONSIBILITY

Community engagement has always been an integral part of the corporate culture and values of both Rottendorf Pharma and the Rottendorf Foundation.

Rottendorf Pharma supports several environmental and social organizations, both at its headquarters in Ennigerloh as well as at its distribution site in the USA. These include Lummerland and the Enniger hilft Kindern (Enniger Helps Children) association in Ennigerloh and the Buffalo Field Campaign in the USA.

The philosophy of company founder Andreas Rottendorf to not only exemplify the idea of social responsibility but to carry this idea over into the workforce is one that the Company continues to pursue. For example, employees have the opportunity to volunteer to help the Buffalo Field Campaign, with Rottendorf Pharma covering the travel costs associated with this work.

The Company also actively encourages its staff to do volunteer work, supporting them wherever possible and releasing them from work where required.

Rottendorf Pharma also sponsors 6,250 m<sup>2</sup> of flowering pasture in Ennigerloh.



# Human rights

By joining the UN Global Compact, Rottendorf Pharma is reaffirming its position on compliance with labor and human rights. In its Code of Conduct, Rottendorf Pharma undertakes to protect human rights and actively tackle all forms of child and forced labor.

No employee may be directly or indirectly compelled to work at Rottendorf Pharma by means of violence and/or intimidation, and remuneration and other benefits must at least comply with applicable local and national legal norms and standards. Child labor and any exploitation of children is not tolerated.



The overall risk of human rights violations within the Company is considered to be very low, as Rottendorf Pharma does not have any production facilities or distribution sites in high-risk countries. Both the Company's production site in Germany and its distribution site in the USA are required to meet stringent legal requirements governing compliance with human rights.

Rottendorf Pharma also actively contributes to the upholding of human rights within its supply chain. For products and services purchased by the Company and not provided by the client, the focus is on selecting suppliers who are required to meet the stringent quality and safety standards customary in the pharmaceutical industry.

The Company primarily procures active ingredients and excipients via partners and suppliers within Europe with a low risk of human rights violations.

To allow Rottendorf Pharma to assess any potential negative impact of its business activities and relationships on human rights issues in greater detail in the future, the Company is planning to expand its supplier monitoring efforts. This should enable it to identify any risks along the value chain associated with human rights at an early stage and minimize them accordingly. It should also allow the Company to run training sessions to make its employees aware of issues in this area.

Rottendorf Pharma is aware of its responsibility in the area of occupational health and safety, including towards its suppliers and producers along the value chain. As part of the expansion of its sustainability work, the Company analyzes and evaluates its existing structures in this area and introduces additional reporting and management processes where necessary.

#### Code of Conduct

[www.rottendorf.com/uploads/pdfs/RPH\\_CoC-2017\\_web.pdf](http://www.rottendorf.com/uploads/pdfs/RPH_CoC-2017_web.pdf)

# Labor standards

High labor standards are firmly enshrined in Rottendorf Pharma's mission statement. The Company believes it is important to offer its employees and service providers the best possible protection and a positive working environment. This includes trustful, constructive collaboration with the Workers Council, extensive career and talent management, and active social dialogue.





## EMPLOYEES


At the end of the 2020 financial year, Rottendorf Pharma employed 1,048 employees and 74 trainees. 710 of Rottendorf's employees are male while 412 are female. The average age of all employees is 39.

Employee remuneration is based on a collective agreement. The Company also provides comprehensive services to further promote the health and wellbeing of its staff. Employees can make use of flexitime arrangements and mobile working wherever possible. These arrangements primarily apply to office workers, as the production unit requires a shift system. There is a cafeteria for employees as well as comprehensive childcare offered via a partnership with a local kindergarten. The Company also offers a pension and social counseling services.


Rottendorf Pharma has set itself the following goals with regard to its employees:

- To improve the Company's feedback culture by introducing a fully integrated and holistic performance review model from 2022 onwards
- To promote continuing education and encourage employees to broaden and deepen their knowledge by carrying out strategic human resources planning and using the RPH Academy
- To enhance the visibility, relevance and sense of belonging using the Rottendorf employer brand
- To be officially certified as an attractive employer by the end of 2023
- To develop working time models geared to each phase of life (such as semi-retirement)
- To increase the trainee rate to 7% by the end of 2022
- To record employee satisfaction in a structured manner
- To gather suggestions for increasing employer satisfaction and implement the first efficiently realizable ideas by Q3 2022
- Concept to optimize occupational health management





Rottendorf Pharma advocates equal opportunities, diversity and non-discriminatory cooperation and has enshrined this in its Code of Conduct. Mutual trust and respect are extremely important. Rottendorf Pharma treats all of its employees equally, regardless of gender, age, color, culture, ethnic origin, sexual identity, disability, religious faith or ideology.



