axicorp Pharma GmbH complies with Good Distribution Practice (GDP) as stated in Directive 2013/C 68/01.

Does the axicorp Pharma GmbH have a wholesale permit?
Yes, our registration number is DE_HE_WDA_2019_0043/ II 23.1 Co 18 L 18.01/1053-B, issued: 24.04.2020 by Regierungspräsidium Darmstadt, Germany.

In accordance to the GDP Guidelines a responsible person (RP) is designated (i.e. Anna-Karina Gerner). The RP meets the qualification and all conditions provided by the German legislation. The RP has delegate some duties to other competent personnel (e.g. QP, Personnel of Purchase Department). The role, responsibilities, and interrelationships of all personnel is clearly indicated (e.g. job descriptions, SOP, working instructions).

Does the axicorp Pharma GmbH have a manufacturing permit?
Yes, our registration number is: DE_HE_01_MIA_2020_0046/II23.1 (Co) 18 L 18.01/1053-B, issued: 24.04.2020 by Regierungspräsidium Darmstadt, Germany.

Is the axicorp Pharma GmbH routinely inspected by authorities?
Yes, according to national law we are inspected routinely by the respective authority Regierungspräsidium Darmstadt, Germany.

Does the axicorp Pharma GmbH have a quality system?
Yes, our quality system is based on national law, EU-GMP/GDP Guidelines and ISO 9001:2015. All of our working processes are defined by standard operating procedures, work instructions and/or written processes. The staff has defined responsibilities and is trained according to the respective work field. A system of quality assurance is in place to ensure deviation management, change control system, pharmacovigilance, risk-management, complaint management, qualification/validation and qualification of suppliers.

How are pharmaceuticals transported?
All pharmaceutical products are transported by qualified suppliers.

How are pharmaceutical products received and stored?
Upon arrival the pharmaceutical products are inspected for their correct origin and identity, as well as for damages. The receipt of cold chain products is prioritized, after passing the checks for incoming goods they are immediately transferred to the appropriate climate chambers.
Our warehouse and production area has a controlled climate system with monitored temperature between 15 – 25°C. Cold chain products are stored in climate chambers, where the temperature is controlled to be within 2 – 8°C. Temperature is checked daily by QA staff. In the unlikely event of unspecified storage temperatures the climate system is connected to an alarm system. The warehouse is separated into different storage areas for raw materials, released products, returned goods, blocked products and recalled products. Physical separation of goods is supported by our computer system. The storage and production area is under surveillance of an intruder-alarm-system.

We ensure that the level of quality of products as determined by GMP is maintained at axicorp Pharma GmbH.

Friedrichsdorf, 18.06.2020

Dr. Katrin Hofmann
Head of Quality Control & Quality Assurance

Dr. Achim Berthold
COO Operations, Quality & Drug Safety