# 2025



# **Environmental Statement of Novartis Pharmaceutical Manufacturing GmbH**



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#### **Disclaimer**

This Environmental Statement was prepared in accordance with Regulation (EC) No. 1221/2009 as amended (EMAS Regulation) and meets the requirements for a registered organization under the European Union's EMAS scheme. The content of this statement relates to the Kundl and Langkampfen sites of Novartis Pharmaceutical Manufacturing GmbH in Austria and has been compiled with the utmost care and to the best of our knowledge and belief.

The information presented is based on the status of internal environmental management processes, environmental performance indicators, and legal requirements as of the publication date.

Despite careful review, no liability can be assumed for the completeness, accuracy, or timeliness of the information provided.

This Environmental Statement has been reviewed and validated by an environmental verifier accredited in Austria in accordance with the EMAS Regulation. It is intended to inform the public and interested parties about the organization's environmental performance and does not constitute a legally binding commitment.

No liability is accepted for damages arising from the use of the information contained in this Environmental Statement, except in cases of intent or gross negligence.

## **Foreword**

#### Dear reader!

The year 2024 marked a turning point for Novartis in Austria. Following the successful spin-off of Sandoz in 2023, Novartis is sharpening its focus on innovation and sustainable development. Our strong commitment to research and development enables us to create breakthrough therapies that improve people's lives. In Austria, we rely on cutting-edge technologies and innovative approaches to promote environmentally friendly solutions and minimize our ecological footprint. Together with our partners and the community, we strive to shape a healthier and more sustainable future.

With this Environmental Statement, we are for the first time presenting the consolidated environmental activities of Novartis Pharmaceutical Manufacturing GmbH. This report replaces our previous sustainability report, with all environmental indicators now compiled in a single, dedicated document.

Further information and in-depth analysis can be found in the Novartis Integrated Report at www.novartis.com.

As a manufacturing company based in Tyrol, environmental standards and social responsibility are especially important to us. By upholding our high standards for quality, safety, and environmental performance, we supply patients around the world with life-saving medicines from Kundl and Schaftenau. We are proud that once again this year, we have succeeded in further reducing our environmental footprint in Austria across all three key areas – climate, waste, and water – and are contributing to a livable world for future generations. By consistently implementing our environmental policy, we aim to continue strengthening public trust, which is essential for fulfilling our mission to find innovative ways to improve and extend people's lives.

A particular highlight is our commitment to continuously improving our environmental management systems in line with EMAS guidelines. Through regular audits and the implementation of best practices, we ensure that our environmental standards are not only maintained but also continually enhanced. This reflects our ambition to lead the way in sustainability and environmental protection.



Roland Gander General Manager, Novartis Campus Kundl & Schaftenau

Soul

Roland Gander

# We are Novartis

Novartis is a pharmaceutical company with more than 78,000 employees worldwide, engaged in the research, development, manufacturing, marketing, and sale of a broad range of innovative pharmaceuticals.

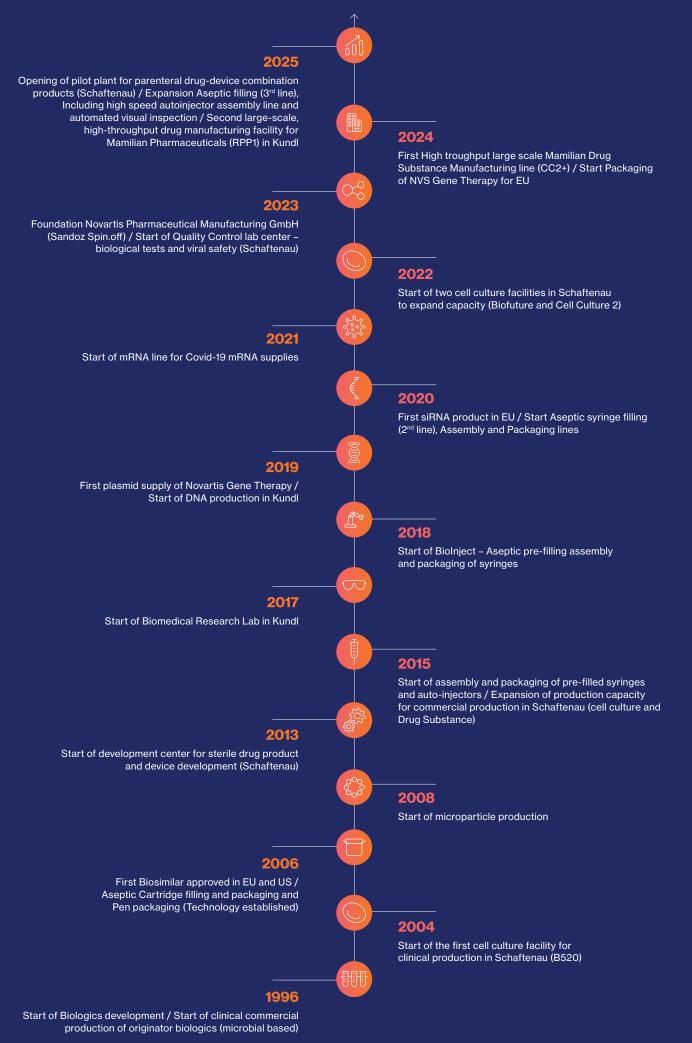
In 2024, our medicines reached nearly 300 million patients around the world.

Novartis is headquartered in Basel, Switzerland, and operates 197 sites globally, including manufacturing facilities, R&D centers, and offices.

- Our purpose is to find new ways to improve and extend people's lives.
- Our vision is to become the most valued and trusted medicines company in the world.

In October 2023, Novartis completed the spin-off of its generics and biosimilars division, Sandoz, marking a key milestone in our transformation from a diversified healthcare conglomerate into a focused, innovative pharmaceutical company.







# **Novartis in Austria**

#### **Reimagining Medicine**

At Novartis in Austria, we live our mission every day: to improve and extend people's lives. With our Innovative Medicines site in Vienna and our development and manufacturing hubs in Kundl and Schaftenau in Tyrol, we are one of the country's leading and most innovative pharmaceutical companies – and one of the largest private employers in Tyrol. Our investments in research and development reflect our strong commitment to using science-based innovation to tackle some of society's most challenging healthcare issues.

For more information, visit www.novartis.at

#### Innovation is in our DNA

We develop and produce life-saving medicines and high-quality pharmaceuticals that alleviate society's greatest disease burdens through technological leadership and innovative access models. Novartis is a global company with a strong focus on patients and customers. We are dedicated to the manufacture and delivery of innovative, prescription-only medicines and therapies.

#### **Technology leaders**

Our production sites in Tyrol are beacons of the Austrian pharmaceutical industry. They support half of Novartis's most important innovative medicines across various stages of development and production.

Thanks to substantial investments in recent years, these sites are state-of-the-art and serve as prime examples of how cutting-edge technology can go hand in hand with ecological sustainability. Within the Novartis network, our Novartis Campus in Kundl and Schaftenau is the largest and most technologically advanced biopharmaceutical production site in Austria – and one of the most important for Novartis globally.

#### **Our Three Sites**

Novartis Holding GmbH and its affiliated companies are spread across Austria. Below you will find more detailed information about the locations and the respective entities based there.









Our center of excellence for cutting-edge microbial and cell culture technologies, specializing in the development and production of innovative biologics and biosimilars. Production includes recombinant proteins, plasmid DNA, and mRNA.

#### Sites:

- Drug Substance Kundl
- Technical Research & Development (TRD/Development)
- Biomedical Research

#### Schaftenau

Our central development and manufacturing site specializing in biotechnologically produced medicines – from research and development to active ingredients and final product manufacturing.

#### Sites:

- Drug Substance Schaftenau
- Drug Product Schaftenau
- Technical Research & Development (TRD)
- Global Clinical Supply
- Regulatory Affairs

#### Vienna

Business Units & Sales (incl. Quality and Regulatory Affairs)



- €1.6 billion invested from 2015 to 2024 (including €160 million in R&D and infrastructure in 2024 alone)
- More than 3,300 associates working at Novartis in Austria
- 6.2% domestic market share
- 713,000 patients reached (nearly 10% of the Austrian population)
- 42 clinical trials currently underway in Austria (phases 1 4)



# **Our Strategy**

We aim to build a leading, focused medicines company powered by advanced therapy platforms and data science. As we implement our strategy, we are guided by five key priorities to shape our future and create sustainable value – for our company, our shareholders, and society.

#### **Unleashing the Power of Our People**

We are driving a cultural transformation to empower our people to fully apply their talents and energy. We are building an organization where people are inspired, curious, and self-driven to make an impact.

#### **Delivering Breakthrough Innovation**

In our pursuit of transformative therapies, we challenge medical paradigms and explore new ways to cure disease, intervene earlier in chronic conditions, and significantly improve patients' quality of life.

#### **Achieving Operational Excellence**

We continuously challenge how we work, rely on agile teams, and increase productivity to free up resources that fuel our ability to innovate.

#### Winning with Data and Digital

We aim to spark a digital transformation at Novartis through advanced analytics, artificial intelligence, and cutting-edge technologies – to accelerate innovation and drive greater efficiency.

#### **Building Trust with Society**

We seek to earn society's trust by acting with integrity and a strong sense of purpose. We are also committed to finding new ways to ensure patients gain faster, easier access to our medicines.





# What Sets Us Apart

With our innovative medicines, we aim to provide solutions that address the evolving needs of patients. But we want to go a step further: our goal is to help people and society better manage health conditions and the role of medicine in their lives.



