Optimizing Pharmaceutical Processes

Ravensburg Vetter West (RVW)
Center for Visual Inspection and Logistics

Project Completion June 2017

Application for Facility of the Year Award 2018
Category Operational Excellence

Vetter Pharma International GmbH
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A unique site that optimized the supply chain

According to industry experts, the demand for drugs in prefilled injection systems will continue to grow. Meanwhile, government agencies around the world are increasing their regulatory requirements. Due to these developments, pharmaceutical and biotech supply chains have gained far greater significance. That is why Vetter built Ravensburg Vetter West (RVW) – to bundle all supply chain processes within a single, innovative structure that stands ready to meet any future requirements. The site offers the company’s customers outstanding efficiency, flexibility, safety and sustainability, and is setting influential standards for the industry worldwide.

Vetter is a Contract Development and Manufacturing Organization (CDMO) and a global leader in its field. The company has considerable experience in many areas, most notably early drug development and clinical and commercial filling utilizing various packaging systems, from vials and cartridges, to syringes. Vetter’s customers include small and medium enterprises as well as the top 20 leading pharmaceutical and biotechnology companies. Having a global headcount of approximately 4,300 employees, Vetter is headquartered in Ravensburg in the south of Germany. The company operates production facilities in Germany and the USA, and maintains sales offices in Japan, Singapore and South Korea.

More capacity, more services
Vetter decided to increase its capacity for visual inspection and warehousing of pharmaceutical products due to a steady increase in customer requests, as well as stricter guidelines initiated.

<table>
<thead>
<tr>
<th>RVW in figures</th>
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<tbody>
<tr>
<td>Net building surface</td>
<td>50,000 m²</td>
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<tr>
<td>Total staff</td>
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<tr>
<td>Pallet capacity 15°-25° C</td>
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<td>Pallet capacity 2°-8° C</td>
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<tr>
<td>Chest freezers</td>
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<td>Constant climate chambers</td>
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<td>Incubation chambers</td>
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<td>Loading and unloading ramps</td>
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<td>Media availability</td>
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<tr>
<td>2 Block heating and power plants</td>
<td>5.5 mn kW/year</td>
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<tr>
<td>Heating output</td>
<td>4,800 kW</td>
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<td>8 emergency generators</td>
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<td>Circulated volume of air</td>
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by regulatory agencies. Unfortunately, its existing facilities did not offer an effective alternative for expanding or optimizing the overall logistical infrastructure. As such, a completely new structure was needed; one that was able to meet capacity demands and allow for process optimization. The plan was to erect an autonomous site in an area of Ravensburg that could act as a central hub for all of the company’s logistical processes. It also had to include extremely efficient processes, flexible use of space and options for expansion if necessary. Environmental concerns and energy efficiency were also prioritized.

Creating a state-of-the-art center that would meet all of the requirements for visual inspection and logistics was deemed to be the best solution. Ravensburg Vetter West was built in a modular way: The commissioning of the first construction stage began in 2012, and the commissioning of the second in 2016. The site provides warehousing for cold storage and room temperature products, capacity for freezers, constant climate chambers, and state-of-the-art incubation chambers. Visual inspections can be performed manually or automatically. RVW also features a lab for testing packaging materials, storage space for auxiliary materials, a central archive, and two hundred office work stations. The departments and staff from an existing Vetter building were moved into the new location in 2017, and all capacities for visual inspection and logistics bundled.

The following key features have been optimized at RVW:

**Efficiency:**
- A hub for an intelligent, facility-wide logistical concept
- Extensive automation
- Optimized spatial concept, with short paths for material flows
- Streamlined and carefully coordinated work processes
- Continuous process optimization
- Precise and anticipatory project planning

**Flexibility:**
- State-of-the-art storage with a distinct temperature areas
- Capacity for manual and automated visual inspection
- Material and products that are quickly available
- Optional expansion flexibility of either the existing space or the site itself

**Security and safety:**
- Strict segregation of material flows according to temperature
- cGMP standards or better
- High supply and process safety
- Ultra-modern workspaces
- Comprehensive operational safety and building security concept

