

REFERENCEPROJECT



DR. KADE Pharmazeutische Fabrik GmbH



Inspection Readiness for the Production of Pharmaceutical Ointments and Creams – Preparation for Inspection by the Russian Health Authorities (MIT)

The Customer

DR. KADE Pharmazeutische Fabrik GmbH as a pharmaceutical manufacturer has always focused on quality “Made in Germany”. Gynaecology, proctology, gastroenterology and vitamins are the key areas of expertise. The company is based in Berlin. It develops, produces and distributes pharmaceutical and health products for Germany and the international market, undergoing continuous further development of the business and product range.

The Project

The company, employees and processes needed to be ideally prepared for an upcoming inspection by the health authorities from the Russian Ministry of Industry and Trade (MIT). Optimisation potential for general GMP compliance had also be realised with foresight.

The Task

While the regulations for Russian/Eurasian GMP largely correspond to those for EU GMP, certain particularities had to be taken into account. Aside from cultural differences, there is a greater focus on processes in production and logistics.

The Services

The GMP system was reviewed for possible weaknesses based on an on-site analysis in the form of self-inspections. Starting points for improvements were identified and improvements were subsequently implemented in teamwork with the customer. Risk analyses, qualifications and validations were carried out or updated in addition and existing GMP documents were reviewed, revised or created. The supporting IT systems were reviewed and data integrity was verified. Comprehensive employee preparation and training, including the use of role play, was an important element.

The Realisation

The specified time frame was met thanks to comprehensive scheduling, effective project management with regular team meetings and the flexible deployment of personnel. Employees from gempex were in close contact with the customer’s team on site in accordance with the project plan. Thus, the goal was efficiently reached in good cooperation.

The Result

The inspection by the Russian Ministry of Industry and Trade was passed successfully for the important export market of Russia.

gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, DIN ISO 9001 and comparable quality standards. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes permanent support for everything related to the customer’s ongoing GMP operations.

| Key Performance |
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| <ul style="list-style-type: none"> • Inspection preparation • Self-inspection • Qualification, validation • Documentation • IT-Validation • Training |