

Method Transfer

The formal transfer of a test methodology is a required GMP process that qualifies a receiving laboratory to utilize a method that originated in a transferring laboratory. This process is intended to ensure and document that the method performs as intended within the receiving laboratories environment.

Eurofins BioPharma Product Testing offers advantages over other contractors in providing both ICH and USP based protocol writing support as well as maintaining a large breadth of testing capabilities and capacity, using the latest technologies, to support the method transfer process.

Why Choose Eurofins BioPharma Product Testing?

We have more than 30 years of experience executing method transfers for finished products, API, bulk drug, reference standards and virtually any other sample type.

We have dedicated writing staff available to work with our customers to generate compliant protocols in accordance with ICH guidelines and the USP, including USP <1220>.

We have successfully completed thousands of method transfers utilizing all available types of equipment/procedures for both pharmaceutical and biopharmaceutical products, as well as intermediates.

We provide quick turnaround time on feasibility assessment of the methods, execution of the protocol and generation of the final report.

We offer a flexible process that allows on-site training at our laboratory or travel to the client site for more complex and/or technique-based methods.



Types of Transfers

Eurofins BioPharma Product Testing's extensive experience allows us to work closely with our clients to determine the most appropriate strategy for an efficient method transfer. Our approach is based on regulatory guidance combined with a risk analysis. Transfer options typically include:

- **Comparative Testing** – This is the most common approach and requires the testing of homogeneous lots of material by the sending and receiving laboratories. The transfer protocol will stipulate the details of the procedure, the samples that will be used and the acceptance criteria.
- **Covalidation** – When multiple laboratories are required for GMP testing, covalidation between two or more laboratories is the most efficient transfer strategy. In this case, the receiving laboratory is part of the validation team and performs the intermediate precision experiments to obtain data for the assessment of reproducibility.



Recommendations for a Method Transfer project

The degree of success for a method transfer is often proportionate to the degree of collaboration between the client and the contract testing laboratory. We work closely with all parties involved to provide an efficient, timely and cost effective transfer:

- **Revalidation** – In cases where the transferring laboratory is unavailable for comparative testing, revalidation is often the best option. Under this option, a risk-based approach is used to determine which elements of the original validation will be repeated by the receiving laboratory.
- **Transfer Waiver** – A transfer may be omitted based on the experience of the receiving laboratory (current use of a procedure on another product, transfer of personnel, etc.) or the procedure being transferred is in the USP-NF. Verification should apply in this case.
- The transferring lab should provide a copy of the method and validation report early for initial discussions.
- Both parties should build time into the project for feasibility (familiarization) to allow the receiving laboratory to gain familiarity with the new method(s) prior to execution of the formal protocol.
- The transferring laboratory must work closely with the receiving laboratory and use their experience to develop a risk-based approach for the transfer.

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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