Special Topic Pharma Logistics

Cold chain logistics - Special field of competence in Glatt's Pharma Logistic Center

To gain customer's trust and confidence in the field cold chain logistics is a big hurdle for a logistics service provider. Please see for yourselves of the comprehensive service setup and the exceptional infrastructure with which Glatt is convincing their customers.

It's the major advantage of the Glatt Group since many years acting in the pharmaceutical industry as a leading player for integrated process solutions: Extensive knowledge and experience gained in the field of developing, processing and manufacturing powder solids, granulating as well as coating and pelletizing … based on this strong and powerful pharmaceutical experience, "missing pieces of the puzzle" have been added in the recent past: Warehousing including packaging activities, project logistics and supply management services complete the picture now.

Let's have a closer look on a special field of competence: The Glatt pharma logistic center has now established a cold chain logistics organization and infrastructure which is state-of-the-art and which exactly addresses the customer's needs.

Temperature ranges

In addition to a high-bay warehouse with 5.000 pallet spaces, fully-automatic operated below room temperature (15-25°C), a cool, frozen and a deep frozen area is being offered, covering required range of temperatures:

- **Cool** (2–8°C)
- **Frozen** (-25°C)
- **Deep frozen** (-80°C)

Figure 1: Insight into the frozen and deep frozen area

The frozen and deep frozen area is flexibly scalable. In case customers are looking for room, area and required infrastructure to be equipped with an additional battery of refrigerators and freezers, Glatt will make an appropriate offer.

Figure 2: Cool products (2 – 8 °C) fully integrated into high-speed commissioning line

Products to be kept under 2-8°C conditions are not only stored in cool rooms, if required, "fast moving" products with a marketing authorization can be placed in a special area in order to integrate them into a high-speed commissioning process ("pick-by-voice").

Monitoring / Storage conditions control

- The warehouse provides temperature monitoring and control systems for all temperature controlled rooms, cold rooms, refrigerators and freezers, used to store temperature-sensitive products
- Each sensor is connected to a multipoint monitoring system with a sufficient determined recording frequency per hour for each sensor position
- Monitoring sensors are calibrated and located where greatest variability in temperature is expected to occur within the qualified and/or tested storage volume
- Electronic temperature records are regularly checked; records are kept according to internal instructions or specific customer's requirements
- The temperature monitoring system is equipped with alarm functions; violation of lower and upper alarm limits triggers an alarm; a certain group of persons has to react accordingly
- In case storage conditions are required such as humidity, light protection, etc., these conditions are provided as well
- In case refrigerators and/or freezers are dedicated to a customer, the customer can be granted access via internet to his product related monitoring data

Comprehensive object and goods protection

Property access is restricted: Fence or outer-shell of the building and electric sliding gate; outer-shell of the building is completely monitored by light barriers and motion detectors

Alert system for the event of burglary, disruption & periodical routine calls

- Acoustical, visual
- Silent, with automatic dialling unit
- Alarm forwarding to central control centre
- Redundant connection: Two separate mobile phone networks: GSM (GPRS) & UMTS

Regular guard walk-throughs by local Safety and Security Service:

- During the night
- At the weekend

Firefighting

- Fire detectors throughout all storeys of the building
- Fire detectors throughout the HIGH RACK WAREHOUSE with 5000 pallet places (Supervision of each HRW row and each HRW level)
- Alarm forwarding to central Control Centre

Rooms, equipment & procedures

Rooms and equipment are appropriate for the class of occupancy and product storage arrangements:

- Rooms and key equipment are qualified, key processes and software systems are validated
- Equipment is regularly serviced in accordance with the equipment manufacturers' recommendations and local regulations
- Goods receipt and goods dispatch area are designed to avoid conflict be-tween incoming and outgoing goods and are protected from direct sunlight, dust, dirt, rain, snow and wind, and from extremes of heat, cold and solar radiation that could damage the products
- Pest control system is activated

- Deliveries are examined at receipt in order to check that containers are not damaged and consignment corresponds to the order
- Pharmaceutical products are promptly transferred to the appropriate warehousing area where cautions are taken to avoid that any non-authorized individuals could enter warehousing areas
- A cleaning program for all temperature controlled rooms is implemented, floor areas are fully accessible for cleaning
- Goods are not stored directly on the floor and storage is not permitted for any non-pharmaceutical products except transport-related items such as icepacks, gel packs and the like
- Waste is collected in designated closed containers and arranged for safe disposal at frequent intervals

Personnel

- Personnel involved in the logistics activities are competent on the basis of appropriate training in the requirements of cold chain and the handling of temperature sensitive products
- Personnel training on cold chain requirements are based on written standard operating procedures (SOPs); they receive initial and continuing training relevant to their tasks, in accordance with a written training program covering at least:
  - Applicable pharmaceutical legislation and regulations
  - SOPs and safety issues - Response to emergencies
- Trainings are assessed as applicable to evaluate the effectiveness of the actions taken; appropriate records are maintained, including details of subjects covered and participants trained
- A responsible person, acc. to drug law appointed by the management and having clearly specified authority is responsible for ensuring that a quality system is implemented and maintained; Glatt's group of Qualified Persons is continuously working on guidance for topics on quality assurance, quality control, quality improvement and quality risk management

Power supply / Emergency power generator

The cooling systems are either redundant or the equipment is available in duplicate wherever possible. This not only allows load distribution between the systems in normal operation, a backup system is then also available should a unit fail once.

The power supply of the entire logistics centre is secured in every case. A high-performance emergency power generator is activated automatically in the event of a total power failure.

Quality Management System / Documentation

SOPs cover, among other things:

- Methods for pharmaceutical products requiring specific warehousing conditions
- Drug orders and shipments preparation (including a description of the shipping configuration of the protective package used and taking into consideration the requirements for labelling, sealing and warnings for the shipment and warehousing activities
- Use of equipment and instruments related to the cold chain (refrigerator, cold room, freezers, etc.
- Calibration of monitoring and regulation instruments dedicated to cold chain equipment
- Verification of the pharmaceutical product condition and labels in the receiving area (required verifications to ensure that containers have not been opened)
- Management of specific warehousing; labelling policy and others that include cleaning, alarm management, qualification of thermal equipment, qualification of transport system, etc.
- Handling of complaints, returns, suspected falsified drug products and drug product recalls

- CAPA handling
- Self-inspections

Records of investigations and actions taken in the event of excursions outside predetermined temperature conditions, as per labelled storage conditions are kept for a determined period according to internal instructions.

Documents and in particular instructions and procedures relating to any activity within the cold chain logistics that could have an impact on the quality of pharmaceutical products, are designed, completed, reviewed and distributed with care. They are available at all time and reviewed regularly.

Convinced that Glatt should be your reliable partner in the field of cold chain logistics?

A long and deep experience in the development and manufacturing of galenic dosage forms, now complemented by a profound know-how in the areas of warehousing, packaging and worldwide distribution solutions enables Glatt to offer you an extraordinary service portfolio.

Interested to get more Information? Get in touch with us:

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