#### **Our Culture**

Our team of talented, committed, and responsible associates from a wide range of professional backgrounds works together to fulfill our mission of reimagining medicine. We believe it is essential for our people to contribute their full potential. This is how we create a company culture built on inspiration, curiosity, and personal accountability.

#### **Our Values**

Our values are the foundation of our company culture. They define the professional behavior we expect from our associates. These values serve as a guiding framework for how we hire, develop, and recognize our people.

#### Inspired

We want our people to see meaning and purpose in their work. That's why we encourage our associates to champion our patients and live our mission. We empower them to give their best every day so they can achieve their personal and professional goals.

#### Curious

Developing innovative, breakthrough medicines takes courage and creativity. We believe curiosity fuels scientific discovery. That's why we value inquisitive minds – people who are passionate about learning and eager to explore new and better ways forward.

#### **Unbossed**

Our people thrive when they can shape their own work environment and bring their ideas to life. We encourage our leaders to remove barriers and unleash the full potential of their teams. We also empower them to build confidence and set clear goals.

#### Integrity

We care deeply about our people, patients, and customers. That's why we hold ourselves to the highest ethical standards. We act with honesty and courage, and strive to do what is right. This creates space for constructive dialogue and better decision-making.

#### Our pharmaceuticals

We develop and produce life-saving medicines and high-quality pharmaceuticals that help alleviate the greatest disease burdens in society – driven by technological leadership and innovative access models.

We focus on four core therapeutic areas:

- Cardiovascular, renal, and metabolic diseases
- Neuroscience
- Immunology
- Oncology



#### **Our key topics**

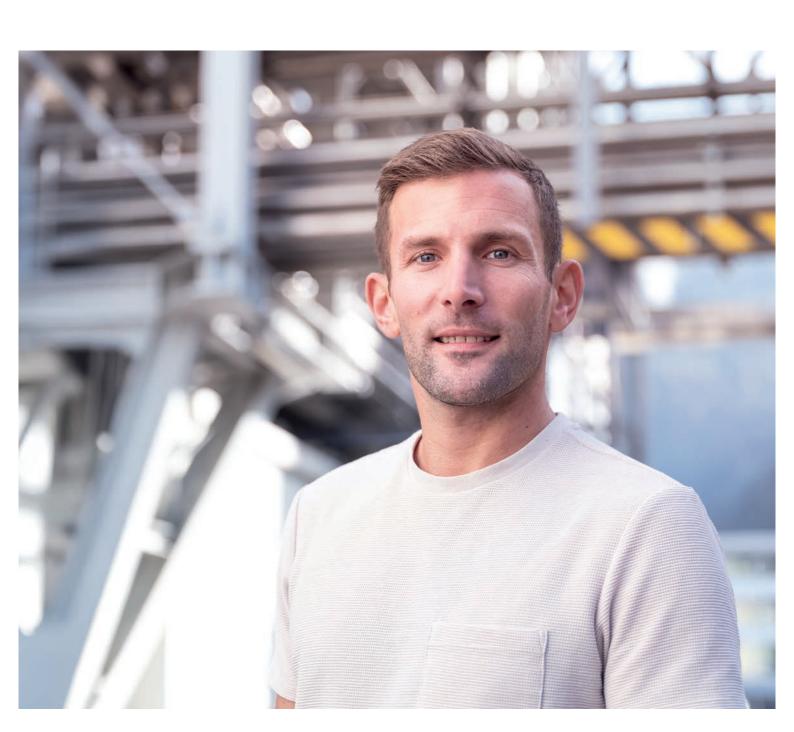
Novartis monitors trends and changes in its operating environment to identify and assess the relevance of the most material issues. The materiality assessment is presented below, which differs from that of the Group only in relation to environmental issues. Due to the higher ecological foot-

print of the Kundl and Schaftenau sites, this issue is given higher priority.

More detailed information on the general materiality assessment can be found in the Novartis integrated annual report at www.novartis.com.

	Water and wastewater management	Patient health and safety  Decarbonization	Large impact
Good governance Sustainable financial performance	Innovation  Waste management and recycling  Employees and culture	Access to medicines Ethical business practices	External stakeholders
Biodiversity			Low impact
Low impact	Internal stakeholders	Large impact	

# Health, Safety and Environment (HSE) Management Systems at Novartis



#### **Certifications**

The Novartis research, development, and manufacturing sites in Kundl and Schaftenau are certified according to ISO 14001, ISO 45001, and ISO 50001. Recertification was carried out by TÜV Austria GmbH. An additional annual surveillance

audit ensures ongoing compliance with the respective standards. In addition to ISO certifications, this environmental statement marks the first application for entry into the EMAS register for both locations, Kundl and Schaftenau.



# Principles of Our HSE Management Systems

Protecting the health and safety of employees, neighbors, and other relevant stakeholders affected by our business operations, as well as environmental protection, are core values at Novartis.

Through our HSE Policy, Novartis clearly outlines its commitments to occupational health and safety, environmental compatibility, and ecological sustainability. Internal controls and periodic audits are integral components of the Novartis HSE Management System.

The HSE Guideline defines the required roles and responsibilities.

To ensure consistent standards across all Novartis sites, HSE Handbooks set out the minimum requirements and performance expectations for the HSE Management Systems at Novartis.

All Novartis associates share responsibility for health, safety, and the environment. Everyone is expected to uphold this commitment by looking after themselves and others, and by protecting the environment for future generations.

HSE departments play a key role by coordinating and monitoring local HSE activities and by developing site-specific HSE procedures.

The HSE Handbook provides an overview of the HSE Management System, including the energy management system, at Novartis Pharmaceutical Manufacturing

GmbH in Kundl and Schaftenau. It summarizes all internal and external requirements in a concise format.

# We comply with local laws and regulations – and meet internal requirements

Compliance with internal and external requirements is part of our culture and is reinforced through communication, accountability, and active engagement with authorities. Regular audits and reviews ensure adherence to all applicable local laws and regulations. In addition, regular Seveso and environmental inspections are conducted by the relevant authorities. Legal developments are monitored continuously, and the legal obligations register is updated annually.

#### We care about the health and safety of our employees

We promote and support programs aimed at maintaining and improving the physical and mental health of our employees and external partners at our sites.

We provide safe working conditions and are committed to protecting our employees from potential health risks and injuries

Before any potentially hazardous work is carried out, a risk assessment is conducted. If necessary, appropriate protective measures are implemented to ensure safe execution.



All employees must be familiar with and comply with local safety regulations.

#### We are environmentally responsible

We implement and maintain processes and procedures to ensure compliance with relevant environmental regulations and obligations. We also take action to minimize the environmental impact of our operations. This includes supporting initiatives to reduce our carbon footprint, waste generation, and water usage.

Through additional voluntary analyses and measurements, we ensure compliance with international standards and programs.

# We integrate HSE considerations into the development of products, processes, and technologies

Employees participate in HSE hazard assessments and risk analyses. Potential risks are systematically identified in accordance with our internal guidelines. This ensures that HSE considerations are integrated early into product and process development, procurement, manufacturing, and investment projects. Potential risks from new production processes have been systematically assessed for many years.

These results may lead to process optimizations or additional safety measures in our facilities. Particular attention is given to environmental protection, efficient use of raw materials and energy, and minimizing wastewater and waste.

## We are building a responsible supplier network

Suppliers are expected to meet the HSE requirements outlined in the Novartis
Third Party Code and our External Partner Risk Management (EPRM) framework.

We promote good HSE management practices among our direct partners in the supply chain and collaborate with them as closely as possible.

Our procurement practices support environmentally responsible suppliers, products, and services.

We audit suppliers to ensure compliance with Novartis standards.

#### We drive continuous improvement of our HSE Management Systems and performance

Based on improvement recommendations from internal and external HSE audits, as well as Novartis initiatives and targets, we define annual goals and launch new programs through our HSE Plan. Responsibilities and timelines are clearly established to ensure continuous improvement of our systems.

Management supports the annual HSE objectives and regularly evaluates HSE performance against these goals.

We derive corrective measures from incidents and events to prevent recurrence – even from incidents outside Novartis.

#### We communicate transparently

HSE results are communicated openly, both internally and externally. We proactively engage with internal and external stakeholders, including local communities and neighbors, and take their concerns seriously.

## We operate a sustainable energy management system

Our energy management system ensures reliable energy supply to our Kundl and Schaftenau sites through agreements with trustworthy energy providers under optimal conditions. We actively promote the use of renewable energy sources.

Across all production processes, we aim to gradually reduce energy consumption. Our goal is to reduce overall energy use and sustainably lower our carbon footprint – even as we expand our production facilities.



# Measures to Ensure the Safety of Our Employees

The safety of our employees is our top priority. This begins with the safe handling of microorganisms, extends to systematic reviews of production processes through process risk analyses, and includes ensuring the technical safety of all facilities and equipment.

We implement a wide range of initiatives to keep accident rates consistently low – with the ultimate goal of preventing them altogether. A key element in this effort is a strong safety culture. The visible and authentic commitment of our leaders is an essential part of our leadership approach.

Another cornerstone of our safety management is incident analysis. Workplace accidents and near misses are thoroughly analyzed and documented, with appropriate follow-up actions and preventive measures implemented.

Activities involving new organisms are regularly reviewed and approved by the Biological Safety Committee.

## Measures to Protect the Environment

The responsible use of raw materials and energy, along with comprehensive environmental protection measures, form the foundation of our environmental policy at the Kundl and Schaftenau sites. Key focus

areas related to resource and energy use include sustainable energy consumption, waste and material management, efficient use of cooling and process water, and minimizing the amount of raw materials used.