**Sustainability:**
- Holistic energy concept
- Certified sustainability standards
- Comprehensive use of regenerative energy
- Exceeds Germany’s energy savings norms
- Reuse of waste heat and treatment of water

**Unique combinations**

What makes the RVW facility unique is the intelligent combination of all these features. Vetter is now better prepared to satisfy the growing needs of its customers, fulfill the requirements of official agencies, and meet the challenges of the supply chain of tomorrow. The world’s international pharmaceutical and biotech companies are not the only beneficiaries. Patients too, will experience positive results.
Segregated products and safe processes

RVW is a state-of-the-art facility that bundles all processes required for transportation, warehousing and quality control of pharmaceutical products. The building was designed to comply with established cGMP guidelines so it could meet the highest technical and quality standards.

The facility’s concept is based on the idea of a supply chain with optimized product flows that is not only extremely safe, but incorporates perfectly harmonized processes. RVW has ample capacity for logistics and visual inspection, constant climate chambers for stability tests, as well as incubation chambers for microbiological quality control of customer products. The facility also has a packaging laboratory and an independent warehouse for technical materials and hazardous substances (e.g., disinfectants, cleaning products, etc.), which, by law, must be stored separately. A comprehensive material tracking system has been implemented to secure the supply chain processes. In addition, all products are registered the moment they arrive at the site. That means they can be rigorously tracked throughout the entire supply chain.

Intelligent cold chain management
Immediately upon delivery, products are strictly segregated according to their temperature. As such, room temperature products (15 – 25 °C) and cold storage products (2 – 8 °C) can be transported, stored and inspected separately according to pharmaceutical guidelines. Guaranteeing the integrity of the cold chain throughout for cold storage products is crucial. Vetter achieves this through the application of a variety of systems that are deployed and linked intelligently, guaranteeing predefined temperature areas that are precisely matched with the stringent requirements for pharmaceutical products.

The high-bay storage area is divided into two temperature zones with automatic temperature and humidity control (in the 15 – 25 °C area). There are 26,500 pallet spaces for room temperature products and 7,100 for cold storage products, so that substances, primary packaging materials and filled-and-finished injection systems can be stored...
under cGMP conditions and consistent climate conditions. This unique concept extends to product handling as well. Special loading ramps and hub zones in the 2 – 8 °C range avoid temperature fluctuations even when products are being loaded or unloaded. The visual inspection area at RVW has been designed in the same manner. Products are placed in special preparatory zones, which are cooled to 2 – 8 °C, prior to being manually or automatically inspected in a class E cleanliness area.

The visual inspection is directly connected to the high-bay storage area by means of an interim storage space, which is either cold or room temperature. Pallet conveyor technology is used to move the products. From there, according to incoming orders the batches are transferred to the preparation chambers, which can be cooled if need be, and deposited in front of the inspection chambers, avoiding any potential mix-up of the batches.

**Safety comes first at RVW**

There are seven chambers with enough space for a total of 317 chest freezers for storing raw materials. Each chest has a volume of 556 liters and storage temperatures that range from -20 to -80 °C. The pharmaceutical substances, which are often highly sensitive and very valuable, are stored in these chests under strict safety standards. To make sure the freezers are always in operation, RVW offers multiple emergency power supplies and back-up chests. Furthermore, each chest has an own emergency liquid nitrogen cooling option in the event the power should fail altogether. Dry ice is also on hand to ensure that the raw materials can be sufficiently cooled for short periods, for example, during transportation.

Thanks to a comprehensive security concept, Vetter also guarantees operational and building security for the entire RVW facility. Among other items, this concept includes an automatic monitoring and alarm system for temperature and humidity regulation, a multiply-redundant power supply, a facility-wide fire alarm and sprinkler system with a 1.5 million liter water supply, and approximately 40,000 sprinkler heads. Permanent video surveillance, selective access control, a 24-hour guard service and an independent radio connection with all other company facilities are also key components of the RVW security concept.

