



# Site Guidelines for

Occupational Safety, Occupational Health, Environmental Protection,  
Energy, and Sustainability

at GP Grenzach Produktions GmbH – including special guidelines for externals  
Good Manufacturing Practices (GMP)

#andiespitze

Effective from: October 2022

## Emergency procedure

### Accident / Emergency:



Landline **444** (or 112)

Cell phone **NEVER**  
**+49 7624 909 444** 112

- **Who:** is reporting
- **Where: Read from the telephone:** building, floor, room, **North/South**
- **What:** Nature of the damage
- **How many:** Number of casualties, type of injury
- **Wait: for further questions**
- Meet/brief Emergency Medical Responder at the entrance

### Keep the route for the Responder clear and brief Responder

Production = North

Administration = South

Wait in front of the entrance.

Keep elevator (goods elevator if necessary)  
available or find an employee who can operate this.

Accompany the Responder.



### Support the Responder by:

precise responses to questions and by carrying out instructions

### Factory alarm / Gas alarm / Evacuation alarm



#### Fire Service Emergency number:

**555** / +49 7624 909 2555  
**112**

- **Where:** did the accident take place?
- **What:** exactly has happened?
- **How:** many casualties?
- **What:** types of injuries?
- **Who:** is reporting?
- **Wait for further questions.**

#### Factory alarm

1 min. continuous tone

- Await further instructions / all-clear

#### Gas alarm

1 min. siren

- Close doors and windows
- Switch off air-conditioning units
- Await further instructions / all-clear
- Seek refuge in the nearest building
- In the open, evade the gas cloud transversely to the wind direction

#### Evacuation alarm

1 min. intermittent tone sequence

- Evacuate the building immediately
- Disconnect electrical loads from the electricity supply
- Change equipment to emergency operation
- Do not use elevators
- Warn others and provide assistance
- Attempt to extinguish any fire
- Locate the Assembly Point

## Preventing Fires



No naked flames: fire, naked ignition sources;  
smoking prohibited

### Response in Case of Fire

Remain calm  
Report fire



Tel.: **555 / 112**  
Cell: **+49 7624 909 2555**

Get to safety

Warn persons in danger  
Take the helpless with you.  
Close doors and windows  
Follow signposted exit routes  
Do not use elevators  
Find the Assembly Point  
Pay attention to instructions



Attempt to  
extinguish any fire



**Use a fire extinguisher**

**An emergency call** can be made from any  
telephone by dialing the emergency numbers.

### Accident / Emergency

**Landline telephone 444**

**Cell phone +49 7624 909 444**

### Fire / Hazard Situation

**Landline telephone 555**

**Cell phone +49 7624 909 2555**

Special emergency telephones have been installed;  
these can only be used to call these two emergency  
numbers in the case of a total power failure.

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*The use of the terms "employee",  
"Responder", etc. is gender-neutral.*

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### Good Manufacturing Practices (GMP)

# Organization

## Principles for Health, Safety, Environmental Protection and Energy

As a company which incorporates and aspires to management systems in accordance with DIN EN ISO 14001, 50001, 45001, GP Grenzach Produktions GmbH complies with the following principles for environmentally compatible behavior.

The contents of the principles for health, occupational, environmental protection and energy management for GP Grenzach Produktions GmbH comprises essentially eight points:

**1. Goal:** Continual improvement of our performance in the HSE2 Management Systems. **2. Responsibility:** Protection of employees and the environment regardless of economic interests. **3. Leadership task:** Improving employees' role model function, awareness of responsibility. **4. Occupational health and safety:** Striving for optimum safety and the physical and mental wellbeing of our employees. **5. Environmental protection:** Continual reduction and avoidance of environmental pollution. **6. Energy-related performance:** Continual reduction of our energy consumption by means of optimum use of resources. **7. Cooperation:** Development of effective standards in collaboration with stakeholders for the ongoing protection of man and the environment. **8. Communication:** Conducting open dialog with employees, neighbors, public authorities, etc.

The respective current version can be found on the GP Grenzach intranet for HSE2 or on the Internet at <https://www.grenzach.bayer.de>. The employees have the duty to consider and to implement measures for the improvement of occupational, health, environmental protection and energy efficiency as they are given opportunity.

7 agencies will provide vital support:

- **Occupational Safety Specialists**  
+49 173 917 51 17 / +49 173 607 57 88  
+49 173 329 50 44
- **Works Committee**
- **Safety Officer**
- **Occupational Safety Committee**
- **Energy Manager**  
Tel. +49 17 36 13 09 41
- **Environmental Manager**  
Tel. +49 17 33 29 50 44
- **Company Physician**  
Tel. +49 7624 14 – 2582

## Occupational Safety Specialists

The tasks of the Occupational Safety Specialists within the scope of occupational safety, accident prevention, workplace safety including ergonomic design of the workplace, emerge specifically from the (German) Occupational Safety Act. The Occupational Safety Specialists are responsible for GP Grenzach Produktions GmbH within their area of competence. At the same time, the **Head of the Safety and Environmental Protection Department** is the Lead Safety Specialist and coordinates the work of the Safety Specialists. The **Safety Specialists** are responsible for the training and advanced training of the Safety Officers, for accident investigation and reporting and for the selection of personal protective equipment. They are also responsible for issues regarding machine safety and hazardous materials and with regard to external companies related to occupational safety. GP's Fire Safety Officer is responsible for matters concerning preventive fire safety.



## Works Committee

Together with its other duties, the duties of the Works Committee also include the supervision of the industrial and operational environmental protection (Art. 89 of the (German) Industrial Relations Act). In order to observe these activities, the Works Committee largely aids the Occupational Safety Specialists in accident investigation (Art. 193 of the (German) Social Security Code VII), inspections and in the Occupational Safety Committee.

## Sustainability Team / Energy Team

The Sustainability Team consists of the Energy Management Officer and representatives of the sections at the site which have a relevant impact on the resource-saving and efficient use of energy at the site. At times, the Sustainability Team is responsible for maintaining the energy management system and for achieving the sustainability objectives.

