General guidelines for the site of Bayer Bitterfeld GmbH with its buildings and people staying there.

Our Values for

Sustainability, Safety, Health and Environment
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General rules of conduct

Access rules

// General

· The instructions listed here have been issued to ensure safety, health, energy and environmental protection requirements based on our integrated management systems. Apart from these instructions, which must always be observed, all employees must also find out about the special dangers in their area of work.

· Before starting work for the first time, employees and non-employees receive documented instruction on the rules of conduct, special operational hazards and the safety and warning devices.

· Non-employees must report to the responsible works supervisor before entering and leaving the area.

· All work must be agreed with the works supervisor before starting work.

// Access to the Site

A personal ID card is required to enter the Site. The card allows you to use the turnstiles at the gates. Depending on the job or company in which you work, this pass enables further access within the company. The necessary rights must be applied for in advance by your supervisor/ coordinator.

The ID card is the property of Bayer and is not transferable. The loss must be reported immediately to the Emergency Response Center (Tel. 2110).

Emergency call
Internal phone 2112
Mobile phone 03494 9781 2112

Helmets are compulsory for cyclists

Parking only in marked areas

Maximum speed 30 km/h
The traffic regulations apply.

Photography/filming prohibited
Exceptions are to be requested from the site management.

Alcohol and drug ban
Persons under the influence of alcohol or drugs are expelled from the site!

No smoking
Exceptions in designated areas.
General

// Buildings

**Infrastructure**
- H 399 Office container
- H 510 Compressed air station
- I 502 Transformer station
- I 542 Technical warehouse
- I 582 Workshop
- K 332 Rainwater basin
- K 370 Transformer station
- K 371 Analysis station
- K 603 Administration
- K 604 Canteen
- K 605 Storage room
- K 695 Social building
- K 750 Scales

**Production area**
- K 400 Project container
- K 501 Logistics area
- K 502 Warehouse
- K 503 Production building
- K 504 Packaging building
- K 505 Production building
- K 506 Canteen
- K 507 Sewage control station
- K 508 Warehouse
- L 401 Office

The exact location of the building can be found on page 7

// Special regulations for the clean room

- Bayer Bitterfeld GmbH is a pharmaceutical company with special access and behavioral rules.
- The production area is divided into clean room classes, in which different rules of conduct apply.
- Before entering the clean room, a separate training course must be completed and the prescribed clothing must be put on.
- The entrances to the production area are the entrances to buildings L401 and K503.
- An automatic driverless transport system is installed in the production area. These vehicles always have the right of way.

Good Manufacturing Practice (GMP)

// What does GMP mean?

GMP means "Good Manufacturing Practice" and includes the guidelines for quality assurance of the production processes and production environment in the manufacture of medicinal products and active ingredients. The GMP guideline valid for the EU is the “EU GMP guideline for human and veterinary medicinal products”. In pharmaceutical production quality assurance plays a central role, since here deviations can have a direct impact on the consumer's health. Bayer Bitterfeld GmbH holds a manufacturing license for medicinal products. Thus, the above guidelines also apply to us.

// Why is?

The required quality of a medicinal product is not based on the final control but rather on all upstream processes that can influence the product quality. These range from suppliers of raw materials/packaging materials, manufacturing processes, analytics, storage and shipping to employees, hygiene, buildings and technical equipment. The quality management system (QMS) forms the basis and framework for all associated activities.

// What is important?

- Compliance with personal hygiene in the cleanroom area (e.g. washing and disinfecting hands, no jewelry)
- Compliance with clothing regulations
- Checking the status of health
- Compliance with general hygiene requirements (e.g. cleaning and disinfection regulations, eating, chewing and drinking bans)
- Carrying out controls in various areas (e.g. monitoring of the microbiological status, in-process controls)
- Training of employees and non-employees

If you have any questions or comments, please contact the specialist department.
Integrated management

// HSE policy

Safety, energy efficiency, health and environmental protection are for Bayer Bitterfeld GmbH corporate goals of equal priority alongside economic efficiency and customer orientation. As a company that operates an integrated management system according to the ISO 14001, 45001 and 50001 standards and has it checked by external certification bodies, we follow the following principles:

- Consideration of legal and other requirements
- Annual HSE goals and measures to achieve them
- Eliminating hazards and minimizing risks to safety and health at work
- Purchasing energy-efficient products and services
- Considering energy efficiency options when new, modifying or renovating equipment and facilities
- Preventing adverse environmental impacts of air, water and soil e.g. by avoiding noise and preparing for emergencies
- Open dialogue and continuous information.