Our environmental protection efforts focus on safeguarding soil and ground-water, minimizing air and wastewater emissions, reducing odor impact on local residents, and keeping noise emissions to a minimum.

#### Sustainable Energy Use, Energy Sources, and Energy Savings

Natural gas and electricity are our main energy sources. The primary electricity consumers are compressors and electric motors, with a significant share used by agitators and compressed air systems for fermentation operations. Other major consumers include chillers, heat pumps, ventilation systems, and water pumps.

At our Kundl and Schaftenau sites, we use natural gas to generate process steam, focusing on high efficiency and minimal energy losses during steam production.

Waste heat is utilized both internally and externally in the form of district heating at a temperature range of 85 – 90 °C. The main sources of waste heat are fertilizer drying systems and the exhaust heat from air compressors.

## Our Contribution – What Matters to Us

Our energy management system aims to gain a deeper understanding of which processes contribute to overall energy consumption and to identify measures for improving energy efficiency. This is achieved through monitoring and measurement, analyzing key energy consumers, and evaluating potential savings based on economic feasibility.

Thanks to the implementation of numerous measures, we are able to reduce our site's energy demand by 1 – 1.5% annually.

# Novartis Environmental Strategy

The ambitious environmental targets of Novartis, as validated by the Science Based Targets initiative (SBTi), focus primarily on the elimination of greenhouse gas emissions. Other key priorities include sustainable water use, avoiding the release of active pharmaceutical ingredients into wastewater, and reducing or eliminating waste across the company. Below are the global target milestones for 2025 and 2030. Current progress toward these targets is published in the Novartis Integrated Report 2024.

When it comes to carbon neutrality, a distinction must be made between electricity and natural gas. Since 2014, Novartis has been purchasing electricity certified

as carbon-neutral by its energy supplier. Nevertheless, optimization projects continue to be implemented on an ongoing basis.

To replace natural gas, we are investing in power-to-heat (P2H) technology. This area has seen significant technological advances in recent years. Using CO<sub>2</sub>-neutral electricity, P2H enables the nearly loss-free generation of process steam in a climate-neutral manner.

By the end of 2025, electric steam boilers will be installed at both Kundl and Schaftenau. As a result, the Schaftenau site will be able to operate entirely without natural gas, and by 2026, all Novartis production units in Kundl will be supplied with CO<sub>2</sub>-free process steam.

The operational implementation of the Novartis environmental strategy at the Kundl and Schaftenau sites is also well underway in the areas of waste and wastewater management.

#### **Use of Raw Materials**

The production of active pharmaceutical ingredients (APIs) and intermediates requires substantial resources such as organic solvents, nutrient media, and micronutrients for the fermentation process, as well as various chemicals used in the

Area	Target 2025	Target 2030
Climate	Carbon neutrality in our own operations (Scope 1 and Scope 2 greenhouse gas emissions from energy)	90% reduction in absolute Scope 1 and Scope 2 greenhouse gas emissions compared to the 2022 baseline
		42% reduction in absolute Scope 3 greenhouse gas emissions compared to the 2022 baseline
Water	Halve water consumption at our sites compared to the 2016 baseline	Eliminate all impacts on water quality from production wastewater
	Eliminate all water quality impacts from production wastewater	
Waste	Phase out polyvinyl chloride (PVC) in product packaging	Reduce waste for disposal by 30% compared to 2022
	Halve the amount of waste for disposal compared to the 2016 baseline	

downstream processing of fermentation solutions.

Recovery of usable by-products, along with reuse and recycling, also plays an important role. By designing our production processes accordingly, we recover high-value by-products as secondary raw materials. One example is fertilizer made from bacterial biomass from the on-site wastewater treatment plant in Kundl.

A key economic and environmental factor is the efficient and sustainable use of organic solvents.

# Waste, Recyclables and Recycling

Our top priority is to avoid waste entirely or reduce it as much as possible. Unavoidable waste is sent for external recycling, provided it is environmentally sound.

All waste generated at the Kundl and Schaftenau sites is handed over to authorized waste collectors and treatment companies rather than being processed on site. Many of these companies are EMAS-registered and are therefore regularly audited.

Solvent recovery methods and technologies for extracting by-products such as Biosol forte® make a significant contribution to avoiding large volumes of waste each year.

In 2021, waste logistics at the Kundl site were outsourced to an external partner company with decades of experience in waste management. This company does not act as a collector or processor but supports the sites in internal and external logistics as well as a variety of optimization processes.

#### **Water Use**

We handle water with great care – both in its use and disposal. The production of active pharmaceutical ingredients in Kundl requires large volumes of cooling water, which is extracted primarily via company-owned wells located near the Inn River. This setup allows us to draw mainly bank filtrate, helping to conserve groundwater. Drinking water used in pro-

duction and for sanitary facilities also comes from our own deep wells.

At the Schaftenau site, cooling water is likewise drawn from company-owned groundwater wells. Drinking water had previously been supplied via the municipal network, but due to the site's dynamic growth, a dedicated drinking water well was built in 2023 and successfully put into operation in 2024. The municipal network now serves only as a backup.

#### Soil and Groundwater Protection

Our production buildings and utility systems are connected through a dense network of pipelines. To protect soil and groundwater, we have consistently avoided the storage or transport of hazardous substances in underground tanks or pipelines.

Hazardous substances such as acids, alkalis, and solvents are transported safely in pipelines routed overground on pipe bridges above paved surfaces, allowing any leaks to be detected immediately.

Pipelines for process wastewater either run underground in an energy supply tunnel or are also routed on pipe bridges.

Because the facilities in Kundl and Schaftenau are classified as IPPC (Integrated Pollution Prevention and Control) installations, baseline reports are required. When new IPPC-relevant facilities are built or when significant modifications are made to existing ones, the baseline reports are updated and submitted to the relevant authority.

At the Schaftenau site, there are localized areas of soil contamination resulting from activities by a previous company located at the site. These areas are being remediated in coordination with the authorities. Otherwise, comparable soil and groundwater protection measures are in place in Schaftenau as in Kundl.

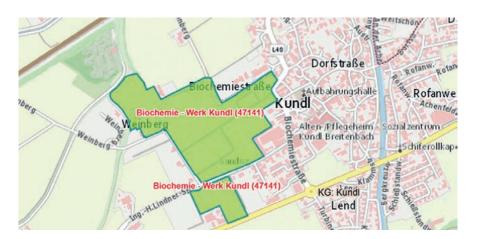
One difference is that, unlike Kundl, Schaftenau lacks an energy supply tunnel, so in addition to sanitary wastewater pipelines, some channels for lightly contaminated production wastewater (WAW) are installed underground.

#### Kundl

ID	47141
Area type	Former site (Altstandort)
Industry	321 - Manufacture of pharmaceutical active ingredients
Area [m²]	200.000
Status	Assessed – no contaminated site
Date of assessment	December 3, 2024

#### Schaftenau

ID	47175
Area type	Former site (Altstandort)
Industry	321 - Manufacture of pharmaceutical active ingredients
Area [m²]	150.000
Status	Assessed – no contaminated site
Date of assessment	Jannuary 21, 2025





Source: altlasten.umweltbundesamt.at/altlasten/addrsearch - (Query date: May 12, 2025)

In 2024, Phase 2 of the supplementary investigations in accordance with § 13 of the Austrian Remediation of Contaminated Sites Act was completed by the Federal Ministry.

As a result, both sites were removed from the register of suspected contaminated areas under the Contaminated Sites Act. This outcome reflects the success of our decades-long efforts to protect soil and groundwater.

# Wastewater and Protection of the Aquatic Environment

Wastewater management at the Kundl and Schaftenau sites is centered on two key aspects: compliance with all legal limit values and permit conditions, and the prevention of active pharmaceutical ingredient (API) discharges into the aquatic environment to reduce the risk of antibiotic resistance.

Given the high volumes of antibiotics produced at the Kundl site by Sandoz, the

Infrapark bears a particular social and environmental responsibility. We fulfill this responsibility through risk management, regular monitoring, and awareness programs.

Routine monitoring of effluent from the on-site wastewater treatment plant (BARA) confirms that relevant APIs are almost completely degraded during treatment, and that both international limits for APIs in wastewater and Novartis's own stringent standards are consistently and significantly undercut.

#### Air Emissions – Minimizing Atmospheric Pollution

The use of solvents and the operation of the on-site wastewater treatment plant at Kundl generate exhaust air streams that may contain odors and solvent vapors.

At both Kundl and Schaftenau, exhaust air has for many years been captured via closed systems and site-wide exhaust networks. Most emissions are treated thermally to reduce them to a minimum.

Additional cleaning technologies, such as activated carbon adsorption, cryocondensation, or scrubber systems, are used when thermal treatment could lead to secondary emissions (e.g.,  $NO_x$ ).

Emissions of chlorinated hydrocarbons from refrigeration systems pose a considerable greenhouse gas risk. As a result, we are transitioning to natural refrigerants such as ammonia, carbon dioxide, or other climate-friendly alternatives to phase out all environmentally harmful substances over the medium term.

#### **Odor Management**

Biological processes at the Kundl site inherently generate odor-laden exhaust air. In the past, this led to complaints from neighboring communities. Thanks to numerous optimization measures, we have achieved lasting improvements.

The most odor-intensive air from the Kundl wastewater treatment plant is fully captured and incinerated in a dedicated system. Exhaust air from fertilizer production is also treated thermally. These efforts have led to consistently low levels of odor complaints from the local community.