## Company Physician and First Aiders

Together with his general occupational medical tasks, the Company Physician at Roche Pharma AG is also responsible for us for all health protection issues within the scope of occupational safety and accident prevention. In particular, his tasks emerge from the (German) Occupational Safety Act. First Aiders are trained.

## Safety Officer

Employees in each department of our company are designated and trained as Safety Officers. Essentially, the task of the Safety Officers extends across their immediate working area. They support the operational supervisors in their accident prevention tasks by their conduct and their personal influence on their colleagues. It is also their task to call their colleagues' attention to unsafe behavior and to report deficiencies in apparatuses and equipment to their supervisor.

The name and telephone number of the Safety Officers can be found on the list of officers or the emergency notice.

## Occupational Safety Committee

The Occupational Safety Committee has the task of advising with regard to occupational safety issues, accident prevention, fire prevention and first aid and of preparing recommendations for Senior Management.

## Our business is your health – 24/7!



Thomas Zeyner



Isabella Heitz



Cornelia Finke



Babett  
Bullesbach Braun



Udo Binninger



Bernd Müller

### Company Medical Service

Monday to Friday  
7:30 a.m. – 4:30 p.m.  
Factory Emergency Service  
via 444 – 24/7  
Tel.: 07624 / 14-2582  
e-mail:  
grenzach.betriebsarzt  
licher\_dienst@roche.com

Company Medical Service

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## Culture / Conduct

The Occupational Safety Committee comprises:

Senior Management,  
The Occupational Safety Specialists,  
Two representatives of the Safety Officers,  
Two representatives of the Works Committee  
One Roche Pharma AG Company Physician,  
One representative from Production,  
One representative of the laboratories,  
One representative from Maintenance,  
One Fire Prevention Officer or a representative,  
Staff Management.

The Chairman of the Committee is the Senior Manager.

### Management System Officer

In the HSE2 Department, there is a Waste Management Officer, the Head of the Management Systems for the Environment and Occupational Safety and the Energy Management Officer. The officers for Business Continuity Management, Water Pollution Control and Hazardous Goods are also represented in the HSE2 Department.

### Reporting Near-accidents and Safety Observations

At GP, safety is our most important consideration. For this reason, we think it is very important that our employees come to work safe and return to their families just as healthy. All employees are therefore asked to report unsafe situations, near-accidents or safety hazards via Intellex (see QR code). Only if we approach hazards proactively will accidents be prevented.

### Reporting Incidents

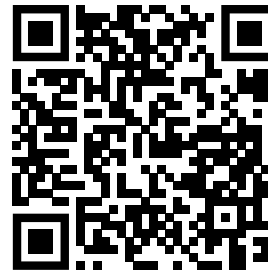
All employees are asked to report incidents such as accidents and damage immediately to their supervisors via Intellex (see QR code). The reappraisal and the insight gained from this help us to prevent such events in the future. Your report will help us to prevent such events in the future.

### Conduct as part of the team

In conduct as part of the team (CPT), we have another tool for proactively working on our culture and our behavior and thus for preventing further incidents. By positive reinforcement and anonymity we create dependable and sustainable changes in our behavior.

Your safety and health is important to us and help us to improve every day.

#andiespitze.



Intellex. Link can only be accessed using a company cell phone.

# Occupational Health and Safety

## Commuting

Just as in the workplace, accident insurance cover is in place for the direct route between home and the workplace. This also applies to carpooling, detours to take the children to daycare, business trips, home office, etc.

## Instruction

Every employee is trained by his supervisor when hired and generally at least once a year thereafter on the particular risks associated with his occupation (Job Safety Analysis, "JSA" and operating instructions, "BA").

If the employee is not clearly aware of the safety measures to be observed or if items of equipment are missing, the supervisor should be advised immediately.

## Personal Protective Equipment (PPE)

Where required, every employee receives: work clothes and work shoes or safety boots, safety glasses, safety helmet and other safety equipment such as gloves and a respirator mask.

**Every employee is obliged to use the PPE provided.**

See PPE catalog: see HSE if you have any questions.

## Foot Protection

Safety boots must be worn for any task where there is the risk of an injury to the feet – the obligation to wear safety boots applies to the entire factory grounds and rented areas with the exception of Administration in Building 60, South Side.

## Safety Helmets

Safety helmets must be worn in certain signposted areas. This applies, for example, to the entire sewage system of the site and on **construction sites**.

## Safety Glasses

Safety glasses should be worn in all signposted areas and anywhere where the eyes are placed at risk, e.g. when handling acids and corrosive liquids, when welding, grinding, etc. in certain cases where spraying liquids under pressure is to be expected, a **face mask** or **safety goggles** should be worn.



# Occupational Health and Safety



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## Occupational Health and Safety

Where required, suitable respiratory protection equipment – particle filter, gas filter, breathing helmet, compressed air hose equipment, self-contained breathing equipment – is to be used.

This must be worn whenever harmful gases, mists or dust may appear.

Measurement heads are installed in the surrounding atmosphere of the production facilities. These emit a visual and acoustic signal when the oxygen content falls below 17% v/v. In this case, **the area is to be evacuated immediately.**

Tasks where respiratory protective equipment is used may only be performed by trained employees. Depending on the type of equipment and the type of task to be performed, this will require a medical examination for fitness to utilize respiratory protection.

## Hearing Protection

**Hearing protection should be worn** in the **noise sectors** signposted with blue mandatory signs since a noise level of at least 85 dB(A), which will damage hearing, has been measured here. Noise protection is also recommended.

## Protective Gloves

Protective gloves must be worn for tasks where the hands are at risk. Depending on the type of risk, chemical-proof gloves or gloves protecting the hands against mechanical injury are required. Additional hand protection is available in accordance with the skin protection plan. Please use the skincare products prior to breaks and after work, particularly if you must wear gloves at work.

## Eating and Drinking

On hygiene grounds, food and drink **may not be consumed at workstations** in GMP zones but only in the designated break rooms.