**Officially approved security and safety**

International regulatory agencies have already certified RVW as meeting cGMP quality standards. Since the facility was first put into commission in 2012, it has been inspected a total of nineteen times. Sixteen inspections were successfully completed. Three others, including one by the FDA and one by a local German authority in September and October 2017 respectively, are still “waiting for acceptance.”

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**List of RVW’s inspections**

Status: November 2017

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<th>Year</th>
<th>FDA</th>
<th>ANVISA Brazil</th>
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<th>MFDS Korea</th>
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<th>Turkish Authority</th>
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Bundled innovation

RVW features a significant number of innovative solutions that make it unique, including flexible options for utilizing space and expanding the site, solutions tailor-made for customer needs, optimized paths and transportation systems, as well as an outstanding system that guarantees a stable power supply.

Flexibility in space utilization and future expansion were already being considered at the earliest planning phases. RVW was built in a modular manner, in two successive construction stages to allow for full integration following completion. Connecting pathways between the two sections for staff and material were opened up shortly after the second construction stage was finished and were part of the original blueprint. This concept was applied to the facility’s next construction stage, which has already been planned. The technical equipment for power, climate control and fire prevention have also been set-up for an increase in capacity. Thanks to the modular design, Vetter can enlarge the facility successively in the event of customer demand with running operations not impacted in any way. Flexibility for new construction projects was also foreseen inside the building. As an example, the potential for creating need-based cold storage out of room-temperature storage areas is possible.

Fast storage and retrieval

RVW combines state-of-the-art logistics with optimized processes for visual inspection, making the supply chain extremely reliable, efficient and flexible. All routes and processes have been designed for optimal material and staff flows. For example, the receiving area is directly connected to the high-bay storage area. From there, a lock leads to visual inspection and back. This considerably reduces warehousing and retrieval times, in particular when combined with an automatic pallet transportation system, an IT-controlled routing system and an SAP-administered high-bay warehouse.

The intelligent integration of RVW into the company’s overall logistics means that production sites can be supplied quickly and at short notice. Several factors play a key role here, not least of which is the proximity of RVW to Vetter’s three production sites, which are at most, twenty-five kilometers away. Online-controlled product transmission was also implemented, and truck clocking and materials can be delivered fifteen hours a day.

Improving processes

The goal is to continuously increase RVW’s efficiency. To do this, Vetter will steadily optimize all processes by combining well-established technologies with intelligent solutions. For example, in an effort to accelerate partial picking, the company has introduced a special system that involves conveying entire pallets to a goods-to-man workstation. The ordered units are picked from the pallet. Anything that is not needed is returned to the high-bay warehouse. This speeds up the partial picking process by up to 20%.

Vetter places high value on process planning and implementation. The company taps into its extensive experience cooperating with international pharmaceutical companies and biotech firms. In the RVW facility, the CDMO has managed to implement processes that are tailor-made to respond to the individual requirements of its customers while meeting the demands of regulatory agencies.
Significant Contributions in Project Uniqueness and Innovation

Unique redundancies for the power supply
To help ensure round-the-clock integrity of product and processes, the energy supply system of the RVW facility boasts a six-fold backup. This equates to RVW being prepared for any type of power-cut scenario. The basic power supply comes from the public grid. Medium voltage (20,000 volts) ensures grid stability and is switched to 400 volts in a transformer station at RVW. Two independent cables, each of which can carry enough power to supply the entire facility, ensure redundancies as a first line of defense against a power cut. If both cables are somehow damaged, two autonomously driven standby power units (one per site section) take over. Each unit can supply one or both sections of the building with medium voltage.

Should these two 20,000-volt plants also fail, two additional standby power units are available to supply low voltage (400 volts), and can secure the supply of all temperature-critical areas like cold storage, chest freezers, incubation chambers, constant climate chambers, etc. The low voltage units can be replaced directly with mobile 400-volt standby power units. And, because both sections of the building are connected by a medium-voltage and low-voltage cable, each can tap into the power supply of the other. As a final backup system, the sixth redundancy, each chest freezer is connected to an automatic emergency liquid nitrogen supply. A six-fold redundancy is, for all intents and purposes, unique within the pharmaceutical industry.