We remain committed to addressing any concerns in the interest of maintaining a high quality of life for residents.

#### **Noise**

Noise levels at the Kundl site are now comparable to the ambient baseline in the Inn Valley, which includes background noise from railways, highways, and nearby facilities. This has been achieved through a series of measures over the past few years.

Strict construction requirements apply to all new facilities.

At Schaftenau, the location within an industrial zone makes the situation less sensitive; however, the same strict standards apply.

## Transport, Logistics and Traffic

Due to the high demand for raw materials, storage and logistics are critically important and governed by strict internal guidelines. These include clear categorization of materials, requirements for separate storage, and safety measures tailored to each storage class. These guidelines are rigorously applied in day-to-day operations.

Our experienced external logistics partners are also required to comply with all relevant regulations and are regularly audited

Bulk goods are delivered to Kundl primarily via the site's own rail connection.

# Fire Protection and Site Fire Brigades

Each year, our fire brigades at the Kundl and Schaftenau sites handle approximately 300 emergency responses. Serious incidents have been rare in recent years, thanks in part to extensive early fire detection systems and alarm protocols. Our production and storage buildings are equipped with around 16,000 fire and gas detectors.

Our in-house fire brigades play a vital role in our safety system. They are integrated into the regional emergency response network and receive support from external fire departments when necessary.

As chemical response units, our site fire brigades are also part of the Transport Accident Information and Support System (TUIS), providing assistance to local volunteer fire departments in responding to major fires and transport-related incidents beyond our site boundaries.



# What We Achieved in 2023/2024



#### **HSE-Management**

Target 2023/2024	Target Achievement	Result 2023/2024
got 2020,202 :		

Establishment of a new HSE organization due to the Sandoz/Novartis separation and development of a cross-company HSE culture	100 %	The HSE organization at the Kundl and Schaftenau sites was restructured, and cross-company HSE policies were established via the site policy.
Adjustment of the HSE communication plan following the spin-off and creation of a cross-company information exchange forum	100 %	The HSE communication plan was revised in the HSE manual following the spin-off, and a forum for information exchange (Sandoz/Novartis/BASF/Veolia) was launched.
Redistribution of delegated functions and responsibilities due to the spin-off	100 %	The list of delegates was fully revised and all responsible individuals were appointed.
Finalization of the Novartis GOP implementation	100 %	All site-relevant Novartis GOPs were fully implemented.
Management Walkthrough Rate of 15 per 200,000 working hours	100 %	The target was clearly exceeded in both 2023 and 2024.
90% of all pSIF and LTI cases to be investigated using RCI (Root Cause Investigation) and findings to be shared within the network	100 %	All pSIF and LTI cases were investigated.
Offering of a leadership seminar with a focus on supervisor responsibilities; training emphasis on VEXAT and hazardous goods	100 %	The training sessions were offered and conducted according to target specifications.
Full availability of the new Novartis safety data system (HazCom) for the management of safety data sheets and substance information	75 %	The safety data system is fully operational; however, some system weaknesses still need to be addressed.

#### **Environment**



#### Target 2023/2024

#### Target Achievement Result 2023/2024

Completion of the new central waste collection point and implementation of additional measures to support multiple companies at the site with waste logistics	50 %	The new central waste collection point has not yet been built; a complete redesign took place in 2023/2024.
Finalization of the waste logistics concept and start of operational implementation (DSK area)	100 %	The waste logistics concept was planned and implemented as part of the new cell culture facility in Kundl.
Continued support for the ALSAG (Contaminated Sites Remediation Act) Phase 2 investigation	100 %	The ALSAG investigation by the Ministry was finalized.
Re-greening of former container storage areas at the Kundl site	100 %	The re-greening project was implemented.
Submission of an application for an increase in discharge limits to the water authority	100 %	The increased discharge permit for wastewater at Schaftenau was approved by the water authority.
Completion of the BARA (on-site wastewater treatment plant) expansion	100 %	The BARA expansion project in Kundl was completed on schedule.
Reduction of wastewater volume by 4% through implemented projects (despite overall increase due to new production processes)	0 %	Wastewater volumes could not be significantly reduced.

#### **Energy**



#### Target 2023/2024

#### Target Achievement Result 2023/2024

Reduction of energy consumption (electricity & gas) by 6% through implemented projects	50 %	Only about 50% of the planned savings were achieved.
In-depth assessment of two selected projects from the decarbonization plan:  1. Substitution of natural gas with biomass at the Schaftenau site  2. Low-temperature drying of fertilizers at the Kundl site	100 %	Feasibility for both projects was demonstrated through pilot trials.
Installation of at least one rooftop photovoltaic system in Kundl	0 %	No photovoltaic system was installed.
Evaluation of energy savings potential in the area of clean utilities (WFI, DBR)	100 %	Savings potential was evaluated and a cold WFI generation system was installed.

# **Our Goals for 2025/2026**

#### **HSE-Management**



Topic   Site, Area	Plan 2025	Who & When
<b>Seveso</b> Kundl	Development of a cross-company Seveso operating procedure for all relevant companies at the Kundl site.	Deadline: 31. 12. 2025 Responsibility: HSE
IPPC Kundl and Schaftenau	Development of a cross-company IPPC operating procedure for all relevant companies at the Kundl and Schaftenau sites, including responsibilities for revising or updating the respective baseline report.	
Legal Obligations Register Kundl and Schaftenau	Expansion of the current legal obligations register to include department-specific responsibilities.	
<b>HSE-Annual Report</b> Kundl and Schaftenau	The HSE annual report is to be supplemented with relevant chapters – such as site inspections and additional reports from departments – in order to better meet the requirements of an internal operational audit.	

#### **Energy**



Topic   Site, Area	Plan 2025	Who & When
Steam Boilers Kundl and Schaftenau	Completion of the electrically operated steam boiler systems currently under construction at both sites.	Deadline: 31. 3. 2026 Responsibility: Technical Services, Veolia
Energy Monitoring Kundl and Schaftenau	Implementation of a modern, web-based energy monitoring platform.	Deadline:31. 3. 2026 Responsibility: Technical Services, Veolia
Energy Saving Activities Kundl and Schaftenau	Regular exchange among relevant stakeholders to place stronger focus on energy-saving activities.	Deadline:31. 12. 2025 Responsibility: Technical Services, Engineering, Veolia, HSE
Waste Heat Utilization Kundl	A large-scale heat pump for the 85 – 90 °C temperature range in the central cooling system (Building 143) is to be implemented following the completed preliminary planning phase.	Deadline:30. 6. 2026 Responsibility: Technical Services, Veolia
Waste Heat Utilization Schaftenau	Evaluation of a heat pump for 55 °C hot water supply.	Deadline:31. 12. 2025 Responsibility: Technical Services, Veolia



#### **Environment**

Topic   Site, Area	Plan 2025	Who & When
Wastewater Volumes Tenant buildings, Kundl	Implementation of wastewater metering in production buildings, including sampling systems in accordance with state-of-the-art standards.	Deadline:30. 6. 2026 Responsibility: Technical Services, Veolia
Wastewater Allocation All resident companies, Kundl and Schaftenau	Establishment of precise allocation of wastewater volumes and loads to the respective companies.	Deadline:30. 6. 2026 Responsibility: HSE
Baseline Report Schaftenau	The baseline report for the Schaftenau site is to be completely revised based on the Kundl model.	Deadline:30. 6. 2026 Responsibility: HSE
Waste Logistics - ZASS Schaftenau	The Central Waste Collection Point (ZASS) at the Schaftenau site is to be secured against unauthorized access by fencing and a barrier system.	Deadline:31. 12. 2025 Responsibility: Technical Services, REFS
<b>Waste Logistics – ZASS</b> Kundl	The provisional central waste collection point is to be replaced by a modern waste management concept.	Deadline:30. 6. 2026 Responsibility: Technical Services, Veolia
Acetonitrile Wastewater Disposal Kundl	Further optimization of acetonitrile wastewater disposal, aiming both to reduce volumes and to enable future external recycling.	Deadline:31. 12. 2025 Responsibility: DSK
Hazardous Waste Kundl and Schaftenau	Certain waste streams are currently classified as hazardous for historical reasons; these classifications must be reevaluated.	Deadline:31. 12. 2025 Responsibility: HSE, Veolia
<b>Waste Analysis</b> Schaftenau	To reduce the volume of commercial waste, consistent separation is essential.  A pilot project involving waste analysis with an external disposal partner will be carried out in 2025.	Deadline:31. 12. 2025 Responsibility: HSE, Veolia
Environmental Reporting Kundl and Schaftenau	A site-specific handbook is to be created to meet the various environmental reporting obligations.	Deadline:31. 12. 2025 Responsibility: HSE
NO <sub>x</sub> Measurement (RNO) Kundl	Continuous monitoring of nitrogen oxides is to be installed in the exhaust stream of the regenerative thermal oxidizer (RTO).	Deadline:31. 12. 2025 Responsibility: Technical Services, Veolia
VOC Balancing Kundl and Schaftenau	Responsibilities for the annual VOC (volatile organic compounds) balance between Novartis and Sandoz are to be defined more clearly and separated more strictly.	Deadline:31. 12. 2025 Responsibility: HSE



# **Environmental Aspects, Impacts and Resources**

The spin-off of Novartis Pharmaceutical Manufacturing GmbH from Sandoz GmbH became effective under commercial law on July 1, 2023, and has had significant implications for the presentation of environmental performance indicators.