The consumption of alcoholic beverages is prohibited across all company grounds. Should an accident ascribed to the consumption of alcohol occur, the insurance cover may be cancelled.

## Conduct in the Workplace

Operating machinery and equipment without initial briefing and outside of the usual working area is prohibited. Machinery may only be operated with intact safety equipment. Damage and defects must be immediately reported to the supervisor and repaired. Refrain from horseplay and frivolous behavior; these are liable to lead to accidents.

In order to avoid unnecessary search operations by the Factory Fire Department in the case of an incident, a subsequent cancellation of each call is necessary if the workplace is evacuated.

**Alarm and emergency call equipment must not be operated improperly.** If this is operated unintentionally, wait for the response from the alarm control center.

### Traffic Regulations on the Factory Grounds

The factory grounds are private property. **The regulations of the (German) Traffic Code apply: factory traffic (including forklift trucks, rail traffic and preceding escort rail vehicles) ALWAYS HAS PRIORITY.** Caution: Rail vehicles also travel **COUNTER TO the direction of travel of motor vehicles.**

**Pedestrians must use the walkways on the northern and western sides of the factory grounds. They may not walk across the truck delivery area on the eastern side of Building 60 to reach a building.**

The posted traffic signs should be observed. **The speed limit** has been set at **20 kilometers per hour.**

The **right of way rule “right before left”** applies on all roads in the plant. Vehicular traffic on the factory grounds should be reduced to a minimum.

Stopping on the left-hand side of the oncoming lane in the direction of the exit is permitted. This also applies to taxis.

**Building 60, south side – stopping alongside the building is absolutely prohibited since this area must be kept clear for emergency vehicles at all times.**

These may stop on the hatched areas there (regarding pedestrians on the way to the cafeteria, see page 26). In particular, we refer to current notices regarding traffic changes for pedestrians and all other road users within the factory grounds.

Using a cell phone while walking and on stairways is prohibited.

On the way to the cafeteria, a distance of 1.5 meters should be maintained from parking vehicles in order to avoid serious accidents when backing out of a parking space.

Tradesmen may also park in the parking bays on the northern side of Building 60 if they must go to their vehicle frequently. The east ramp may also be parked on for loading and unloading; other delivery vehicles and access to stairways must not be obstructed in doing so. External employees / tradesmen with a parking permit from the gate may only park in the blue parking bays; hatched areas must not be used, either for stopping, loading and unloading or for parking (traffic areas for fire and emergency vehicles).



## Occupational Health and Safety



Private vehicles require a parking permit



Parking area for bicycles



Driving special purpose vehicles

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The use of headphones is prohibited in all operating areas including company grounds (aside from for operational purposes); break rooms are exempt from this regulation provided alarm signals and calls for help from colleagues can be easily heard.

### Bicycles / Motorcycles / Small vehicles

The use of **personal bicycles is not permitted on company grounds**. These, together with motor cycles, must be parked in the roofed bicycle stands. Riding on pedestrian walkways (< 2 meters wide) is prohibited.

Transportation means such as inline skates, skateboards, kickboards, etc. is also generally prohibited across the entire company premises.

### Private vehicles (automobiles)

Private vehicles may only drive on the company premises with the appropriate permit in the form of registration with Factory Security and must have a transponder.

The parking bays signposted for this purpose should be used for parking. The arrows indicating the direction of travel applied to the roadway should be observed.

### Rail traffic always has right of way.



Pedestrians and motor vehicles: **PLEASE ALWAYS WAIT** until the tank car train has passed by and **DO NOT** walk or drive between the advance car and the tank car train. In this case, the tank car train engi-

neer must make a dangerous emergency stop. Due to the very longbraking distance, it is possible that the tank car train will not stop in time and will run over the pedestrians or the vehicle. This may also lead to damage to the tank car.

### Driving special purpose vehicles

Only trained GP employees with a valid **driving license, proof of initiation and equipment training and a valid movement order with an assignment order** are permitted to drive **GP-owned special purpose vehicles within on-site transportation** (pallet transporters, forklift trucks, etc.). In order to drive their own special purpose vehicles on the company premises, employees of external companies require the driver's licenses stipulated in the statutory regulations. These are to be presented to the GP safety engineers and the construction site manager on request.

## Energy channels

Access to the energy channels and roofs is essentially not permitted. Exceptions apply to employees who perform specific tasks there.

**Energy channels may only be accessed after notifying the Main Gate (+49 7624 909 27 25), with an EX warning and personal emergency signaling device.**

The name and approximate location should be advised. The employee must sign out again on leaving the energy channels. Safety helmet, safety glasses and EX-protected electric tools such as a flashlight must be taken along. Work should generally only be performed with the appropriate valid work permit.

## Server rooms (e.g. Building 60, basement distribution)

Access to the server room is only permitted after consultation with the IT Department and advising the Main Gate, telephone +49 7624 909 27 25, with a personal signaling device.

## Storage

Storage secured against falling and for the prevention of accidents or rolling should be provided for pallets, drums, steel cylinders and other containers. Containers with liquids should be stored on drain pans.

**Doors, gates, traffic routes and safety equipment may not be moved.**

## Repairs

**Lock Out, Tag Out (LOTO)** should be utilized if the facility safety policy must be circumvented, this may result in danger to

life and limb or this has been defined as a measure emerging from a hazard assessment.

Locks may only be removed by the respective key-holder. Forcible removal is essentially not permitted.

Work may only be performed using flawless and tested tools and auxiliary equipment in accordance with regulations. Remaining under suspended loads is prohibited. Floor hatches, pits, shafts, canals and other dangerous recesses should be secured against falling in by means of barriers in accordance with regulations.

Equipment and pipe work should be cleaned if possible and disconnected from the rest of the equipment prior to commencing all repairs. Particular care should be taken when disengaging flanges. Here, a face shield or safety goggles must be worn.

Blind disks may only be installed and removed by the workshop staff or by specially trained company employees.

Regarding the use of ladders, steps, scaffolding, platforms or electric devices, see page 24; regarding the testing of tools, see page 25.