You can find the current version of the HSE policy in the central notices or on request: www.bayer.com/de/de/bitterfeld-kontakt.

// Contact for assistance

- System management officer (Head of HSE)
- Energy manager/energy team (site engineering)
- Safety specialists/safety and health officers
- Workers council
- Occupational physician/first aider

Energy management

// Everyone can contribute

Energy efficiency, as a company goal of equal importance, means for Bayer Bitterfeld GmbH to reduce the consumption of energy in a sustainable way. Thus, in addition to the direct and indirect greenhouse gas emissions, energy costs are also reduced. Environmental and safety-conscious work also contributes not insignificantly to this.

In order to do justice to this topic, an energy management system in accordance with DIN EN ISO 50001 was implemented in 2013. The energy team forms an essential part of the energy management system. At regular intervals there is an exchange on energy-related topics. Projects are initiated that are intended to help achieve the BAYER Group goal: “Climate-neutral by 2030”.

In addition to the energy team, your commitment is also in demand. Because you, too, have slumbering ideas about recognizing and using potential energy savings.

Example of a savings potential: Optimization of the cooling capacity
Environmental protection

// Waste

The HSE department provides support with the professional disposal of all waste generated in the company.

There is an established waste management and contacts in all companies routine processes are handled by the control center. Special disposals are to be reported to the Head of HSE.

It is forbidden to take rubbish with you! Violation is considered theft and will be prosecuted.

// Sewage

There is a separate sewage system on the site. Uncontaminated water (e.g. rainwater) is transferred to the chemical park via a retention basin.

Waste water from production is treated in the sewage treatment plant. Irregularities in waste water disposal (e.g. incorrect discharge, material leaks) must be reported to the emergency response center immediately.

It is forbidden to dispose of chemical residues, batch residues, including residues of cleaning agents and disinfectants via the waste water.

// Emissions

Spilled or leaked substances are to be treated according to the operating instructions. In the event of substance emissions, the control center must be informed immediately via an emergency call. If there are no special operating instructions, assistance from the plant fire brigade must be requested via the control center.

// Dangerous goods

Dangerous goods are characterized by the fact that they are dangerous goods that are transported (transport law). In contrast to this, the law on dangerous substances deals with the handling of dangerous substances in the company. At Bayer Bitterfeld GmbH there are specially trained personnel for shipping dangerous goods.

Occupational health and safety

// General rules of conduct

- The use of mobile phones is NOT permitted without restrictions. The respective department regulates the release.
- The workplaces, recreation and changing rooms as well as sanitary facilities must always be kept clean and tidy.
- Every employee is obliged to report possible sources of accidents.
- Tools/aids may only be used if they are in proper/tested condition according to the german law (Betriebssicherheitsverordnung)
- Each employee and non-employees must wear the prescribed work clothing and protective equipment.
- Traffic routes, emergency exits, escape routes and access to rescue and extinguishing equipment are marked as such and always kept clear.

// Work with a permit

Work involving special hazards requires a permit.

These include:
- Working in containers, pits and confined spaces
- Working at heights (including roofs, pipe bridges)
- Working on electrical systems
- Working with a risk of fire or explosion
- Working on safety devices

Working for that require a permit may only be started when all necessary safety measures / precautions have been taken and the corresponding release authorizations have been signed.
Occupational health and safety

Occupational health and safety are mutually dependent and are seen as a unit at Bayer Bitterfeld. For example, the committee for both topics is held in one event. Chaired by the management, the committee meets 4 times a year.

In addition to presenting the current key figures, operational occupational safety, health and environmental protection issues are discussed.