For some key figures, data collection was previously carried out on an annual basis. As a result, a precise separation between the two companies for the spin-off year 2023 is only possible to a limited extent. Ultimately, the Novartis share for the years 2022 and 2023 was determined retrospectively to enable meaningful comparison.

Various systems – such as steam generation, compressed air supply, cooling, and

the on-site wastewater treatment plant
– were fully transferred to the newly established Novartis Pharmaceutical Manufacturing GmbH as of the date of the spin-off.

Specific indicators can only be partially determined in this Environmental Statement, as Novartis Pharmaceutical Manufacturing GmbH also operates as the site infrastructure provider at the Kundl and Schaftenau locations. Therefore, product-specific indicators have only limited significance. Some indicators are presented for the entire infrastructure site. This also results in corresponding indirect environmental aspects in terms of water consumption, wastewater disposal, and the tenants' thermal and electrical energy requirements at both locations.

# Use of Resources and Production Volumes

The following overview provides a summary of the key indicators reflecting production output and the corresponding use of resources.

Material and Energy Quantities Kundl and Schaftenau	2022	2023	2024	2023 → 2024
Production of active ingredients and intermediates Kundl [tons]	188.3	453.5	323.0	- 28.8 %
Production of active ingredients and intermediates Schaftenau [tons]	25.1	31.7	32.1	+1.3 %
Fertilizer production [tons]	11,610	11,257	11,725	+4.2 %
Electricity consumption [GWh]	148.5	150.3	153.9	+2.3 %
Natural gas consumption [GWh] <sup>2)</sup>	271.0	279.3	293.5	+5.1 %
Other thermal energy sources [GWh] <sup>3)</sup>	3.04	3.03	3.88	+28.1 %
Total thermal energy [GWh]	274	282	297	+5.3 %
Water consumption [million m³]2)	29.3	29.7	31.2	+4.9 %
Process wastewater to BARA Kundl [1,000 m³] <sup>2)</sup>	1,650	1,661	1,839	+10.7 %
Sanitary wastewater to ARA Kirchbichl [1,000 m³] <sup>2)</sup>	59.5	60.2	61.4	+2.0 %
Sanitary and process wastewater to ARA Kufstein [1,000 m³] <sup>2)</sup>	331	343	383	+11.7 %

#### **Specific key figures**

The following specific key figures can be derived for Novartis Pharmaceutical Manufacturing GmbH for the years 2023 and 2024. Not all basic data is available for calculating the specific key figures due to the company split for the year 2023. Previous years cannot be presented.

Emissions will be examined in more detail in a later chapter. Both sites are highly sealed to protect the soil and groundwater. Although biodiversity is very important to Novartis, it is not a significant aspect of this environmental statement.

	2023	2024
Electricity consumption [GWh/ton of production]	0.33	0.48
Thermal energy consumption [GWh/ton of production]	-	0.52
Raw material input [tons of raw materials/tons of production]	-	113.6
Water use [1000 m³/tons of production]	15.6	29.5
Process wastewater [1000 m³/ton of production]	1.68	2.23
Waste volume [tons of waste/ton of production]	7.5	11.4

<sup>2)</sup> Natural gas, water, and wastewater consumption also includes the share of other resident companies (Sandoz/BASF) at the Kundl and Schaftenau sites, as Novartis Pharmaceutical Manufacturing GmbH operates as the infrastructure park provider.

<sup>3)</sup> Diesel fuel and extra-light heating oil are used for testing emergency power generators and as backup supply; the steam boiler also includes energy released during VOC incineration.



## **Production**

In 2024, Novartis produced a total of 355 tons of active pharmaceutical ingredients and intermediates at its Kundl and Schaftenau sites.

Due to the continuously evolving product portfolio, the quantities of various biologic active ingredients produced in Kundl fluctuate significantly, making year-on-year comparisons impractical.

In 2024, over 11,700 tons of fertilizers (Biosol® and Biosol Forte®) were also produced. The volume of Biosol® has

been declining significantly for several years. Biosol® is extracted fermentation sludge from Sandoz's penicillin production, which is dewatered by Novartis and dried at high temperatures. The decreasing quantity of Biosol® – despite stable penicillin output – indicates significantly more efficient fermentation. The same amount of active ingredient is now produced with fewer raw materials.

Biosol Forte® is the dried bacterial biomass from the on-site wastewater treatment plant. Since the start-up of BASF's detergent enzyme production, the amount of this fertilizer grade has noticeably increased.

#### **Water**

Water consumption at the individual production units at the Kundl and Schaftenau sites has been monitored using meters for many years. This allows for a straightforward allocation of non-potable and potable water usage among the infrastructure park users, as outlined in the following table.

In 2024, non-potable water consumption was slightly higher than in 2023, primarily due to the commissioning of new facilities by Sandoz and BASF at the Kundl site.

The HVAC and cleanroom air-handling systems for the production areas are almost exclusively operated using non-potable water, either directly or indirectly via cooling systems. The recurring high outside temperatures caused by climate change also had a measurable impact on non-potable water consumption in 2024.

At the Kundl site, non-potable water is sourced from eight on-site deep wells. An

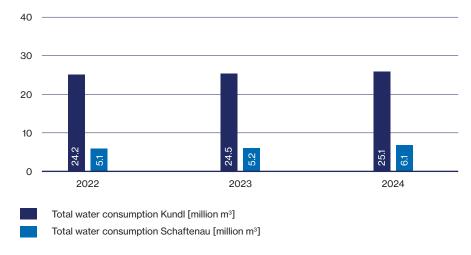
additional five deep wells are reserved for fire protection purposes but contribute only marginally to total consumption.

Potable water at Kundl is extracted from two on-site deep wells, in accordance with the site's water rights permit. Approximately 80% of the potable water is used as feedwater for the water treatment systems.

At the Schaftenau site, non-potable water is sourced from six on-site deep wells.

Until mid-2024, Schaftenau sourced its potable water from the municipal water supply. A new on-site potable water well, with a permitted withdrawal rate of 25 I/s near the kindergarten area, was approved by the water authority and successfully commissioned in 2024. Simultaneously, a 720 m³ potable water storage tank was constructed on the eastern edge of the site to buffer peak demand. Municipal water is now reserved solely for emergency supply.

#### Water Consumption Kundl and Schaftenau



The distribution of water consumption (non-potable and potable water) among the different companies at the Kundl and Schaftenau sites in 2024 is as follows:

Water Balance 2024	Kundl [million m³]	Schaftenau [million m³]	Total [million m <sup>3</sup> ]
Novartis	9.5	5.9	15.4
Sandoz/BASF/ District Heating	15.6	0.2	15.8
Total	25.1	6.1	31.2

#### **Wastewater**

The wastewater volumes directed to the in-house wastewater treatment plant (BARA) in Kundl are recorded with a high degree of accuracy.

However, a detailed allocation to the various companies located at the Kundl site is currently difficult, as corresponding meters for individual buildings are only partially in place. Despite the lack of measurement infrastructure, accurate distribution of wastewater streams was achieved using various mass balance methods.

The figures presented in the following graphics represent the combined volume of sanitary and process wastewater. Cooling water and stormwater are not included in the reported volumes.

Sanitary wastewater in Kundl is calculated based on the number of employees,

whereas in Schaftenau, the volume is measured using dedicated meters.

#### **Wastewater Kundl**

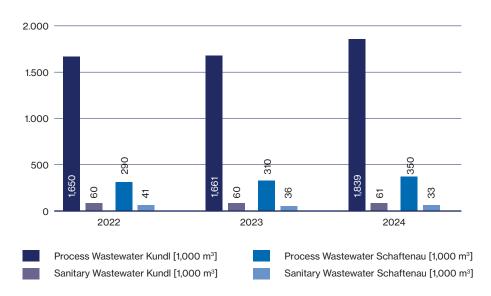
Novartis operates one of Austria's largest industrial wastewater treatment plants at its Kundl site. In terms of chemical oxygen demand (COD), the plant's capacity corresponds to the load generated by a population of approximately 320,000 people.

Process wastewater at the Kundl site is routed to the in-house treatment plant for advanced purification. Sanitary wastewater, which accounts for around 3% of the total wastewater volume, is directed to the municipal treatment plant in Kirchbichl.

For decades, we have invested in advanced technologies and continuously improved our processes to ensure long-term protection of water bodies.

Our efforts go beyond compliance with all regulatory discharge limits. Annual independent assessments of the Inn River's ecological status consistently confirm

#### Wastewater Volume - Kundl and Schaftenau



The distribution of wastewater volumes (process and sanitary water) among the various companies at the Kundl and Schaftenau sites for 2024 is as follows:

Wastewater Balance 2024	Kundl [1,000 m <sup>3</sup> ]	Schaftenau [1,000 m³]	Total [1,000 m <sup>3</sup> ]
Novartis	544	372	916
Sandoz/BASF	1,356	11	1,367
Total	1,900	383	2,283

that our treated effluent has no negative impact on aquatic ecosystems.

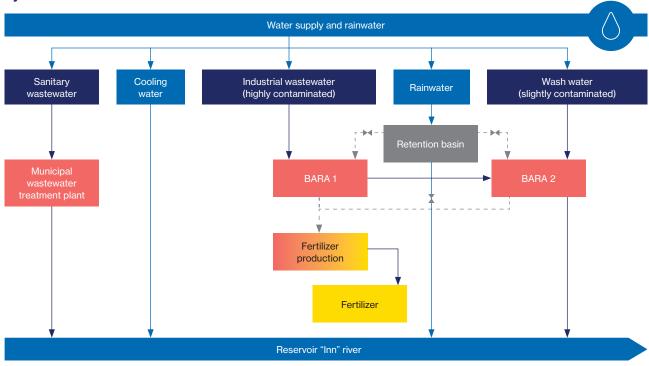
A major milestone was reached in 2024 with the full implementation of an expansion project for the treatment plant. Since April 2024, the facility has been in full operation with a newly added multi-stage membrane treatment system. Analytical data show a significant improvement in the effluent quality.

