

REFERENCE



**IDEXX Switzerland GmbH**

**Proof of GMP Compliance and Neutral Certification for Veterinary Diagnostics**

**Customer Profile**

IDEXX is the global market leader in the fields of veterinary diagnostics, veterinary practice management software and water microbiology tests. The company originated in the USA, employs over 9,000 people worldwide and offers its products in more than 175 countries around the globe. It aims to promote the health and well-being of pets, people and farm animals.

**The Project**

Like many companies operating in the world market, IDEXX has to meet a variety of requirements imposed by the different regional regulatory authorities. Some companies require full GMP, others utilise the prestige they gain with a product manufactured in compliance with GMP. But what to do when the respective authority does not regulate the product in question? IDEXX had itself audited for its veterinary diagnostics by the independent company Bureau Veritas and thus obtained GMP certification. The plant qualification was to be carried out in parallel together with gempex as a measure arising from the certification audit.

**The Task**

A line consisting of six plant sections was to be qualified in parallel to ongoing production while conserving internal resources.

**gempex Services**

The risks were ascertained in a team with consultancy and moderation by gempex. After this detailed analysis of the current state, it quickly became clear that the qualification of the six plant sections would have to be broken down into 23 main components relevant for GMP. Qualification steps and procedures were established in a qualification master plan.

The main components were defined using a risk-based approach, an inventory of the technical documentation was taken and the relevant sensor systems were tested. Tasks were completed cooperatively. Training on GMP fundamentals and the basics of risk analysis and qualification procedures was provided prior to the respective qualification phases.

**The Result**

The IQ and OQ were completed in parallel with production, on time for the follow-up audit. The PQ encompassing important mappings of incubators is ongoing and also on schedule. With regulatory compliance at the lowest possible cost, the line is now ready for GMP-compliant production with all main components.

IDEXX obtained confirmation of the certification without any problems in the course of the surveillance audit that followed.



*gempex GmbH supports leading companies in the chemical and pharmaceutical industries with the implementation of quality requirements according to GMP, GLP, DIN ISO 9000 and comparable quality assurance systems. Main activities are consultancy and the professional execution of validation and qualification projects, including consultancy during design, construction and reconstruction of facilities. This includes ongoing support in all questions concerning the running GMP production plant.*

Key Performance
• GMP Training
• Analysis of the current state
• Training in conducting qualification procedures
• Qualification masterplan
• Equipment qualification