

REFERENCE



Axolabs GmbH

**Validation of Excel Spreadsheets to Enhance Resources:
IT Validation, Documentation, Compliance Testing, and Data Integrity**

The Customer

Axolabs GmbH, based in Kulmbach, is a world-leading contract research organization in the field of preclinical and clinical development of DNA- or RNA-based therapeutics. Axolabs provides high-end solutions and consultancy services for the development of innovative drugs and has more than 20 years of experience in the development of oligonucleotide therapeutics. The broad range of services for therapeutic oligonucleotides and mRNAs includes, in particular, bioinformatics, chemical synthesis of oligonucleotides, oligonucleotide conjugates and formulations, analytics, bioanalytics, and in vitro testing.

The Project

Axolabs uses several complex Excel applications for the collection, processing, and evaluation of analytical data. To relieve internal resources, these Excel sheets had to be validated with external help in accordance with the GAMP[®] 5 guideline to assure GxP compliance. The compliant use in a regulated environment had to be ensured.

The Task

Requested were an independent assessment and formal validation of the Excel applications developed. gempex's task was to document the existing implementation in a traceable manner, verify compliance with regulatory requirements, and ensure data integrity throughout the entire lifecycle of the applications.

The Realization

Axolabs provided fully developed Excel sheets compliant with GAMP[®] 5 categories 4 and 5, including developer documentation, the quality of which proved to be very high. Through a structured description of how the system works, gempex provided full transparency regarding data flows during data entry, processing, output, and data storage. In close collaboration with the developers on this highly complex topic, the Excel applications and the included VBA code were additionally tested for correct implementation, robustness, and GxP compliance. The validation documentation was efficiently and clearly consolidated into a streamlined One-Document-Concept (ODC).

The Result

With the Excel applications now GxP-compliant validated, Axolabs fully meets the regulatory requirements for data integrity and compliance. Complex analytical evaluations can be prepared in a standardized manner, performed under controlled conditions, and documented in a traceable way. Securely and efficiently.

gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 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

- IT Validation
- Excel Validation
- GAMP[®] 5
- Validation Documentation
- Data Integrity
- Resource reduction
- One-Document Concept (ODC)