REFERENZPROJEKT

Advanced Bioanalytics

IBR Inc., Institute for Biopharmaceutical Research

GMP-Upgrade for obtaining an official GMP certificate by Swissmedic

The Customer
IBR Inc. is a contract research institute in the field of biopharmaceutical research. Founded in 1998, the company has been meeting bioanalysis demands from pre-clinical to clinical research with numerous established methods (therapeutic antibodies, biologicals, biosimilars, antibody-drug conjugates, vaccines etc.). Studies are conducted according to the regulatory requirements for GLP and GCP quality standards and meet the eCTD requirements (www.ibr-inc.com).

The Project
To meet customer demand in the market, IBR Inc. wants to also put its bioanalysis services to use in the product approval segment and expand its quality system according to the GMP requirements. In order to ensure the best possible approach, IBR Inc. chose gempex GmbH as the consulting firm to prepare for GMP certification.

The Task
gempex GmbH's scope of performance initially encompassed a review of the existing situation at IBR to obtain an objective understanding of the laboratories and processes. The findings were recorded and evaluated in the course of a gap analysis with the customer's close involvement. Evaluating the IT systems being used, such as the document management system, was included as well.

The Realisation
The gap analysis was conducted by a gempex GMP expert with the support of a very experienced consultant. Based on the results of the gap analysis, a catalogue of measures was prepared to identify the steps to be taken by IBR Inc. to obtain the GMP certification. The measures were presented and discussed in a workshop with the employees involved at IBR Inc. Some of the recommendations encompass technical measures, the preparation of documents relevant for GMP and the use of a new document management system. Priorities (low, medium, high) were assigned to the recommended measures to ensure a smooth process, and a pre-audit under consideration of the recommended measures was conducted to prepare for the official inspection by Swissmedic.

The Result
The adaptation of structures and GMP-specific documents implemented according to the gap analysis led to a positive assessment in the initial audit, carried out by the Zurich canton therapeutic products agency on behalf of Swissmedic in November of 2018, and to GMP certification by Swissmedic on 1 February 2019 (www.ibr-inc.com/gmp-certificates/?L=0).

Die gempex GmbH unterstützt führende Unternehmen der chemischen und pharmazeutischen Industrie bei der Umsetzung von Qualitätsanforderungen nach GMP, DIN ISO 9001 und vergleichbaren Qualitätsstandards. Die Hauptaktivitäten liegen in der professionellen Abwicklung von Validierungs- und Qualifizierungsprojekten einschließlich der Beratung bei Planung und Bau von Anlagen. Dies beinhaltet die dauerhafte Betreuung bei allen Fragen rund um den laufenden GMP Betrieb.

Key Performance

- *Gap analysis*
- *Catalogue of measures*
- *Laboratories*
- *Clean rooms*
- *GMP compliance consulting*
- *GAMP5*
- *Data integrity*
- *Pre-audit*