RVW’s energy supply system

1 Order picking: complete pallets from the high-bay storage
2 Pallets transported by conveyor to the good-to-man workstation
3 Partial picking is performed at the good-to-man workstation

The sixfold backup of the power supply system guarantees the site’s integrity in emergencies.
Beyond regulatory norms: Samples from each batch are checked at the packaging materials testing lab.

Top quality conditions

A key priority at Vetter, and one without compromise, is ensuring the highest possible quality of the customers’ pharmaceutical and biotechnological products. That is why the company has set the highest quality standards throughout the RVW site. In some areas, they actually exceed accepted regulatory guidelines. The high media availability supports this quality claim: At RVW, it is near 99.8%.

High quality standards were always an integral part of the planning for the facility’s design. Short transportation routes, direct connections between individual areas, strict segregation of material flows, and extensive automation reduce risks and sources of error to a minimum. Each process is audited several times as part of the company’s stringent quality management system in order to meet the growing needs of both the market and customer in the long term. All equipment and systems run smoothly due to a tight service and maintenance schedule.

Beyond cGMP guidelines

Vetter’s process and quality standards are quite often more stringent than accepted cGMP regulations. The cold chain at RVW, for example, stretches from the product receiving area to distribution, readying for visual inspection and, finally, shipping. The visual inspection area has separate rooms that have been optimized for the Japanese drug market, where regulations are among the world’s strictest.

The packaging materials delivered to the company are also checked in a special laboratory designed according to the latest standards. Thirty-five employees work under cGMP conditions and inspect samples for cosmetic, functional and pharmaceutical defects. Rather than rely on the usually prescribed skip load, Vetter takes samples from each batch – up to 900 per month. At the lab for packaging materials, a number of factors ensure the quality level, most notably, one-way product routing and optimized working conditions for manual inspections (e.g., large inspection rooms, ergonomically designed work stations, gentle lighting for the eyes, etc.). Semi-automatic solutions are yet another way to ensure quality, for example, to check the dimensions of packaging materials, or to inspect the release mechanism on a pen injector.

Priority: back-up and safety systems

All RVW storage areas have been equipped with a complex back-up system to ensure the integrity of the semi-finished and finished products that need to be kept under specific climate and temperature conditions, even if the main systems should fail. Multiple back-up systems are in place for the power supply for climate control, heating and cooling systems. Any abnormalities or failure will be picked up by a monitoring system that sends out an alarm and quickly activates the backup.
RVW is the central hub for all logistics at Vetter and serves as an interface for three production sites, fourteen cleanrooms and the Packaging Service, which supports the company’s customers in all issues concerning suitable secondary packaging. Site centralization saves the company about 865,000 euros annually. Optimally and continuously harmonized processes are the only way Vetter can implement in-time preparation and rapid processing of the products for each station in the supply chain.

Products arrive at the site by trucks via delivery ramps. The clocking of the trucks and movement of the goods is tracked using an online tool. Logistics companies can use this tool to book a particular window of time during which they can deliver their wares. Receiving and shipping inventory can therefore be scheduled with greater accuracy and processed rapidly, avoiding rush hours and waiting periods. After registering the goods, if need be, a sample can already be removed under cleanroom conditions (class C cleanroom). All samples, be they Vetter’s or a supplier’s, are immediately sent to the packaging materials testing laboratory, where they are checked for quality.