Our holistic approach includes measures such as:

- Preventive assessment of hazards/stress
- Occupational health care and prevention
- Protection of special groups of employees, e.g. Pregnant women
- Observance of the basic rules of ergonomics

SIGI program

As part of the integrated management system, HSE targets are defined annually. There is a special program for coordinating and directing the measures to achieve the goals.

Instruction

Every employee is trained when they are hired and thereafter generally at least once a year in the specific dangers associated with their employment.

Personal protective equipment PPE

All employees receive, if necessary: Work clothing, safety shoes, protective goggles, hard hat and other protective equipment such as gloves and respiratory mask. Every employee is obliged to use the PPE provided.

Risk assessments

The risk assessment describes the process of systematic identification and evaluation of all relevant hazards to which employees are exposed in the course of their professional activity. These include risk assessments for:

- Activities (occupational safety law)
- Work equipment (industrial safety ordinance)
- Hazardous substances (hazardous substances ordinance)

The risk assessment must be carried out before starting the activity, commissioning or use and regularly to repeat.

The central repository can be viewed by all employees. Work equipment may only be used after instruction!

Restrictions on employment

Restrictions apply to certain groups of people. These include pregnant women and young people. Separate risk assessments are carried out for these groups of people.

Hazardous substances

Hazardous substances are used in the company, which are primarily to be found in the laboratories, warehouses and in production. When handling these substances, special caution is required. Details on material properties with protective measures, hazard warnings, rules of conduct, first-aid measures can be found in the operating instructions in accordance with §14 of the Ordinance on Hazardous Substances. These are usually on site. Safety data sheets are stored centrally in the control center and can also be viewed online.
Occupational health and safety

// Escape and rescue plans

There are escape and rescue plans in every building/floor. These are used for orientation and identification of:
// Rescue and fire protection facilities
// Meeting points and assembly points.
Familiarize yourself with the plan before entering a floor.

// First aid

Employees are legally obliged to provide first aid as far as possible. Each department has trained first responders who should be consulted. Additional first aiders can be alerted via the transport technology or the plant fire brigade. At the same time, the emergency call must be made immediately.

Internal phone 2112
Mobile phone 03494 9781 2112

Fully automatic defibrillators are located in the site, which end cardiac arrhythmias with targeted electric shocks and can thus prevent sudden cardiac death. They can be operated by anyone (including non-first aiders).

First aid kits with first aid material are installed at central points. These facilities are entrusted to the care of the staff and may only be used in the event of an incident. After use, first aid kits must be exchanged.

// Incident investigation

In order to avoid similar or comparable events, it is necessary to investigate the incident quickly. This should be done with the person concerned, HSE, works council and supervisor on the same day, the following day at the latest.

Employees of external companies

// General

The following applies during the stay of employees of external companies on the site:

The instructions in this brochure must be followed without restriction!

The responsible coordinator of the commissioned company undertake to disclose the content of these safety instructions including the safety and regulatory regulations (SOV) to the employees or subcontractors employed by him and to ensure that they are observed. He also undertakes to comply with the statutory working time regulations for his employees.

// Access regulations

The operational coordinator applies for the external company employee's access authorization to the plant. A distinction is made between:

// Visitor ID - max. 5 days (no special right, only fence)
// Short-term ID - max. 4 weeks (without photo with special right)
// Permanent ID - (with photo and special right)

The ID is to be worn constantly. External company employees are generally given a factory entrance. It is imperative to observe the parking regulations!

Plant security carries out random checks at Gate 1 and stationary traffic (parking regulations).

External companies may only enter the factory premises for loading and unloading and for material transport with the company vehicle. External company personnel with private cars must park in the outdoor car park.

// Waste disposal

Waste from material that a service provider brings with him must be taken away and disposed of himself. The service provider may dispose of waste originating from BBG materials (e.g. building rubble, scrap metal, cables, etc.).
Employees of external companies

// Before starting work

Before starting work, the employee of the external company must register with the person responsible there and be instructed. In principle, access to the correspondingly marked areas is only permitted if the employee has properly registered with his client.

Each employee must remain in his or her work area at all times.

The operation of machines and equipment outside one's own work area is prohibited.