Moreover, since the full commissioning of the membrane system, the BARA has

demonstrated far more stable emission characteristics. Since April 2024, no notable exceedances of discharge limits have occurred, and the effluent values have remained consistently low.

The Kundl site operates a five-channel wastewater separation system. The following summary outlines the key characteristics. A schematic diagram illustrates the entire wastewater system, including sanitary wastewater, the on-site treatment plant, and the fertilizer production process based on bacterial biomass.

#### **System Overview – Wastewater Kundl**



	Characteristics
Sanitary wastewater	The sanitary wastewater is discharged into the municipal wastewater treatment plant in Kirchbichl.  The pipeline system downstream of the contributing buildings is mostly underground.  Sanitary wastewater accounts for only about 3–4% of the total wastewater volume at the Kundl site.
Cooling water	<ul> <li>Cooling water has no direct contact with products and is discharged directly into the receiving water at a maximum temperature of 35°C.</li> <li>The cooling water is periodically tested for hydrocarbons to detect possible leaks in heat exchangers.</li> <li>The pipeline system outside the buildings is underground.</li> <li>Approximately 95% of the extracted groundwater is used as cooling water and does not enter the wastewater system.</li> </ul>
Rainwater	<ul> <li>Rainwater is collected in an underground system and retained in a holding basin before being discharged into the receiving water after online analysis.</li> <li>The pipeline system is generally underground.</li> <li>In uncritical areas (roof runoff, parking lot drainage), rainwater has been infiltrated on-site for several years to reduce overload of the receiving water during heavy rainfall events.</li> </ul>
Industrial wastewater	<ul> <li>Industrial wastewater is highly contaminated wastewater from production facilities.</li> <li>The pipeline system is routed through underground utility tunnels or above-ground pipe bridges.</li> <li>About 90% of the influent load to the BARA comes from this wastewater.</li> </ul>
Wash water	Wash water is lightly contaminated wastewater from production facilities.      The pipeline system is routed exclusively through the underground utility tunnel.

#### Comparison of limit values for the wastewater discharge from the BARA Kundl

The BARA Kundl once again demonstrated excellent performance in 2024. The key indicators show that the organic load of the production wastewater is almost completely eliminated in the wastewater treatment plant.

Below are the wastewater parameters of the in-house wastewater treatment plant

compared to the most relevant legal discharge limits. The data refer exclusively to process wastewater generated in Kundl and the associated pollutant loads discharged into the Inn after treatment. All legal reporting and notification obligations were fully met in 2024.

Vastewater Balance Kundl 2024	Discharge Parameters	Results 2024
Total wastewater volume Daily average	7,200 [m³/d]	Average daily value: 5,025 [m³/d]     All daily average limits met
Total bound nitrogen (TNb) Minimum removal efficiency	75 %	Overall efficiency: 93.1% All daily average limits met
Total inorganic nitrogen Concentration Annual average	≤ 35 [mg/l]	Average concentration: 21.4 [mg/l]
Total inorganic nitrogen Concentration Daily average	≤ 45 [mg/l]	Minor exceedances of daily averages from Jan to Mar 2024
Ammonium Concentration	≤ 20 [mg/l NH <sub>4</sub> -N]	Average concentration: 2.2 [mg/I NH <sub>4</sub> -N]     2 exceedances in Feb 2024 reported to the water authority
Nitrit Concentration	≤ 5 [mg/l NO <sub>2</sub> -N]	Average concentration: 1.59 [mg/l NO <sub>2</sub> -N]     All daily average limits met
Total phosphorus concentration Concentration	≤ 3 [mg/I P]	Average concentration: 1.9 [mg/I P]     All daily averages in accordance with     AEV-Pharmaceuticals met
Total organic carbon (TOC) Minimum removal efficiency Daily average	95 %	Average overall efficiency: 96.1 %
Total organic carbon (TOC) Minimum removal efficiency Reporting threshold	90 %	No daily average value below 90 %
Chemical oxygen demand (COD) Minimum removal efficiency Daily average	95 %	Average overall efficiency: 96.0 %
Chemical oxygen demand (COD) Minimum removal efficiency Reporting threshold	90 %	No daily average value below 90 %
Undissolved solids Concentration Annual average	≤ 35 [mg/l]	Average concentration: 2.6 [mg/l]
Undissolved solids Concentration Daily average	≤ 45 [mg/l]	All daily average limits met
pH Value	6.5 - 8.5	Average daily value: 8.2     All daily average limits in accordance with AEV-Pharmaceuticals met
Temperature	≤ 35 [°C]	Average daily value: 31.2 [°C]     All daily averages below 35 [°C]

#### Influent and effluent loads of the BARA Kundl

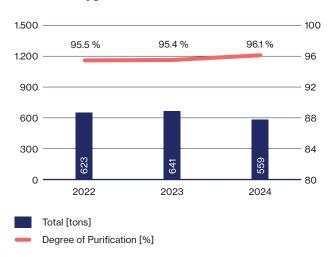
Since 2017, the pollutant loads in the effluent have been steadily decreasing due to the improved cleaning performance of the BARA Kundl. The expansion of the wastewater treatment plant with a membrane

system as a fourth treatment stage, along with various optimizations – such as automatic carbon source dosing to improve the C/N ratio – has led to significant improvements in all effluent parameters.

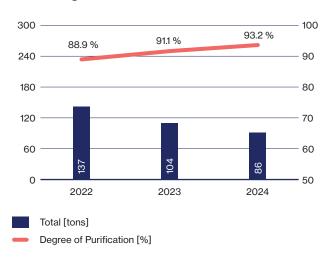
Comparison of Influent and Effluent Values at BARA	2022	2023	2024	2023 → 2024
Process wastewater for treatment [1,000 m³/year]	1,650	1,661	1,839	+10.7 %
Influent load Chemical Oxygen Demand (COD) [tons/year]	13,789	13,957	14,164	+1.5 %
Effluent load Chemical Oxygen Demand (COD) [tons/year]	623	641	559	- 12.8 %
Influent load Undissolved solids [tons/year]	4,948	4,961	5,254	+5.9 %
Effluent load Undissolved solids [tons/year]	27	19	5	- 73.7 %
Influent load Total nitrogen [tons/year]	1,234	1,163	1,267	+8.9 %
Effluent load Total nitrogen [tons/year]	137	104	86	- 17.5 %
Influent load Total phosphorus [tonns/year]	87	105	119	+13.3 %
Effluent load Total phosphorus [tons/year]	3.0	4.1	3.5	- 14.6 %

#### **Effluent Load and Degree of Purification of BARA Kundl**

#### **Chemical oxygen demand**

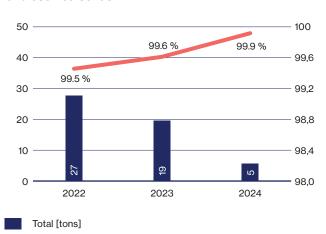


#### **Total nitrogen**



#### **Undissolved solids**

Degree of Purification [%]



#### **Total phosphorus**



#### **Wastewater Schaftenau**

The process and sanitary wastewater from the Schaftenau site is directed to the municipal wastewater treatment plant in Kufstein for proper treatment. Only the highly contaminated process wastewater is transported by tanker trucks to the BARA facility in Kundl, where it additionally supports the denitrification process.

In December 2023, the site successfully completed the legal proceedings for the increase in water discharge consent. Nearly all discharge parameters were approximately doubled in the new water law notice and indirect discharger agreement,

preparing the production site well for the coming years. The necessary adaptations to the Kufstein wastewater treatment plant were implemented accordingly.

# Comparison of Limit Values for the Schaftenau Site to ARA Kufstein

The following table presents a selection of the most important new limit values and discharge parameters for ARA Kufstein (indirect discharge), along with the 2024 results.

All statutory reporting and notification obligations were fully met in 2024.

Abwasserbilanz Schaftenau 2024	Einleitparameter	Ergebnisse 2024
Total Wastewater Volume per Week	9,100 [m³/w]	Average weekly value: 5,900 [m³/w]     All weekly values met
Total Wastewater Volume max. Daily average	1,800 [m³/d]	Average daily value: 948 [m³/d]     All daily values met
Total Bound Nitrogen (TNb) per Week	1,330 [kg/w]	Average weekly value: 262 [kg/w]     All weekly values met
Total Bound Nitrogen (TNb) max. Daily average	270 [kg/d]	Average daily value: 37 [kg/d]     All daily values met
Nitrite Concentration	≤ 10 [mg/I NO <sub>2</sub> -N]	Average: 0.0 [mg/I NO <sub>2</sub> -N]     All daily values met
Total Phosphorus per Week	350 [kg/w]	Average weekly value: 95 [kg/w]     All weekly values met
Total Phosphorus max. Daily average	75 [kg/d]	Average daily value: 14 [kg/d]     All daily values met
Sulfate per Week	1,680 [kg/w]	Average weekly value: 315 [kg/w]     All weekly values met
Sulfate max. Daily average	340 [kg/d]	Average daily value: 45 [kg/d]     All daily values met
Sulfate Concentration	250 [mg/l]	Average: 48 [mg/l]     1 single exceedance
Chemical Oxygen Demand (COD) per Week	13,300 [kg/w]	Average weekly value: 4,221 [kg/w]     All values met
Chemical Oxygen Demand (COD) max. Daily average	2,720 [kg/d]	Average: 603 [kg/d]     All daily values met
Undissolved Solids per Week	3,080 [kg/w]	Average: 980 [kg/w]     All weekly values met
Undissolved Solids max. Daily average	630 [kg/d]	Average: 140 [kg/d]     All daily values met
Undissolved Solids Concentration	500 [mg/l]	Average: 205 [mg/l]     All values met (per AEV Pharmaceuticals)
pH Value	6.5 – 10	Average: 8.75     All daily values met
Temperature	≤ 40 [°C]	Max. temperature: 32 [°C]

## **Emissions into the Atmosphere**

#### **Greenhouse Gases**

The amount of direct annual total greenhouse gas emissions (expressed in  $\mathrm{CO}_2$  equivalents) is calculated based on the combustion of natural gas for steam production, the combustion of diesel fuel for emergency power generators, the backup operation of steam boilers using heating oil, and the use of internal company vehicles. Additionally,  $\mathrm{CO}_2$  emissions from the incineration of solvents in the boiler houses are included.