Rottendorf Pharma has set itself the following goals in the area of diversity and equal opportunities:

- To ensure that the proportion of women at the top level of management is at least 50% in the 2020-2025 planning period
- To develop and introduce a long-term plan to further improve work-life balance by Q4 2022

Employees are also called upon to create an atmosphere of respectful interaction and to resolutely oppose discrimination. Employees who feel that they have been discriminated against, unfairly treated or otherwise harassed by the Company or individual colleagues or supervisors have the right to lodge a complaint and are encouraged to speak openly about such matters. The Human Resources department investigates all complaints thoroughly and takes suitable steps to resolve them where appropriate.

Rottendorf Pharma has active employee representation in the form of a Workers Council. The Workers Council has 13 members and represents the interests of the workforce towards the Company. The employer and appointed employee representatives work together on the basis of trust and for the good of both the employees and the Company. This reciprocal trust and cooperation is based on an open and constructive dialogue hallmarked by mutual respect.

	31.12.2020	31.12.2019
<b>Employees, total</b>	<b>1,048</b>	<b>1,005</b>
Plus trainees	74	70
Of which male employees	710	671
Of which female employees	412	404
Of which aged over 50 years	277	265
Of which aged 30-50 years	531	501
Of which aged under 30 years	314	309
<b>Employee turnover</b>	<b>6.34%</b>	<b>7.14%</b>
<b>Share of female managers, total</b>	<b>37.1%</b>	<b>35.2%</b>
Share of women in executive management	50%	50%
First management level (Senior Director)	50%	50%
Second management level (Director)	20%	20%





## TRAINING AND CONTINUING EDUCATION

As a Company actively committed to training, Rottendorf Pharma has its own training laboratory, where it educated a total of 75 trainees in 2020. The greatest proportion of these trainees are laboratory chemists and pharmacists, who make up approximately one-third of all trainees. Other training roles at Rottendorf Pharma include chemical production specialists, warehouse logistics specialists, specialists for system integration, machine and plant operators as well as industrial clerks.

In the Rottendorf Academy, the Company has created an independent organization to promote the professional and social skills of its employees. The aim of the Academy is to encourage the workforce to share its pooled expertise among one another and to promote the personal development of all employees as well as the development of the Company. The Rottendorf Academy also seeks to encourage all employees to enjoy their professional and personal development. In addition to welcome seminars for new staff, professional, Rottendorf-specific and generalized modules are also offered. In keeping with its slogan to “experience expertise”, the Academy’s concept consists of four development pillars: professional skills, social skills, presentations and collaborations.

In addition to mandatory core modules for new joiners, modules to promote professional skills and courses on topics such as quality assurance, digitalization, occupational safety and environmental protection as well as legal issues, employees also have the opportunity to learn a foreign language or attend presentations on a wide range of different subjects, for example.

For managers, a management development program is available that includes at least five days of external training each year.



## EMPLOYEE HEALTH AND SAFETY

Occupational health and safety is integral to all of Rottendorf Pharma's operations. To ensure the health and safety of its employees, Rottendorf Pharma has its own EHS department that is responsible for implementing occupational safety management initiatives as well as promoting and ensuring a safe working environment. A company doctor is available for the health and wellbeing of employees. In addition, every manager is required to instruct and support their employees with occupational health and safety regulations and ensure compliance with these regulations. Employees must report any breaches of these regulations to the relevant department within the Company to ensure that any violations can be remedied immediately.

EHS managers implement procedures to identify workplace risks and reduce the number of accidents. This also includes running training sessions for employees on accident prevention and response, emergency preparedness and the use of protective clothing and equipment. An occupational safety committee that includes a member of management, a safety engineer, the company doctor, members of the EHS team and members of the Workers Council also meets at regular intervals.

Every employee receives occupational safety training at least once a year. This training lasts approximately 60 minutes in production and around 30 minutes for those carrying out screen-based office activities. Additional comprehensive individual intensive training sessions on topics such as protective equipment requirements or handling hazardous materials are also held depending on the main focus areas of each employee. The scope of these training sessions differs depending on the field in question and can last for several working days.

From 2017 to 2019, "falls on level ground, slips, trips, twists and missteps" accounted for 32% of the 102 accidents at Rottendorf Pharma. Uncontrolled moving parts and traffic accidents were each responsible for 16% of accidents during this period, while accidents involving chemicals made up 13% of accidents. The EHS team is constantly working to develop campaigns to raise awareness of safety issues and further reduce the number of accidents at Rottendorf Pharma. Regular EHS audits are a key element of the Company's occupational safety management efforts.

