kohlpharma

Quality Assurance for Wholesale Business

GDP-Self-assessment

1. **The Company**	**Description**
Name of the company	kohlpharma GmbH
Address	Im Holzhau 8, 66663 D-Merzig
Country	Germany
Website	www.kohlpharma.com
Responsible person for wholesale according to GDP	Dr. Christoph Frick, PhD
Phone	+49 (0) 6867 / 920-3201
Fax	+49 (0) 6867 / 920-3208
E-Mail	cfrick@kohlpharma.com
Founding	3rd October 1979
Number of employees engaged in Quality Assurance	8
PRODUCTS	☒ Medicinal Products (human) ☒ Blood Products ☒ Medical Products ☒ Narcotics/Controlled Substances ☒ Hazardous Substances / Cytostatics
Pharmaceuticals are purchased from	☒ Exclusively from authorized and qualified companies with an appropriate permission
Valid GDP-Certificate	☒ A copy is attached hereto.
Date of the last official GDP-Inspection	15th March 2017
Name of the inspecting authority	Ministerium für Gesundheit und Soziales
We have a permission to act with narcotics and blood products	☒ Is available.

Further information according to GDP from 05th October 2013:

2. Quality Assurance		**Yes**
2.1	Is a working GDP QA-System implemented corresponding to type and scope of the activities performed?	☒
2.2	Is the management actively involved in this system?	☒
2.3	Are written standard operating procedures (SOPs) updated, if necessary and reviewed?	☒
2.4	Dealing with possible counterfeits:	
2.4.1	Is there a strategy to prevent the occurrence of possible counterfeits in the supply chain?	☒
2.4.2	Is this documented in the quality assurance system via SOPs?	☒
2.4.3	Are there measures for detecting possible counterfeits?	☒
2.4.4	Is FMD („*Falsified Medicines* Directive") implemented since February 2019?	☒

3. Personal		Yes
3.1	Are responsibilities and competences of the responsible person for GDP verifiable?	☒
3.2	Is the SOP instruction of new employees guaranteed by a training program?	☒
3.3	Are employees trained on a regular basis?	☒

4. Facilities, Rooms and Equipment, Storage		Yes
4.1	The company has special storage areas for - Cold storage - Narcotics (Controlled Substances) - Hazardous Substances / Cytostatics	 ☒ ☒ ☒
4.2	Are the premises suitable according to type, state and equipment?	☒
4.3	Are the premises protected against access by unauthorised parties?	☒
4.4	Are rooms and facilities cleaned regularly?	☒
4.5	Is there a protection against pests?	☒
4.6	Are appropriate climatic conditions guaranteed in the storage areas: 2 to 8 °C? not above 25°C (e.g. 15°C to 25°C)?	 ☒ ☒
4.7	Are the cold storage areas (2 to 8 °C) - qualified? - temperature monitored?	 ☒ ☒
4.8	Is the temperature recorded in cold storage rooms?	☒
4.9	Are the storage areas for other medicinal products <25 °C (e.g. 15 to 25°C): - qualified? - temperature monitored?	 ☒ ☒
4.10	Is the temperature recorded in the storage areas for other medicinal products?	
4.11	In case of temperature deviations: Is there a functional alarm system installed?	☒
4.12	Are cold chain products packed at z 2 to 8°C?	☒
4.13	Is it ensured that no expired medicinal products are dispatched?	☒

5.	Delivery	Yes
5.1	Is the temperature of cold transports monitored and recorded?	☒
5.2	Is the quality of medicinal products ensured during internal and external transportation?	☒
5.3	Are medicinal products protected during transportation (procurement / distribution) and against unauthorized access?	☒
5.4	Is product integrity of a delivery checked prior to its acceptance?	☒
5.5	Are the medicinal products protected during transport (procurement / distribution) and unauthorized access?	☒

6.	Documentation	Yes
6.1	Do delivery documents for purchase and delivery include following information:	
6.1.2	Delivery date?	☒
6.1.3	Name, quantity and strength of medical products?	☒
6.1.4	Name and address of supplier and recipient?	☒
6.1.5	Batch number and expiry date?	☒
6.2	Are the records hereafter followed up:	
6.2.1	Complaints?	☒
6.2.2	Returns?	☒
6.2.3	Destruction?	☒
6.3	Are there procedures to conduct and document recalls?	☒
6.4	Are the records required kept on at least 5 years?	☒
6.5	Are the IT procedures validated for the ERP system (enterprise resource planning system)?	☒

7.	Returns	Yes
7.1	Are returned medicinal products stored separately?	☒
7.2	Is a written instruction available on dealing with returns?	☒
7.3	Are returns checked regarding: integrity, proper storage, integrity of pharmaceutical area of responsibility, storage life and marketability?	☒
7.4	Are corresponding processes documented?	☒
7.5	Is the personnel especially trained?	☒

8.	Self-Inspections	Yes
8.1	Are self-inspections performed regularly?	☒
8.2	Is it ensured that all relevant areas are checked?	☒
8.3	Are records kept on self-inspections and the removal of deficiencies?	☒

kohlpharma GmbH

kohlpharma GmbH
Im Holzhau 8
66663 Merzig
Telefon 06867/920-0
Telefax 06867/920-1018

Dr. Christoph Frick
Responsible Person for wholesale according to GDP