eurofins | BioPharma Product Testing

Method Development and Validation

Whether you need expert testing consultation, method development or validation protocol design, Eurofins BioPharma Product Testing offers you the widest range of laboratory techniques in the industry. We support customers at various stages of the development/validation process and have a proven track record of success on development and validation studies, optimization of existing research methods and transfer of previously validated methods.

Why Choose Eurofins BioPharma Product Testing?

We collaborate with you by thoroughly understanding your testing requirements, designing a project approach to achieve your end goals, developing methods in the most efficient manner to maximize your research budget and validating or transferring the method for its intended use.

We offer phase appropriate method validation. All work is performed under full cGMP compliance.

We have the most experienced staff, performing more than 600 validation, qualification, verification and transfer protocols for our customers per year.

We place an emphasis on building relationships and rapport with our clients.

Our Method Development and Validation Teams works hand-in-hand with the receiving lab to ensure a seamless transfer of methods.

We assure timely delivery of services by establishing a project schedule and monitoring progress through weekly conference calls when useful.

Services available

Method Development

Prior to starting any project, we will discuss the project requirements with the client to ensure an appropriate scope is defined. We utilize our knowledge of method development on hundreds of products to assist with the development process, as well as referencing the Analytical Quality by Design approach. We evaluate attributes such as precision, linearity, accuracy and specificity during development to ensure the method is suitable for validation.

Method Optimization

Methods may be optimized for a variety of reasons such as improving chromatographic resolution of a principal peak or supporting a formulation change. In addition, methods not validated to current industry standards may require optimization to allow for successful validation

Method Feasibility

When methods are submitted for qualification or validation, we recommend performing feasibility prior to proceeding. Feasibility allows us to gain familiarity with the method and evaluate the method for attributes such as precision, linearity, accuracy and specificity with the hopes of avoiding protocol acceptance criteria failures.

Method Development and Validation Suitability For:

Chemistry/Biochemistry

- Assay/Potency, Purity/Impurity, Dissolution
- Cleaning Validation Analysis (Specific and Non-specific analyses)
- Assay, Impurity and Dissolution methods for Comparator products
- Residual/Impurities Testing
- Leachables
- Excipients

Microbiology

- Bacteriostasis/Fungistasis for Sterility
- Inhibition/Enhancement Screening for Endotoxin
- AET and Microbial Limit
- Mycoplasma Testing

Molecular and Cell Biology

- Cell-based Assays
- ELISA
- qPCR

Protocol Writing

- Method Validation/Qualification/Verification
- Method Transfer

Method Qualification

Performed on methods supporting early phase product. Performed to ensure method is appropriate for its intended use. Qualification may or may not be performed under the direction of the protocol.

Method Validation

Performed on methods supporting later phase product. Methods are validated consistent with the Ph. Eur/USP general chapter and the ICH guidelines. Validation is performed under the direction of a protocol.

Method Verification/Suitability

Performed on compendial methods to ensure that the methods perform acceptably on your API or product matrix. Verification is performed under the direction of a protocol.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

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