// Work equipment

All work may only be carried out with flawless and tested tools, auxiliary equipment and PPE. Devices with a test period may only be used if the test period has not expired. (Evidence of inspection sticker/inspection book on site) BBG equipment may only be used by external companies in justified exceptional cases with separate instruction.

When working with ladders and scaffolding, it is important to observe TRBS 2121 (including parts 1 and 2). Only special overshoes may be worn on ladders and scaffolding in the clean room area. These feature a red rubber sole. (Talk to your company coordinator.)

// Protective measures

All external company employees must wear additional protective equipment required by the work permit in addition to the protective equipment prescribed for the employees. The equipment will not be provided by Bayer.

Behavior in case of emergency

// Behavior in the event of events involving people

If, despite all the precautionary measures, an event does occur, please follow the following course of action.

**event**

Are people injured?  
NO: Report unsafe action.  
YES: Request first aid via the emergency response center

First responders on site?  
NO: Report first aid case  
YES:  

Do you need to see a doctor?  
NO:  
YES: EMERGENCY CALL 2112

It is essential that a person be posted at the entrance to the building.

The ambulance receives a note accompanying the accident at the gate with information on any substances involved, on the trade association (BG RCI) and the telephone number for the return transport.

// Emergency call

Who is calling?  
Where did it happen?  
What happened?  
Who is injured?  
What injury?  
Was first aid given?
Behavior in case of emergency

// Alarm devices
Any person who detects a danger must report this immediately to the control center. The control center initiates all other necessary actions. There are two additional support functions in the production area:
// Incident coordinator (EFKO)
// Fire brigade instructor
The fire alarm system reports a possible fire event in its catchment area directly to the plant fire brigade and parallel to the emergency Response center.

// Fire extinguisher
After reporting and securing the scene of the event, taking into account self-protection, firefighting can be started using a fire extinguisher. The location of the nearest fire extinguisher is in the escape and rescue plan. In the event of danger, leave the danger zone and go to the assembly point outside the building. Fire extinguisher training courses are held for all employees at regular intervals.

// Assembly points/collection points
At the assembly points and meeting points, completeness is recorded using a works ID card. All persons present must register with the works ID, so the control center can determine which persons are missing. The collecting points are integrated into the operational warning system and are further informed. There is the additional possibility of contacting the control center via intercom/telephone. Nobody is allowed to leave the seat without signing off. Further instructions from company/fire brigade/emergency response center are to be awaited.

Behavior in case of emergency

// Alarm order
The buildings of Bayer Bitterfeld GmbH are equipped with a comprehensive fire alarm system and an operational warning system.

In the case of emergency, people in the buildings are alerted by acoustic signals and voice announcements. A distinction is made between four warning tones.

Advance warning
Announcement: "The fire brigade has responded to a reported damage event, further information will follow."
Behavior: An alarm has been received by the emergency response center and is being checked by the fire brigade on site. Increase attention, an alarm could follow.

Internal alarm
Announcement: "Hui - Hui - Hui"
Behavior: Danger in the building, go to the collecting point outside the building quickly and safely. Pay attention to your colleagues and outsiders.

External alarm
Announcement: "Tut - tut - tut"
Behavior: Danger from outside, do not leave the building. Close all windows, go to the collecting point in the building. Watch out for your colleagues and strangers.

All clear
Announcement: "Gong"
Behavior: Cancellation of previously reported hazards. Collecting points may be left.
Alarm order in the industrial park

Behavior with "internal alarm"

- Alarm: Crash-Ton: Hui - Hui - Hui...
- Announcement: Warning text

What needs to be done?
- Immediately go to the collecting point, outside the building
  (observe the wind direction)

Behavior with "external alarm"

- Alarm: Hup-Ton: Tut - Tut - Tut...
- Announcement: Warning text

What needs to be done?
- End the activity safely.
- Close windows and doors.
- Go to the collecting point, inside the building

All clear (alarm over)

- Alarm: Gong
- Announcement: .. there is no longer any danger..

What to do in the event of an accident / fire / environmental hazard

- Inform the Bayer Bitterfeld GmbH emergency response center!
- Internal phone 2112
- Mobile phone 03494 9781 2112