Emissions from refrigerant and  $SF_6$  losses are also accounted for. No  $SF_6$  losses were recorded in 2024.

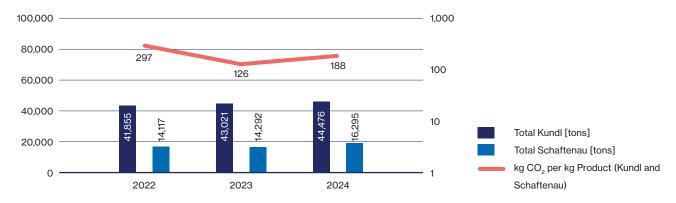
At the Schaftenau site, natural gas consumption increased due to dynamic site development and the expansion of cell culture facilities.

In 2024, emissions totaling 44,476 tons of  ${\rm CO_2}$  equivalents were released into the atmosphere at the Kundl site. At the Schaftenau site, 16,295 tons of  ${\rm CO_2}$  equivalents were emitted.

#### The CO<sub>2</sub> equivalents were determined based on the following factors:

Fuel Medium	Emission factor	Share of total CO <sub>2</sub> equivalent Kundl and Schaftenau 2024	Source
Natural gas	55.60 t CO <sub>2</sub> /TJ	96.7 %	Standard factors for fuels from the national greenhouse gas inventory for use at level 2a in Austria, 2022–2024 edition
Diesel	74.45 CO <sub>2</sub> /TJ	0.1 %	Novartis HSE & ES Indicator Management
Extra light heating oil	79.23 CO <sub>2</sub> /TJ	0.1 %	Workbook, Version 20
VOCs	65.35-84.89 CO <sub>2</sub> /TJ	1.6 %	Determination using stoichiometric combustion calculation and formation enthalpy
Refrigerant	1–14,800 CO <sub>2</sub> Equ/kg	1.6 %	IPCC global warming potential for a 100-year horizon

#### CO, Equivalent Emissions - Kundl and Schaftenau



Since Novartis supplies industrial steam to the companies located at the Kundl and Schaftenau sites, the CO<sub>2</sub> emissions are distributed as follows:

CO <sub>2</sub> Balance 2024	Kundl [tons]	Schaftenau [tons]	Total [tons]
Novartis - Scope 1	44,476	16,295	60,771
thereof Sandoz/BASF / district heating - Scope 2	24,756	497	25,253

# Nitrogen oxides, sulfur dioxide, dust

Combustion gases are generated in the boiler houses during the production of process steam and in the exhaust gas incineration plants used to reduce solvent and odor emissions. NO<sub>x</sub> emissions are largely determined by the total amount of thermal energy required in Kundl and Schaftenau for the production of active ingredients and intermediates.

Nitrogen oxides are generated in Kundl through the combustion of natural gas in the steam boiler systems and through the use of natural gas in the regenerative thermal oxidation system of the BARA. In 2024, NO<sub>x</sub> emissions at this site were significantly reduced compared to 2023 due to a process change in the exhaust gas treatment at the BARA.

The installation of a continuous  $NO_x$  monitoring system in the exhaust stack of the regenerative thermal oxidation of BARA exhaust air is planned for 2025. This will

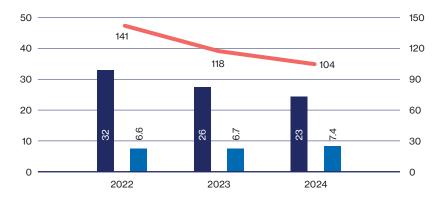
enable early detection of fluctuations in  $\mathrm{NO}_\chi$  concentrations and the implementation of appropriate countermeasures. In Schaftenau,  $\mathrm{NO}_\chi$  emissions have been steadily increasing in recent years. This is due to dynamic site development and the resulting higher steam demand. The operating times of the steam boilers are rising in line with the increasing heating requirements for growing production volumes.

Sulfur dioxide emissions are negligible at both Kundl and Schaftenau, since natural gas is used under normal operating conditions instead of heating oil.

Dust emissions into the atmosphere are also insignificant due to the use of natural gas and highly efficient dust filters (HEPA filters) in the production facilities.

Fortunately, there are also no significant emissions from electricity consumption, as electricity has been sourced entirely from renewable energy sources since 2014, according to the guarantee of origin in compliance with the Electricity Labeling Ordinance.

#### Emissions of nitrogen oxides (NO<sub>x</sub>) at Kundl and Schaftenau



Total Kundl [tons]

Total Schaftenau [tons]

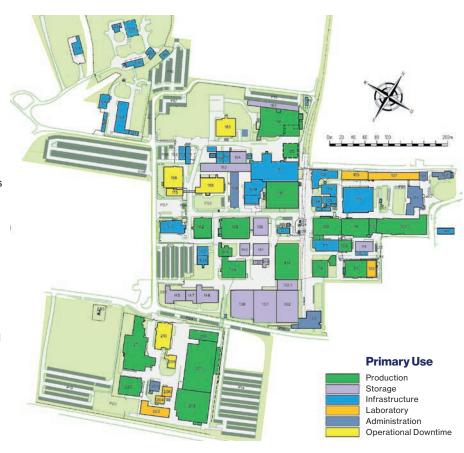
kg NO<sub>x</sub>/GWh Natural gas (Kundl and Schaftenau)

#### **Land Use**

#### Site Plan Kundl

The Kundl site covers a total area of 268,150 m². Of this, 78,800 m² – approximately 29% – is built-up. At this site, solvents, acids, and alkalis are distributed via an above-ground pipeline bridge across the facility. To protect the groundwater in the event of any pipeline leaks, all areas beneath these systems are sealed surfaces for safety reasons. As a result, a significant portion of the site is paved. Any material releases can be reliably collected in the retention basin (see wastewater system overview) and subsequently disposed of in a targeted manner.

The building density at this site is historically very high. As part of restructuring efforts at Kundl, several older production and infrastructure buildings were completely dismantled. This allowed approximately 6,000 m² of built-up area to be returned to a natural state over recent years.



# Primary Use Production Storage Infrastructure Laboratory Administration Operational Downtime

#### Site Plan Schaftenau

The Schaftenau site covers 214,076 m² and is thus about one-quarter smaller than the Kundl site. Of this area, about 38,000 m² – only 18% of the total – is built-up. Due to the local conditions, the Schaftenau site offers significantly more open space for future development.

In 2024, renaturation measures created additional natural areas near Laboratory Building 544.

In the current reporting year, area data was updated based on improved data collection. This methodological refinement led to discrepancies compared to previous years, particularly regarding asphalted and green areas.

Area Consumption [m²]	Total Area Consumption	Built-up Area	Asphalted Area	Total Sealed Area	Total Near- Natural Area	Sealed Area Share
Kundl	268,150	78,800	139,850	218,650	49,500	82 %
Schaftenau	214,076	38,020	72,520	110,540	103,536	52 %
Total	482,226	116,820	212,370	329,190	153,036	68 %



#### Waste Generation – Operational Waste Balance 2024

The waste volume in Kundl is largely influenced by a production process with a high specific waste output. This process is not operated year-round and generates acetonitrile wastewater from biologics manufacturing. Due to GMP requirements, fresh material must be used in the process. The acetonitrile, due to its composition, is not recyclable and currently must be thermally treated. Disposal of the acetonitrile wastewater accounted for approx. 1,321 t in 2024, making up about 86% of hazardous waste in Kundl.

In 2024, approx. 102 t of urea were still incinerated, whereas in the past this material could be fully recycled.

The amount of non-hazardous waste in Kundl increased significantly compared to 2023. Main contributors were wood

waste, commercial waste, and plastic packaging.

At the Schaftenau site, total waste volume in 2024 rose only slightly compared to the previous year (+2%).

Hazardous waste at this location was slightly below 2023 levels (-6%) due to a reduction in solvents from Sandostatin production needing external disposal. In contrast, non-hazardous waste rose by 6%, reflecting the near full utilization of the cell culture facilities and Building 542.

A year-over-year comparison, as with other indicators, is not feasible for waste, as separation or allocation of waste streams between Novartis and Sandoz has not been conducted comprehensively in past years.