Work-related illnesses are not known.

Work-related injuries	2020	2019
Number of work-related injuries resulting in death	0	0
Per 1 million working hours	0	0
Number of work-related injuries with serious consequences	0	1
Per 1 million working hours	0	0.667
Number of work-related injuries	31	46
Per 1 million working hours	20.70	34.35
Main types of work-related injuries	Falls on level ground, slips, trips, twists and missteps	Falls on level ground, slips, trips, twists and missteps

# Environment and climate

Environmental and climate protection is a key element of Rottendorf Pharma's corporate values and goals. The Company works comprehensively and systematically to minimize the environmental impact of its services and commercial activities. Being aware of the need for sustainable corporate governance is essential for protecting and preserving the environment and is therefore at the forefront of Rottendorf Pharma's business. Rottendorf Pharma takes responsibility by thinking globally and taking action locally.





**ENERGY CONSUMPTION AND EMISSIONS MANAGEMENT**

The manufacturing of pharmaceutical products requires the use of large amounts of energy to provide the infrastructure required for pharmaceutical production. All of the Company's sites in Germany have an ISO 50001-certified energy management system.

Energy consumption in kWh	2020	2019
Electricity consumption	14,641,932	13,773,359
Of which renewable energies	9,165,849*	8,622,122*
Natural gas consumption	15,612,986	15,611,269
Fuel	315,137	217,272
Heating oil	261,601	0
<b>Total energy consumption</b>	<b>30,831,656</b>	<b>29,601,900</b>
Of which renewable energies	8,622,122	8,622,122

\* The share of renewable energies at the electricity supplier was 62.6%. Since 2021, the company headquarters in Ennigerloh has been converting to green electricity, after which 100% of the electricity consumed will be from renewable sources.

In 2020, Rottendorf Pharma's electricity consumption totaled 14,641,932 kWh (previous year: 13,773,359 kWh), with natural gas consumption of 15,612,986 kWh (previous year: 15,611,269 kWh) and fuel consumption of 315,137 kWh (previous year: 217,272 kWh). While the Company's heating oil consumption was 0 kWh during the 2019 reporting year, this consumption rose to 261,601 kWh in 2020. This is partly due to the replacement of a gas connection in a boiler house and the temporary transition from natural gas to heating oil as a replacement energy source associated with this. In light of the coronavirus pandemic, the cafeteria was extended by adding a marquee that was also heated using heating oil.

Although Rottendorf Pharma does not currently record its carbon emissions in a structured way to determine its corporate carbon footprint in accordance with the Greenhouse Gas Protocol, this is one of the Company's key sustainability goals.

The Company's production facility uses the organic solvents acetone, ethanol and isopropanol. However, it does not use any substances that have a damaging impact on the Earth's ozone layer. Exhaust air from the production facilities that contains dusty or solvent fumes is processed before it is emitted.

An emission reduction system and secondary oxidation chamber has been installed to reduce volatile organic compounds (VOC). External service providers monitor the Company's VOC emissions at regular intervals.



At 15 mg/m<sup>3</sup>, Rottendorf Pharma's VOC emissions are well below the legal limit of 150 mg/m<sup>3</sup>. The monitoring results are communicated to the environmental protection agency responsible for the district of Warendorf at regular intervals.

Sulphur dioxide (SO<sub>2</sub>) emissions are generated solely by using heating oil, which Rottendorf Pharma only uses sporadically and temporarily as a replacement energy source.

Achieving sustainability in production and ensuring that the energy consumption associated with this is efficient are among the Company's most important goals. As a result, Rottendorf Pharma has steadily introduced various measures to increase energy efficiency in recent years. For example, the Company began developing an online system to log measurement data, replaced filter elements in ventilation systems with efficient compact filters, integrated energy management training sessions for employees into the electronic employee training system, replaced traditional lighting with LED technology, and modernized the cooling systems used in its server rooms.

Rottendorf Pharma has set itself the following targets to further enhance its energy efficiency and to lower emissions:

- To calculate its carbon footprint in accordance with the Greenhouse Gas Protocol within Scope 1 & 2 by the end of 2022, and within Scope 3 by the end of 2024
- To identify carbon savings potential by the end of 2023
- To increase energy efficiency by 5% by the end of 2022 compared to 2016 while maintaining pharmaceutical standards
- To enshrine energy issues and responsible energy consumption in the Company's corporate culture by the end of 2022
- To improve transparency with regard to at least 40% of energy consumption and 80% of natural gas consumption via the online measuring system by Q4 2023



## WASTE MANAGEMENT

Waste management at Rottendorf Pharma is organized via an internal policy that outlines the processes, types, categorization and labeling of waste and the disposal methods for it.