## Elevators

Elevators may not be overloaded; do not transport goods in passenger elevators (exception: laundry transport South and center elevator). A secure, solid storage box should be used when transporting hazardous working materials. Loads should be secured against shifting.

## Occupational Health and Safety



**Do not use  
elevator in a  
hazard  
situation**

Alarm and emergency equipment in elevators may not be operated improperly since this will cause a false alarm for the emergency workers; **if the alarm has been operated in error, wait for the response from the gate.**

**Due to the risk of a power failure or smoke, elevators must not be used if there is an evacuation alarm.**

**When using the elevator to transport solvents, riding along is prohibited. Persons and solvents must ride separately.**

### **Working with a permit**

A work permit is generally required for the following: working in narrow spaces, working where there is the risk of fire or working where there is the risk of falling. Work permits (AES) must be generally issued for all activities. Exceptions are routine activities which are described in a JSA / operating

manual and are undertaken by GP employees.

**Work for which an AES is required may only be commenced if all the qualifications required by the AES are on hand and the required precautions have been taken and the GP Authorized Clearance Officer has granted the final clearance with his signature.**



# First Aid

## Company Medical Service surgery hours

The Company Medical Service (BAeD) in Building 13 is staffed during the advertised opening hours. Incoming emergency calls are received directly by the BAeD during these periods.

If the call is not answered there after five rings, it is automatically rerouted to the alarm switchboard at the Main Gate (Building 108).

Outside the advertised opening hours, all incoming calls to the emergency telephone number are rerouted to the Main Gate.

The paramedics are alerted by factory Security if required.



## First aid measures by employees up until the arrival of the paramedics or the doctor

Employees are legally obliged to provide such first aid as they are able to. Trained first aiders who should be called on are available in each department. Rescue blankets in the first aid carry case should be used to prevent hypothermia.

In the event of an eye injury, the eye must immediately be thoroughly rinsed (use both bottles of eye wash entirely) on the spot (for approximately 10 minutes) with the eye douche or the eye wash solution provided.

At the same time, the Company Medical Service should be notified on

**Landline telephone: 444**

**Cell phone: + 49 7624 909 444**

## The emergency staff should be advised in all cases in order to guarantee help as quickly as possible.

(Note the building section, North/South.)

Hygiene, locker room and zone regulations may be circumscribed where the urgency requires this.

## First aid kits

First aid kits with material for a first aid emergency are mounted in a central location on each floor of the building.

This equipment is the responsibility of the staff and may only be used in an emergency.



The first aid kit must be exchanged at the Company Medical Service after use.

# Fire Safety

## Training

Supervisors will register their employees at the Factory Fire Department for fire safety training not less than every two years. Here (for training with their own PPE, e.g. safety glasses and work coat), qualified training is given in, inter alia, the handling of fire extinguishing equipment and also, if required for the job, the wearing of respirators.

## Work clothing

If clothing is contaminated it should be changed immediately. If there is skin contact, the Company Medical Service should be consulted immediately.

## Fire extinguishing equipment

Adequately identified fire extinguishing equipment is located in each building / on each floor. Employees must know where the fire extinguishing equipment is located

in their work area.

Employees of external companies must be shown the nearest fire extinguishing equipment for this working area by a GP employee on commencing work. Fire extinguishing equipment may only be used appropriately. It may not be blocked by obstructions.

## Fire compartments

The buildings are divided into fire compartments. The fire doors should always be kept closed. Where through traffic is necessary, exceptions apply for the duration of the transportation tasks provided automatic door closers are on hand or uninterrupted supervision is guaranteed in order to close the door in the case of a fire.



## Electronic devices

Portable electric devices must be regularly inspected by a qualified electrician and provided with an inspection plate. This also applies to personal electric devices used in the workplace. These may only be put into operation after the electronics workshop inspection.

## Tidiness

The cleanliness and tidiness of the workplace make an important contribution toward fire prevention. Hence, e.g. waste only belongs in the collection containers provided for this. Medications and aerosol cans may not be placed in the usual trash bins.

## Smoking

Smoking on the premises is essentially prohibited. The only exception to this is in designated break rooms.

## Conduct in a Hazard Situation

In the case of a fire, rescuing people has priority over other considerations. Recognizing the alarm signals and the correct behavior are therefore crucial if a fire breaks out. Warn those in the vicinity by calling out loudly and, without waiting for successful extinguishing of the fire, report the fire to the alarm switchboard at the Main Gate (Building 108), on

**Landline telephone: 555**

**Cell phone: + 49 7624 909 2555**

### The fire call should include:

- name of the person reporting
- building number
- floor
- room (location) of the damaging event
- section (North/South, Building 60)
- nature of the damaging event
- do not hang up the telephone immediately; wait to answer any possible questions

Please state whether you can see the fire or smoke or whether you are only aware of a general smell of burning.

Alarm tones sound in cases of danger. The **factory alarm**, gas alarm and evacuation alarm are different. For more information, see page 02.

A practice alarm is sounded on the 1st Monday of the month at 9:00 a.m., for a duration of 10 seconds.

Should you not hear the practice alarm or not hear it properly, please report this to the Security Section (HSE2).

### In-house firefighting measures

A fire can be fought most easily when it first starts. The available firefighting equipment should be used after the emergency call, if there is the opportunity, although not at the risk of your own life. The Fire Department will be on the scene very quickly and will

take over fighting the fire. The factory Fire Department should be advised.

### Fire-fighting measures in the workplace

An emergency notice with information regarding conduct in a hazard situation is posted at the exit route on every floor.

The operations which must still be performed without personal risk prior to evacuation are indicated here. You must then leave the building as quickly as possible and the Assembly Point specially designated for this purpose for the full head count must be located.

**Only the evacuation alarm is considered to be a signal to evacuate the building and to assemble at the Assembly Point.**

In the event of an incident outside their building, all other employees are obliged to remain at their workplaces or to return there.