The high-bay storage area has over 33,000 spaces for room temperature and cold storage products. Extensive automation reduces manual work and streamlines processing. The products are transported to the storage section by means of a fully-automated pallet conveyor that can perform up to 200 movements per hour. Distribution to the separate storage spaces is completed by employees using high-bay forklifts. An IT-controlled routing system assists by finding the most efficient way to store the goods and avoid empty transports or cross-routing. The forklift drivers can perform up to 200 storage and retrieval actions in an eight-hour shift. A modern warehouse management system with SAP administration performs permanent inventory taking so the company has always a complete overview of current stock in real time.
Making Significant Contributions in Operational Excellence

Optimized conditions for visual inspection

Visual inspection is adjacent to the warehouse, a proximity that allows Vetter to make products to be inspected available according to incoming orders and with very little lead time. In fact, it takes only twenty minutes to supply visual inspection with materials from the storage area i.e., from the time of the order to delivery to the control room. Vetter gives its customers the choice of manual or automated visual inspection. The highly complex Automated Visual Inspection (AVI) machines at Vetter can check up to 400 syringes per minute in fully-automated mode. The filled syringes have to pass through as many as fourteen inspection stations that utilize high-resolution cameras, lighting systems and specially developed sensors to measure absorption and refraction. Syringes that appear to be defective are removed from the machine and taken to a special area for a manual follow-up inspection. Automated Visual Inspection ensures uniformly high quality due to an objective assessment of the product and lowers throughput times. It also allows Vetter to offer a higher inspection capacity if, and when, the volume of customer products increases at a later date.

To maintain consistently high quality in the Manual Visual Inspection (MVI), Vetter has created optimal work conditions for employees. The 347 work stations are located in spacious areas and have been ergonomically designed, with special chairs, height-adjustable tables, table profiles that are adapted to the employee’s posture, and individually adjustable control panels. An intelligent climate control system provides a constant room temperature and good air circulation to avoid drafts at the work stations. The lighting was also designed to be ‘easy on the eyes’, being uniform and pleasant for inspection tasks. The rooms have been properly sound insulated. Special ceiling elements optimize the acoustics and give the employees a space that is pleasant to work in, without any disturbing noise. Tablets are introduced to the division and allow for complete digitizing of documentation and signaling the end of paper usage. This ensures palpably reduced timing for individual process steps and a reduction in the sources of human error.

Fast and secure delivery

Vetter has been certified as an “Authorized Economic Operator Full (AEO-F),” which means the company can provide its customers with optimal support further down the supply chain. For instance, this internationally recognized certification simplifies and accelerates customs procedures. This, in turn, shortens transportation times and eases implementation of pharmaceutical guidelines for transit periods. To support rapid and safe delivery by air freight, Vetter has also acquired certification as a “Known Shipper.” Sensitive pharmaceutical products will therefore, not be subjected to inspections that could damage them. This certificate is a real added value both for the company and its customers as save time and lower expenses along international supply chains.
Precise project planning and controlling

Vetter was able to complete RVW on time and within tight budgetary limits thanks to extremely careful project design and administration. This required a combination of integrated project management, internal know-how, and cooperation with tried-and-true external partners.

The intricacies of planning the process, design, schedule and budget for RVW were administered by Vetter itself. As the project progressed, it also required steering, control and inspection, and approval of the individual project segments. The company tapped into its extensive experience with earlier construction projects and the know-how it has garnered over the years. All partners involved had access to a web server that allowed updated information to be shared in real time. This guaranteed fast data flows and verifiable documentation of the project for things such as inspection, control and approval.

Detailed guidelines and strict controlling

To ensure precise planning and control, Vetter drew up a list of very detailed guidelines, specification sheets and delivery policies for all project partners. Other factors in the successful implementation of the project were integration of the approval agencies, clearly defined approval processes, quality and performance reviews at regular intervals and stringent deadline control. The latter was crucial since the overall project involved a tight schedule with over 6,000 connected processes. By consistently connecting interdependent aspects and regularly monitoring progress, Vetter was able to interfere quickly if a deadline could not be kept and immediately applying corrective measures.

Working together with tried-and-true, highly competent partner companies helped keep the project on schedule and also meet the high quality standards demanded by Vetter. Thus, the two construction stages were finished within the set timetable of about two years each and within the set budget.