Due to the specific requirements for pharmaceutical producers such as GMP regulations (principles of Good Manufacturing Practice), the recycling of materials is not permitted in most cases. This creates higher amounts of waste as plastic containers, for example, cannot be reused once they come into contact with pharmaceutical products. Where potential product build-up can be ruled out, the waste disposal company recycles or processes recyclable materials.

In 2020, Rottendorf Pharma generated a total of 1,080.7 tons of waste. Of this total, 1,020.1 tons (94%) was non-hazardous waste. Of this non-hazardous waste, 671 tons was thermally recovered and 262 tons was recycled. The hazardous waste was almost completely thermally recovered.

Waste	2020		2019	
	Non-hazardous waste (in t)	Hazardous waste (in t)	Non-hazardous waste (in t)	Hazardous waste (in t)
Thermal recovery	671.09	60.37	594.83	56.31
Recycling	262.23	0.26	172.70	0.41
Material recycling	82.86	0	102.30	0
Biological treatment	1.33	0	2.72	0
Reconditioning *	2.79	0	2.78	0
Landfill disposal	0	0	0	1.48
<b>Total</b>	<b>1,020.09</b>	<b>60.63</b>	<b>872.27</b>	<b>58.19</b>
Percentage	94.39%	5.61%	93.75%	6.25%

\* Reconditioning is not included in calculating the total waste volume

Rottendorf Pharma has set itself the following goal in the area of resource consumption:

- To introduce a waste separation system for offices by Q2 2022 and in the pharmaceutical division by Q1 2023



## WATER AND EFFLUENTS

Most of Rottendorf Pharma's water consumption comes from the manufacturing of medicinal products and sanitation facilities for employees.

Water consumption	2020	2019
Water consumption in m <sup>3</sup>	47,975	44,089

A small proportion of the water used to manufacture medicinal products is consumed in production during the granulation and coating processes.

The processes for cleaning equipment and premises generate the greatest demand for water. When changing a product, or after a pre-determined number of batches of a particular product, the machinery and equipment used, as well as the rooms themselves (walls, ceilings, floors) must undergo a thorough cleaning. Large volumes of water, concentrated cleaning agents and rinsing water are required to make sure that the Company meets the highest quality and safety standards and ensure that no product residues remain on any surfaces.

Cleaning procedures for individual product categories are analytically documented and regularly reviewed to guarantee surface cleanliness and rule out the cross-contamination of subsequent products.

Although these processes require increased amounts of water, they are essential quality criteria for manufacturing in the pharmaceutical industry. Any residues could constitute health risks to consumers, thus justifying the amount of water consumed. Rottendorf Pharma is striving to optimize the manufacturing process for each product category to minimize the cleaning processes required when switching from one product to another.

As the Company does not manufacture any chemicals, the wastewater does not need to undergo targeted neutralization or treatment, and Rottendorf Pharma does not have its own wastewater purification or treatment plant. The Company is officially authorized to indirectly discharge wastewater into the communal sewage system, from where it is fed to the communal sewage treatment plant.

Rottendorf Pharma takes wastewater samples at regular intervals in partnership with external service providers; these samples are examined, evaluated and monitored for pharmaceutical substances and other contaminants.

To date, there have not been any incidents in which the Company's operations have caused damage that could have led to potential soil or groundwater contamination. A wide range of measures has been implemented in the warehouse areas to retain any extinguishing water used in the event of a fire.

# Combating corruption

Among other things, Rottendorf Pharma's written Code of Conduct includes policies regarding personal integrity, the integrity of the Company, employment, the Company's assets, and responsible corporate management.



### COMPLIANCE AND ANTI-CORRUPTION

Rottendorf Pharma expressly prohibits every form of corrupt business conduct, particularly the active and passive bribery of public and private officeholders and decision-makers as well as anti-competitive practices. All employees must comply with all relevant legislation relating to bribery and corruption.

Rottendorf Pharma provides its employees with regular training on the topics of compliance, preventing corruption, and data protection practices.

In addition to training sessions, the Company uses rulebooks, guidance and internal investigations to ensure compliance with these regulations.

As in previous years, no cases of corruption came to light during the 2020 reporting period. Similarly, there were no legal proceedings due to anti-competitive conduct or breaches of antitrust and monopoly legislation.

### DATA PROTECTION

Rottendorf Pharma employs a data protection officer who is assisted by an external service provider where necessary. This external service provider offers advice and support and can serve as an external data protection officer.

The internal data protection officer is responsible for holding regular data protection training sessions for the workforce and documenting and evaluating processes and procedures together with each specialist department.



# Imprint

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