## Conduct in a Hazard Situation

- where there are leaking combustible liquids
- where there is gas leak
- where there is leakage of a large quantity of corrosive liquids
- where there is leakage of water-hazardous liquids

or in other events of damage which cannot be rectified without personal risk and risk to other persons using serviceable equipment, call the alarm switchboard at the Main Gate (Building 108), on

**Landline telephone: 555**

**Cell phone: + 49 7624 909 2555**

The necessary measures will be initiated from there.

The **evacuation alarm** will be sounded in the building concerned if necessary.  
The **factory alarm** will sound simultaneously across the rest of the factory premises.

Make sure you know where the fire extinguisher nearest to your workplace is.



**Always keep  
emergency exits  
clear.**

**Keep  
emergency  
exit clear.**

## Energy / Sustainability

Sustainability is more than a current social and political topic and is important to us at the Grenzach site in concrete terms. One of our objectives is the sustainable reduction of the indirect CO2 emissions we generate.

We consistently strive to increase our efficiency in order to reduce our resource usage. Thus, for example, increasing energy efficiency not only contributes to lower energy costs but also contributes to the reduction of CO2 emissions.

**Environmentally aware operation also makes a significant contribution to the safety of our site.**

Our energy management system is certified in accordance with the guidelines of

the international ISO 50001 standard. At the same time, the energy management system supports us in shaping our use of energy as economically and efficiently as possible.

The Sustainability/Energy Team forms an important component of the system. This team exchanges views regarding topics relevant to energy and sustainability at the site at regular intervals and initiates projects which are intended to contribute to, inter alia, saving energy, reducing wasted energy and reducing water consumption.

In particular, alongside the Sustainability/Energy Team, the commitment of all employees to promoting topics relevant to sustainability at the site is sought.

**Because in our enterprise, hidden potentials which we want to utilize optimally in the future also lie dormant.**

Open your eyes and walk through GP Grenzach Produktions GmbH and use the VV [Verbesserungsvorschlagswesen: "suggestions for improvement"] scheme of "the Learning Factory" also for useful suggestions for improvement. Environmentally aware behavior also contributes sustainably to improvement.



Energy-efficient lighting.



Every kilowatt counts.



Steam energy is costly.

## Environmental Protection

### Removing waste

Removing waste is prohibited. Contravention is considered to be theft and will be prosecuted.

### Disposal of waste

GP is entirely responsible for the correct disposal of all created waste to be sorted, up to verifiably legally permitted disposal.

Mixing waste to be collected separately is prohibited. Accurate separation, preventing missorting and not placing the wrong waste in the respective collection bins or trash compactor are very important. If in doubt, see column 3 on this page. The specific separation regulations posted in the break rooms / kitchens should be observed; biological waste always without packaging, and drinking cups, these go into the commercial waste.

The separated waste collected in the factory is consigned to the Remondis disposal contractor for proper disposal. For the correct separation in accordance with SOP 7-HSE-013 and Attachment C, first of all, the departmental Waste Coordinators and the GPLP employees will assist with standard waste (Attachment D of the SOP), the Project Leaders with construction site waste and the Waste Officer (HSE) with particular waste issues.

### Waste is reused

The also legally prescribed separation of waste in accordance with the waste SOP 7-HSE-013 is very important for the optimum as well as the most cost-effective utilization of the waste.

In each department, special containers for certain waste products are installed, in which the waste created is collected (e.g. clear film separated from "hard plastic",

separated from inseparable composite packaging as commercial waste). The locations of containers and compactors on the north Building 60 ramp or certain collection points in the GPLP Stock Receiving Department (lubricating coolant, waste oil, oil rags, electrical scrap, batteries, aerosol cans, etc.) are shown in Attachment C of the waste SOP. Only the exact types of waste for which each of these is provided, without exception, may be placed in the containers.

Questions concerning the separation of waste can be clarified by calling +49 172 833 81 73 or +49 173 329 50 44.

### Aerosol cans

Aerosol cans may not be disposed of e.g. in the commercial or metal waste. There is a specific collection point in the Stock Receiving Department on the north side of GPLP for aerosol cans.

## Preventing wastewater pollution

Where there is the risk that impurities from cooling water will get into the wastewater, the sewer system or the waste coolant / rainwater, OR in the case of incorrect discharge into the chemical/processing wastewater, the ARA Control Room (24 hrs. / 365 days) should be alerted by calling +49 7624 909 2779 and the following should be indicated:  
**name, time, location and accident type, type and quantity of the material and the destination of the discharge if this cannot be interrupted.**

**On request by DSM, cooling water and (if also possible) chemical wastewater samples (GPE Infra) should be sent to the DSM Analytics Department in Building 70.**

All water originating from, e.g., sealed surfaces (roofs, roadways, parking lots) during the rain is regarded as **surface and cooling wastewater**.

**Cooling wastewater** from cooling processes and surface water is drained into the Rhine without treatment since it is not polluted.

Therefore, pollutants and wastewater must not get into the cooling water, surface or rain / roof drainage. For all wastewater containing contaminants, the DSM and GP procedure instructions (7-HSE-014 and attachments) must be strictly observed and, in the case of disruptions, damage, incorrect discharge or a proposed new discharge, the appropriate departments of DSM such as the ARA Control Room and, if necessary, the alarm switchboard at the gate and the Factory Fire Department should be immediately advised.

For that reason, all solid and liquid materials must be securely held in dikes, etc. and contaminants must be immediately completely removed. Contaminants must be collected in an environmentally responsible manner, declared and disposed of via GPLP, giving the source/department.

**Note:** Disposing of chemical, batch, detergent and disinfectant, etc. residues via or diluting these for the wastewater is strictly prohibited (send to GPLP in suitable GHS labeled packaging).

Clearance for discharges and special-purpose discharges should always be approved by GPS/HSE together with DSM.



Reuse resources.



Production wastewater.



Proper disposal.