Transfer during operations

The former Vetter logistics facility located about four miles away from RVW, had already been relinquished by the time the implementation of the second stage had begun. The piece-by-piece transfer to the new site during construction represented a particular challenge. Within the space of six months, approximately 200 employees moved in while operations were on-going. Room temperature and cold storage products, freezers and technical materials were transported in a total of 330 truckloads, including an AVI machine that had to be shut down and then re-installed and validated at RVW. In addition, the change of the storage location of each separate customer product had to be approved by the respective approval agency. Vetter carried out the move without any impact on the availability of its customer products.
For many years, Vetter has consistently made a concerted effort to meet the highest international sustainability standards. The company has already earned a number of key certifications, including the environmental management standard ISO 14000, the energy management standard ISO 50001, and the occupational health and safety standard BS OHSAS 18001. Vetter continued resolutely in this vein when building the RVW site. When planning the site in 2009, the company set itself an ambitious goal for the new building: To surpass the energy consumption limits set by the regulations in force at the time (EnEV2009) by 20%. Today, RVW better the official norms by 24%.

This goal was achieved by implementing a sustainable energy concept that includes building very modern plants with optimal efficiency rates and low energy consumption. All RVW control systems are monitored by specially developed energy management software that continuously adjusts operations for maximum energy efficiency. At the core of Vetter’s energy concept is the ecological combination of various renewable energies:
Significant Contributions in Sustainability

geothermal energy, biogas and solar energy. These different sources of energy are intelligently interconnected to create an autonomous energy source for the entire facility. The net result is savings of 67% of primary energy, with a reduction of 1,600 tons of CO₂ per year at the RVW site.

**Geothermal energy, co-generation plants, solar panels**

Climate control in the high-bay storage area and other part of the building is accomplished using geothermal energy. A complex piping system was installed beneath the foundation with 134 boreholes that reach down 150 meters. The heat from the earth is then be used for heating (425 kW) or cooling (300 kW) the building by processing it with heat pumps.

Two block heat and power plants and a photovoltaic system provide RVW with renewable electric power. One of the two power plants runs on natural gas, the other on biogas from a nearby farm. Block heat and power plants make use of the co-generation principle, meaning that they produce mechanical energy that can be turned into electric power but also produce heat that can be used for the building. As such, they have a high efficiency rate with of up to 90%. The two block heat and power plants at RVW generate nearly 5.5 million kWh of electricity per year, equivalent to the power needed for approximately 1,000 households. Nearly 465 square meters of solar panels on the outside walls of the building produce about 13,000 kWh of electricity annually.

**Sustainable in all details**

The idea of sustainability is a part of every element of the new site. The waste heat of the two block heat and power plants is reused as is the waste heat of other machines, such as the boilers that Vetter uses to heat and cool the building. Rainwater is also collected and reused, in part for the toilets, and in part as evaporation cooling in the re-cooling system of the block heat and power plant. In the technical areas, Vetter installed wear-free machines that do not require oil. They are as much a part of the company’s sustainability concept as the use of long-life, energy-efficient LED lightbulbs in the second construction stage of the building. These are all measures that demonstrate Vetter’s determination to find sustainable solutions at the RVW site, even in the smallest of details.
A Site Unexcelled

Vetter’s RVW facility sets new industry standards for transportation, warehousing and quality assurance of pharmaceutical products. It goes beyond simply meeting official worldwide norms and regulations, and takes these standards to a new level of excellence. The site is worthy of the Facility of the Year Award 2018 in the Operational Excellence category for the following reasons:

1. RVW combines intelligent facility layout, state-of-the-art technologies, and innovative processes, so customers from around the world can be assured of the highest level of efficiency, flexibility, quality and safety in the supply chain.

2. The facility has carefully designed space and optimal working conditions that guarantee that the visual inspection section produces a uniformly high level of quality and faster throughput times regardless of batch size.

3. The building’s modular design allows for simple and gradual creation of more space without expansion work affecting operations. This architecture is a direct response to increasing customer demand for more capacity.

4. Comprehensive safety and security measures and complex back-up systems protect products from a number of potential risks, ensuring integrity of the operations and supply of the facility.

5. The facility’s design concept includes rigorous energy efficiency and environmental friendliness which guarantees sustainable, extremely safe, and, hence, future-oriented supply chain processes.