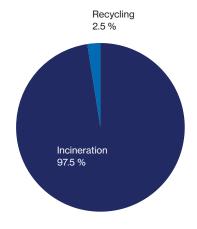
#### Fractions of hazardous Waste - Kundl and Schaftenau

Waste Code	Type of Waste	Quantity [tons]
55374	Solvent-water mixtures without halogenated components	1,406
58201	Filter cloths, filter bags with harmful contaminants	155
53502	Production waste from pharmaceutical manufacturing	137
52725	Other aqueous concentrates (urea for incineration)	102
54122	Silicone oils	75
57127	Plastic packaging and containers with hazardous residues	42
Various	Other hazardous waste (fractions < 42 t)	95
Total		2,012

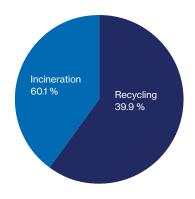
#### Fractions of non-hazardous Waste - Kundl and Schaftenau

Waste Code	Type of Waste	Quantity [tons]
91206	Commercial waste	619
91207	Light fraction from packaging collection	361
91201	Mixed packaging materials	249
17201	Wood packaging and wood waste, non-contaminated	93
18718	Waste paper, paper and cardboard, uncoated	84
57118	Plastic packaging and containers	70
92402	Kitchen and food waste containing animal leftovers	52
31468	White glass	46
Various	Other non-hazardous waste (fractions < 42 t)	99
Total		1,673

#### **Disposal Route for hazardous Waste**



#### **Disposal Route for non-hazardous Waste**



Waste Balance 2024	Hazardous Waste [tons]	Non-hazardous Waste [tons]	Total [tons]
Kundl	1,536	599	2,134
Schaftenau	476	1,074	1,550
Total	2,012	1,376	3,685

## **Energy Consumption**

Direct Energy Consumption at the Kundl and Schaftenau sites has been continuously recorded since the first environmental statement in 1997.

At the Kundl site, total energy demand has significantly decreased in recent years due to numerous energy efficiency projects. Additionally, the phase-out of particularly energy-intensive processes during the site's transformation led to a noticeable reduction in total energy requirements.

The highest natural gas consumption occurred in 2004, with an energy volume of 417 GWh. Since then, consumption has been reduced by about 30%.

The peak electricity consumption was in 2005, with 441 GWh consumed. Compared to 2024, this reflects a reduction of more than 46%.

Since 2014, the electricity used at Kundl and Schaftenau has come exclusively from renewable energy sources, according to supplier disclosures. In 2024, the share of renewable energy in Novartis' total energy consumption at both sites was approximately 48%, primarily due to purchasing 100% renewable electricity.

In 2024, the electrical energy consumption for Novartis Pharmaceutical Manufacturing GmbH at Kundl and Schaftenau amounted to 153.9 GWh, including generation from two PV systems at the Schaftenau site. This represents an increase of around 2.3% compared to 2023.

At the Schaftenau site, total energy demand has increased significantly in recent years due to continuous site development and the commissioning of new major energy consumers.

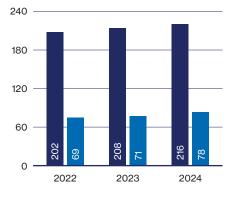
In 2024, energy consumption rose again following the full commissioning of the new CC2+ cell culture facility.

In 2023, two new photovoltaic systems were commissioned in Schaftenau, generating 108 MWh of electricity in the past year. Due to the relatively small contribution compared to the site's total energy consumption, these figures are not presented separately.

#### **District Heating - Kundl**

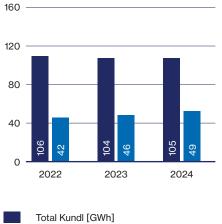
Since 1996, the Kundl plant has supplied waste heat from drying units and compressors to the municipal district heating company. In recent years, the internal demand for low-temperature heat has increased due to process optimization. As a result, more primary energy had to be used for the municipality's district heating network. Nevertheless, the CO<sub>2</sub> savings for households in Kundl remain at a level of around 2,400 tons CO<sub>2</sub> per year.

#### Natural Gas Consumption Kundl and Schaftenau



# Total Kundl [GWh] Total Schaftenau [GWh]

## **Electricity Consumption Kundl and Schaftenau**



Total Schaftenau [GWh]

#### **Energy Consumption Kundl**

Energy Quantities [GWh]	2022	2023	2024	2023 → 2024
Natural Gas	201.8	208.0	215.6	+3.7 %
Heating Oil for Boilers & Diesel for Emergency Generators	0.21	0.37	0.11	- 70.0 %
Energy Release from Combustion of VOC-Laden Exhaust Air	2.79	2.60	3.72	+43.1 %
Electricity Consumption	106.4	104.3	104.7	+0.3 %
Total Direct Energy Consumption	311.2	315.3	324.1	+2.8 %

#### **Energy Consumption Schaftenau**

Energy Quantities [GWh]	2022	2023	2024	2023 → 2024
Natural Gas	69.2	71.3	77.9	+9.3 %
Heating Oil for Boilers & Diesel for Emergency Generators	0.04	0.06	0.05	- 24.2 %
Electricity Consumption	42.4	46.0	49.2	+6.9 %
Total Direct Energy Consumption	111.6	117.4	127.2	+8.3 %

Energy Quantities - District Heating Kundl [GWh]	2022	2023	2024	2023 → 2024
Delivered Energy Quantity	29.4	29.2	28.8	-1.3 %
Thereof Primary Energy	11.4	11.7	12.4	+5.7 %

#### **Energy Consumption - Partner Companies/Tenants**

Process steam is generated from natural gas by Novartis Pharmaceutical Manufacturing GmbH using four steam boiler systems. This steam is then supplied to various companies at the Kundl and Schaftenau sites (Sandoz, BASF, district heating company).

Compared to 2023, the distribution of thermal energy consumption among the partner companies and tenants for 2024 at the Kundl and Schaftenau sites is as follows. Data from earlier years is not available due to insufficient records and therefore cannot be shown.

Energy Quantities [GWh]	2023	2024	2023 → 2024
Novartis	161.1	168.3	+4.2 %
Sandoz/BASF/District Heating	118.2	125.4	+6.0 %
Total	279.3	293.5	4.8 %



# Occupational Safety

The significant increase in the total number of work-related injuries in 2024 is primarily due to three causes: slips and falls, cuts, and impact injuries.

All other causes of higher accident rates – such as chemical exposure, crane operations, or machinery safety – are virtually non-existent. Targeted proactive safety campaigns are being implemented to counter this trend.

Progress was also made in 2024 regarding the rate and speed at which accidents were processed and resolved.

#### **Key Safety Indicators: LTIR and TRCR**

Work-related accidents and illnesses are recorded in a dedicated database, similar to environmental data. Safety data is tracked for Novartis employees, leased personnel, and external contractors working on site. Since 2014, key indicators have been evaluated comprehensively, i.e., including leased employees.

#### Lost Time Injury and Illness Rate (LTIR)

This indicator reflects the number of work-related injuries and illnesses with lost time relative to total hours worked. The reference value is 200,000 working hours.

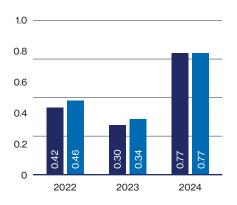
#### **Total Recordable Case Rate (TRCR)**

The TRCR (injury rate) is calculated similarly to LTIR, using the same reference of 200,000 working hours, but includes incidents without lost time as well.

#### **Occupational Safety Indicators**

The following figures apply to Kundl and Schaftenau for the years 2022 to 2024:

#### LTIR/TRCR Kundl and Schaftenau



LTIR TRCR



## Statement of the Environmental Verifier on the Assessment and Validation Activities

The undersigned, Dipl. Ing. Peter Kroiß, Head of the EMAS Environmental Verifier Organization TÜV AUSTRIA GMBH, 1230 Vienna, Deutschstraße 10, EMAS Environmental Verifier with registration number AT-V-0008, accredited for the sector "21 Manufacture of pharmaceutical products," hereby confirms that he has assessed whether the entire organization, as described in the consolidated environmental statement of

Novartis Pharmaceutical Manufacturing GmbH, 6250 Kundl, Biochemiestraße 10

and

Novartis Pharmaceutical Manufacturing GmbH, 6336 Langkampfen, Biochemiestraße 10

with registration number AT-000802, fulfills all the requirements of Regulation (EC) No. 1221/2009 of the European Parliament and of the Council of 25 November 2009 as amended on 19 December 2018 (Document EU-2018/2026) on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS).

By signing this declaration, it is confirmed that:

The assessment and validation were carried out in full compliance with the requirements of Regulation (EC) No. 1221/2009,

The result of the assessment and validation confirms that no evidence of non-compliance with applicable environmental regulations was found,

The data and information in the consolidated environmental statement of Novartis Pharmaceutical Manufacturing GmbH provide a reliable, credible, and truthful representation of all the organization's activities within the scope specified in the environmental statement.

This statement must not be considered equivalent to EMAS registration. EMAS registration can only be granted by a competent body in accordance with Regulation (EC) No. 1221/2009. This statement may not be used independently to inform the public.

The present environmental statement exceeds the requirements of the EMAS regulation. In particular, it includes information on occupational safety and corporate social responsibility, and since 2021 also information on the sales location in Vienna, which is not covered by the certification.

Novartis Pharmaceutical Manufacturing GmbH is also certified according to ISO 45001 by TÜV Austria. The lead verifier for EMAS is himself a safety specialist and lead auditor for occupational health and safety management systems. Therefore, the statements regarding occupational safety and corporate responsibility in the environmental statement were also reviewed as part of the ISO 45001 certification process.

Bad Aussee, 17. 07. 2025

Dipl.-Ing. Peter Kroiß
Head Auditor (engineer)

**じ** NOVARTIS