# Environmental Protection

## Production wastewater / Chemical wastewater

In Building 60 and 70, all wastewater created in routine production goes into the so-called chemical wastewater. The chemical wastewater is purified in the wastewater purification facility (ARA). On no account may liquid wastes such as not specifically approved intermediate product or product fractions, wash solutions, oils, solutions, solvents, etc. be disposed of with the chemical wastewater (specifically approved cases are referred to in the wastewater registry, cf. the SOP and attachments; in each case, the respective current DSM SOP G105 (Cooling Water), G106 (Accidents) and G114 (Laboratory Solvents) and the attachments), applies. Solid and viscous or water-soluble waste, together with trash, gaskets, cable ties, pieces of wood, etc. must be collected using the scoop. This must not be placed in the chemical sewer system.

Chemical/Production wastewater may only be discharged within the structure in accordance with regulations and in accordance with the guidelines of the current workplace regulations. If there is a deviation, the further procedure must be clarified with the supervisor, Water Pollution Control and the ARA (special-purpose discharge proposal). Failed batches must always be disposed of as waste and not discharged into the wastewater.

## Immission control

Every employee should prevent toxic substances from getting into the exhaust air in his area by using suitable measures. This begins in the office and the workshop with the use of the appropriate working materials and continues in the laboratory with the careful management of hazardous materials. This applies particularly in the production facilities by the operation in accordance with regulations of the exhaust air purifying systems installed in accordance with the workplace regulations.



## Hazardous materials

Observe the relevant SOPs on receiving and dispatching hazardous materials and contact the **GPLP** hazardous materials expert (telephone +49 172 717 9983) or the Hazardous Materials Officer (**Safety and Environmental Protection**), telephone 3634.

The following internal agreement has been made between the Senior Management and the Works Committee of GP Grenzach Produktions GmbH:

The guidelines listed above for “Safety, Health, Energy, and Environmental Protection” have been established jointly.

Grenzach-Wyhlen, October 1, 2022

Ilker Aslan,  
Geschäftsführer



Christina Gmeinwieser  
Chairman of the Works Committee



Finn Petersen,  
Head of Safety and  
Environmental Protection



Rena Dittberner,  
Energy Manager



Immission control.



Spontaneously combustible materials.



Hazardous materials labeling.

## Special Guidelines, also for Employees of External Companies

### Introduction

The instructions presented in this brochure have been issued in order to guarantee the safety, health, energy and environmental protection requirements based on our management systems for occupational safety, environmental protection and energy (see principles, page 4). These requirements are to be observed on the company premises of GP Grenzach Produktions GmbH and in the rented areas.

Apart from these essential instructions to be observed, all employees must also familiarize themselves with the particular hazards in their area of employment and, when in doubt, approach the respective GP adviser or the Section Manager for information concerning the particular safety measures.

In each case, when a task is allocated, corresponding guidelines are given for the area of operation and regarding possible additional regulations applicable there.

**Essentially, the following applies to employees of external companies during their employment on the GP premises, both within and outside the building:**

**The instructions of the GP employees are to be followed.**

The manager, proprietor or otherwise responsible employees of the company delegated are obligated to inform the employees or subcontractors deployed by him for work on the GP company premises regarding the contents of these safety guidelines, including the special guidelines for the respective area of operations (e.g. as an attachment) and to ensure their observance.

The special guidelines described here for “external companies” apply unconditional-ly to all subcontractors.

The external company employee will confirm his acknowledgement of the contents of these safety, health, energy and environmental protection guidelines for employees of external companies and the instruction of his employees in this regard (e.g. in the AES). He will also undertake to observe the statutory working hours regulations with regard to the maximum working, break and rest periods for his employees in order to avoid unsafe actions due to exhaustion.

### Access authorization on the factory premises

Factory Security will issue an access authorization for the factory, an external company identification in the form of a “daily factory pass” or a “photographic periodic factory pass” to each external company employee on request from a GP employee.

**The pass should be carried at all times.**



Terminal for safety training



Special purpose vehicles



Fire safety

Prior to creating this pass, Factory Security will check whether the external company employee is sufficiently familiar with the safety and environmental regulations applicable on the factory premises. Only when the test has been successfully completed will the external company employee pass be issued. If the external company employee does not pass the test, he will not be given access to the factory premises.

**In addition**, for **Building 60**, external company employees with a daily factory pass can obtain a “visitor’s pass” from any respective area or departmental manager after a briefing on the clothing and hygiene regulations. This authorizes him to pass through the corresponding airlocks.

**These passes should be returned to the appropriate department or the Main Gate on completion of the respective task immediately and without request. Clarification regarding parking authorization, see page 9.**

### **Protective measures / preventive measures**

In addition to work clothing, all external company employees must also wear protective equipment in accordance with the work permit, if required, e.g.:

- **safety boots** • **safety glasses**
- **safety helmet** • **gloves**
- **respirator mask**

This equipment is not supplied by GP and its potential acquisition is not included in the allocated working time at GP.

The work may not be performed without the PPE stipulated in the permit.

**Wearing safety shoes is obligatory for suppliers, tradesmen and employees of external companies (aside from in administrative areas).**

In addition, **head protection (helmet, bump cap, etc.)** must always be worn on construction sites.

The detailed information regarding the topics:

- **Occupational and health safety**
- **First Aid**
- **Fire safety**
- **Conduct in a hazard situation**

on pages 7 to 15 must be observed unconditionally.



## Special Guidelines, also for Employees of External Companies



Getting the job done.



Working with scaffolding.



Electrical equipment.

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### Getting the job done

Prior to starting the job, the employee of the external company must report to the person in charge in the workshop concerned and must be briefed.

In principle, access to the appropriately signposted areas is only permitted if the employee has reported to his GP employer in accordance with the regulations. Each employee must remain in his work area at all times. Operating machinery and equipment outside of your own work area is prohibited.

### Working only with a permit

**At least one permit (AES) is required for work. The precautions and protective measures defined there must be implemented and the GP Authorized Clearance Officer must have issued the final clearance with his signature.**

**Specific qualifications and certificates for welders, electricians and similar must be verified with the responsible person at GP prior to starting work.**

The detailed information on page 12 must be observed unconditionally.

