METHOD TRANSFER - WHEN, WHY, HOW?

Source: Singota Solutions

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

In the lifecycle of a pharmaceutical product, from research and development to commercial production, analytical procedures are used to assess the identity, quality, purity, and potency. While one laboratory may develop an analytical method, another laboratory may validate the method to ensure robustness and reliability, and different laboratories may be tasked with the testing for stability or release of the product. As a validated method is incorporated into a new area or location, formal method transfer activities should be performed to ensure the results are reliable, accurate, and comparable between testing sites.

Why and what is a formal method transfer? Usually, laboratory personnel will perform analytical testing following a set of instructions outlined in a Standard Operating Procedure (SOP). Sharing the SOP with a laboratory for transfer is not enough to ensure the method is performed similarly or the data generated between laboratories is similar. Equipment, interpretation, and experience may factor into differences that affect results. A formal method transfer is an exercise that demonstrates and documents that a method has been successfully qualified in another laboratory to provide accurate and repeatable results. Additionally, this documentation is often requested by inspectors or auditors during routine assessments. USP chapter <1224> Transfer of Analytical Methods, provides a guidance for method transfers. Per USP <1224> the following elements are recommended for Analytical Method Transfer (AMT).

- Training/ Qualified Personnel

It is essential to have experts from the transferring laboratory to provide assistance to the receiving laboratory. It is equally important to have personnel trained on general procedures of the method(s) to be performed and the details of the Method Transfer Protocol.

- Detailed Procedures and Documentation

A detailed procedure or SOP for the method must be provided. Additional supporting documentation such as method development or validation reports and examples of data should be provided.

- Appropriate Instrumentation and Facilities

The instruments and laboratory equipment used in the method transfer must be qualified and calibrated according to Good Manufacturing Practices (GMPs). The facilities that house the equipment and the sample preparation must also be conducive for the analysis (e.g., temperature, humidity, and lighting).

- Method Transfer Protocol

A written protocol outlining the objective, scope, responsibilities, experimental details, and acceptance criteria must be agreed upon between the originating and receiving organizations.
A well written protocol will clearly address all parameters to evaluate and address how to handle any quality events (deviations, not meeting acceptance criteria) during execution.

The Protocol

The method transfer protocol should include the instrument parameters, reagent and standard preparations, sample preparations, and system suitability requirements of the method, as applicable. If available, the specific lot of study and reference materials should be incorporated. The parameters and corresponding acceptance criteria for evaluation should be defined (e.g., linearity, accuracy, precision, etc.). While it is not necessary to repeat all aspects of the method validation, certain parameters may be appropriate to include. It is important to consider the critical quality attributes (CQA) of the product to decide what to include. ICH Q2(R1) Validation of Analytical Procedures provides a reference for characteristics and when to implement analyses. A description of how to handle any deviations or non-conformance of acceptance criteria should also be included. The “transferer” and “transferee” should provide signatory approvals.

The Execution

Once the method transfer protocol has been approved, the laboratory (or multiple laboratories) will execute according to the detailed procedure. All data and instrument used must be appropriately documented. Any deviations or non-conformance should be addressed through the appropriate quality systems.

The Report

Following the execution of the method transfer, a report should be generated to summarize the results. The report should include the parameters of the study, the acceptance criteria, and how the transfer activities met (or did not meet) the acceptance criteria. In addition, any quality events should be addressed. Instrument setup, sample preparation, and method details should also be included, as well as example data.

The SOP

An SOP for the transferred method will be generated to capture the details to continuously provide accurate analytical results. The SOP should provide clarity on which instruments and reagents are required, or where equivalents are acceptable. Sample preparations for different concentrations or formulations should be included, where applicable. Data calculations and reporting requirements may also be included to maintain consistency between laboratories.

The success of a method transfer may initially be seen in meeting the acceptance criteria set out in the protocol, but ultimately, time and repeated use of a method demonstrates the reliability and robustness of the method. It is important to address the details of the method in the parameters of the transfer study protocol to ensure a long term positive outcome.

Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit Singota.com to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact **solutions@singota.com** to schedule a meeting with our business development team to further discuss your current or future projects.