### Working in containers

The "Guidelines for Using Containers" must also be observed when **working in containers and in narrow spaces.**

Access to the **energy channels** and the roofs is essentially not permitted. Exceptions apply to those employees and workers who must perform specific tasks there.

**Energy channels may only be accessed if the Main Gate (telephone +49 7624 909 27 25) has been notified beforehand.**

The name, company and approximate location should be advised. The employee must sign out again at the gate on leaving the energy channels.

A Fire Department unit will be dispatched if the time is exceeded or the employee forgets to sign out.

**Work in the energy channel** may only be performed in pairs. **The wearing of helmets and protective glasses is obligatory** in the energy channel. A flashlight must also be taken along at all times. All equipment used must be EX-proof.

### Tools

All work may only be performed using **flawless and tested tools**, auxiliary equipment and PPE.

Vital for **working with ladders:**

- Work may only be performed from a ladder if it is **small-scale** work, that is, it can be performed by one person over a brief working time.
- **Straight ladders** should be placed so as to prevent sliding.  
A second person must also ensure that the ladder is secure against sliding.
- If work is to be performed from a ladder where holding onto a firm structural element with one hand is not possible or there is the risk of losing balance, the ladder must also be secured by being lashed to a firm structural element. A safety belt with a short sling rope must also be used. This is also to be attached to firm structural elements using a carabiner hook.
- The regulation described above also applies to work which can be performed from a **step-ladder**, with the exception of being tied to a structural element.

**Essentially, for all work where there is the risk of falling or of falling into something, the employee must be secured by means of a belt and safety line. This is mandatory above a height of 2 meters and optional below this height.**

If safe performance of a task using a ladder is not guaranteed, if in doubt, scaffolding, either mobile or fixed, should be used.

Vital for **working with scaffolding:**

- Scaffolding must be examined by a qualified person after assembly. The result of this examination should be recorded on a scaffolding clearance certificate, on which the other characteristics (permissible load, owner, etc.) are listed. The **scaffolding clearance certificate** should be attached to the scaffolding and should be visible and permanent. A visual inspection should be performed and documented by the employee who

first sets foot on the scaffolding each working day.

**Vital in GMP areas** (p. 25 ff.):

Overshoes may not be worn on ladders, stepladders or scaffolding. Please inform the GMP staff regarding the immediate cleaning and disinfection required prior to the task.

The use of **electrical equipment** is only permitted with the use of specially fused power sources (ground fault circuit breaker). The economical management of energy, particularly the use of energy-efficient tools and equipment, should be borne in mind.

### **Inspection of tools**

The equipment and tools required for the work must be in a flawless safety-related condition.



## Special Guidelines, also for Employees of External Companies

Equipment, the testing of which is governed by the DGUV Regulations, the (German) Industrial Health and Safety Regulations or by BG Regulations, may only be used if the testing interval has not expired and their testing is evidenced by an attached, externally visible inspection plate.

### More efficient and sparing use of energy and resources

The external company is obligated to use energy and resources (e.g. electricity, steam, compressed air, water) sparingly. Likewise, unnecessary emissions into the environment (e.g. noise, dust, odors, waste, wastewater, vibrations, fumes) are to be prevented.

Energy consumers no longer required (e.g. lights, machinery, heating) should be disconnected. Leakage and idling should be avoided. Windows and doors should be kept closed in air-conditioned rooms, except where this would compromise working safety. These measures should be checked thoroughly prior to the completion of work. Only energy-efficient tools and equipment which are compliant with the current state of the art should be utilized. An intermediate meter must be used if tools and equipment have an electrical, steam or compressed air energy requirement greater than 100 kWh per day. The Energy management Officer should also be informed. Please advise us regarding leakage, wastage or potential savings, even if these are not within your area of responsibility.

### Preventing wastewater contamination

#### Surface water and rain drainage, waste cooling water, chemical wastewater, solid waste

Liquid waste (e.g. on construction sites) should be collected separately in separate containers and secured against leakage and overflowing in tubs protected from rain. The detailed information and the information regarding alerting the ARA Control Room on page 18 – 20 must be observed unconditionally.

### Waste disposal

#### Waste materials are reused.

Waste consisting of material brought in by a contractor must be taken away by him and he must dispose of this himself. The contractor may only send waste originating from GP materials (e.g. construction rubble, sheets of glass, cables, etc.) via the Project Management to Remondis for

disposal. The waste must also be sorted as prescribed by the GP Waste SOP. If it has been contractually agreed with the contractor that he has generated the waste, he may himself dispose of the waste in his own established, fully labeled containers; the contractor, however, is strictly obligated to notify GP regarding his disposal waste management facilities for hazardous wastes prior to the disposal, to produce evidence of their qualification and he may only offer this in conformity with the law. Furthermore, however, if GP has generated the waste, the contractor may only dispose of the waste himself

- if the waste contains no hazardous contaminants and is therefore not hazardous waste and
- if he notifies GP regarding the quantity of waste and the associated waste code numbers and notifies the GP Waste Officer for GP's waste balance.



## Walkway to the cafeteria

All GP and external company employees must walk within the marked sidewalk area. Detailed information can be found in the current notices; see also the explanations on page 9 – 10 and the map on the right.

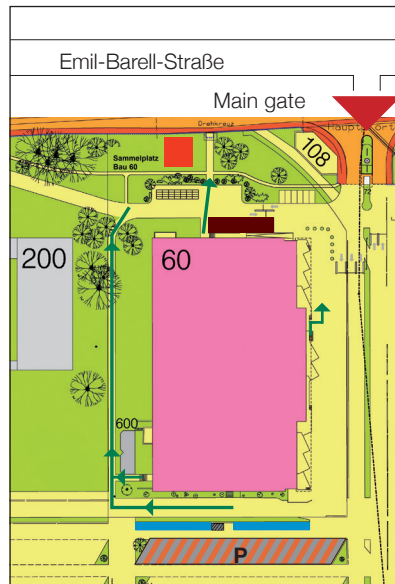
## Stopping in front of Building 60, south side

See p. 9 and the “Traffic Safety” brochure by DSM, Roche and GP. Stopping for picking up and dropping off passengers is only permitted on the hatched areas in the opposite traffic lane (west → east) on the parking lot side. Stopping is **NOT** permitted in front of Building 60 south. Exception: Delivery of saline and landscape gardeners.

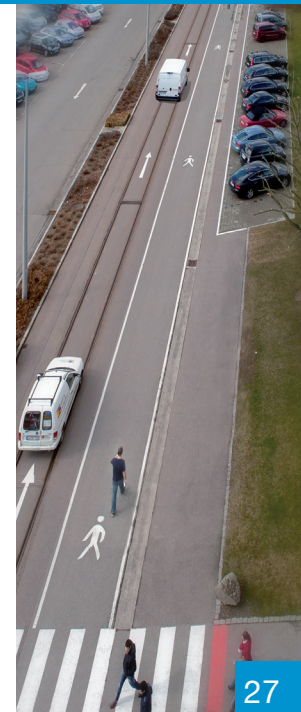
## Logistics area, east

Stopping and walking in the truck loading area is generally prohibited. The exception to this is Logistics employees wearing a high visibility reflective vest. The official pedestrian route is located on the western side.

## Location of waste containers and parking options



- GP Grenzach Produktions GmbH
- Roche Pharma AG
- Waste containers  
Paper, plastic canisters, household trash,  
plastic bags, glass, cardboard boxes
- Parking lot
- Visitors' parking lot  
Taxis, tradesmen
- Emergency escape routes
- Assembly Point



# Good Manufacturing Practices (GMP)



Employees are dressed in accordance with the zone policy.



Machinery is cleaned and sterilized.



Concentration on performing the work in accordance with directions is vital.

## What does GMP mean?

The term “Good Manufacturing Practice” (GMP), “Gute Herstellungspraxis” in German, summarizes the guidelines for the quality assurance of the production processes and of the production environment in the manufacture of pharmaceuticals and active ingredients. GMP guidelines also apply in the production of cosmetics, medical devices and dietary supplements.

The GMP guideline applicable in the EU is the “EU GMP Guidelines for Pharmaceuticals for Human and Veterinary Use”. In Germany, these regulations are a component of the Pharmaceutical and Active Agent Manufacturing Regulations, which are binding for all pharmaceutical manufacturers. GP Grenzach Produktions GmbH holds a manufacturing license for pharmaceuticals. The abovementioned GMP guidelines are applicable for all products manufactured by GP. Please note: GMP does not override any

industrial safety measures (cf. p. 21 – 26, above all regarding ladders and platforms). If industrial safety measures are required in a GMP section, please advise the persons responsible for this section beforehand. Hence, measures can be taken to maintain or to reestablish the GMP status of the section.

## What’s it about?

The GMP regulations are based on the principle that the required quality of a pharmaceutical is not a result of the final examination of the finished product but must be systematically brought about and ensured, even before the first manufacturing step. Therefore, all operational areas and processes which may have an impact on the product quality and the unequivocal verification of this, in particular, employees, hygiene, buildings and premises, technical equipment for production and quality control, raw materials and packaging materials

and their suppliers, manufacturing processes and analytics, storage and dispatch, as well as the documentation, are affected by the GMP regulations. The quality assurance system forms the basis and framework of all activities in connection with this.

## The GMP regulations are intended to ensure, for example

- that, in the production of pharmaceuticals, chemical or microbial contamination cannot result from either mistaking constituents or from contamination;
- that the final product contains not only the precise quantities of active ingredients required but that each process is reproducible and has been performed safely so that each batch exhibits a quality in conformity with the specifications;
- that this quality is guaranteed over the entire life (shelf life) of the product.



## GMP and the applicable guidelines cover, inter alia, the following topics:

- Quality Assurance systems, i.e. the entirety of all measures taken in order to ensure that pharmaceuticals exhibit the quality required for the intended use;
- responsibilities and training of the personnel;
- hygiene, particularly microbial contamination by personnel or air conditioning systems;
- the Zone Policy, i.e. the division of rooms into different cleanliness classes for different work steps (e.g. separating the production sections from storage and break rooms) and their inspection;
- the requirement for the creation, approval, distribution, archiving and phasing out of documents;
- quality of the materials – active ingredients and excipients, packaging materials, bulk materials, finished pharmaceuticals, culture media, detergents and disinfectants, their consistent and clear labeling, appropriate storage and quality testing;
- in-process controls during production;
- management of complaints and product recalls;
- regulations for self-inspection (self-monitoring) and for client and governmental audits (external monitoring);
- validation, i.e. producing evidence that techniques, processes and systems in fact lead to the expected results;
- qualification, i.e. producing evidence that items of equipment are flawless, reliable and work as intended within the framework of defined parameters;

## How is this achieved?

- observance of the clothing regulations for the various sections;
- observance of the zone policy;
- observance of personal hygiene (e.g. no jewelry, no decorative cosmetics in various sections);
- verification of the state of health;
- observation of the hygiene requirements in the various sections (e.g. cleaning and disinfection regulations, prohibition of eating, chewing, drinking and smoking);
- performance of inspections in various sections (e.g. monitoring of the microbiological status, in-process control during various production steps);
- training of the persons working at and for GP Grenzach Produktions GmbH;
- Active willingness of our employees to sign on for the training provided, to participate in training sessions and to apply what has been learned;



## Good Manufacturing Practices (GMP)



The machinery may only be used by trained personnel.



The focus is on the product quality.



The products are carefully inspected.

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- Active development of our employees' awareness of the importance of observing the GMP regulations.

### Why is GMP so important?

Together, we must all guarantee and contribute to the flawless and consistent quality and the guarantee of patient safety of the pharmaceuticals and other products which we produce, test and place on the market. This is the prerequisite for continuing to convince our clients and customers of our quality and reliability and this is the basis for the successful development of GP Grenzach Produktions GmbH in the future.



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