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"Transfer of Analytical Procedures according to the New USP Chapter <1224>" - An Overview

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Abstract: When validated methods are transferred between laboratories and sites, their validated state should be maintained to ensure the same reliable results in the receiving laboratory. The transfer of analytical procedures (TAP), also referred to as method transfer, is the documented process that qualifies a laboratory (the receiving unit) to use an analyticaltest procedure that originates in another laboratory (the transferring unit), thus ensuring that the receiving unit has the procedure, knowledge and ability to perform the transferred analytical procedure as intended. So far there has not been an official guidance on what exactly is expected to maintain 'the validated state'. FDA has released an official guidance on how to conduct and document method transfer. USP has introduced a new general chapter <1224> on TAP and the new USP chapter will become official with USP-35. The new general chapter provides guidance on the basic steps of this process. It summarizes the types of transfers that may occur, including the possibility of waiver and outlines the components of a transfer process. This Chapter continues a series of chapters devoted to providing guidance for the quality of the data-acquisition process(i.e., qualification, validation, and verification). This chapter does not encompass the transfer of microbiological or biological procedures. The new chapter suggests a risk based approach for type and extent of transfer activities. The objective of this overview is to provide an understanding of the requirements of the new chapter and how to effectively implement the analytical method transfer.

Key words: Analytical Procedures, Transfer New USP Chapter <1224>.

INTRODUCTION

When validated methods are transferred between laboratories thereceiving laboratory should demonstrate that it can successfully performthe method. Typical instances when method transfer occurs are from theResearch and Development (R&D) laboratory to the Quality Control (QC)laboratory.Currently, there is noofficial document available that can be used as a guide for performancedemonstration of the receiving laboratory.USP has introduced a new general chapter <1224> on TAP and the new USP chapter will become official with USP-35 NF-30. The new general chapter provides guidance on the basic steps of this process.The chapter describes the most common practices of method transfer which are:

1. Comparative Testing
2. Co-Validation Between Two Laboratories Or Sites,
3. Complete Or Partial Method Validation Or Revalidation
4. Omission Of Formal Transfer, Transfer Waiver

METHODOLOGY

PREAPPROVED PROTOCOL

- A well-designed protocol should be discussed, agreedupon, and documented before the implementation of TAP and should include
  - intended execution strategy,
  - each party's requirements and responsibilities.
- The protocol should describe
  - objective;
  - scope;
  - the responsibilities of the transferring and the receivingunits;
  - the materials and instruments to be used;
  - the analytical procedure;
  - the experimental design; andthe acceptance criteria for all the tests and/or methodsincluded in the transfer.
- the transfer protocol shouldidentify the : specific procedure, characteristics that will beverified and the analysis that will be used to evaluate acceptableoutcomes from the transfer exercise.
- The documentation section of the transfer protocolmay include
  - report forms: to ensure consistent recordingof results and to improve consistency between laboratories.
  - This section should contain the additional informationthat will be included with the results, such aschromatograms, spectra, and deviation reports.
- The protocolalso explains how any deviation from the acceptancecriteria will be managed.

ELEMENTS RECOMMENDED FOR THE TRANSFER OFANALYTICAL PROCEDURES:

- Transferring unit should provide training to the receiving unit
- The receiving unit should run the procedures and identify any issues that may need to be resolved before signing the transfer protocol.
- Training should be documented
- The receiving unit verifies that the laboratory systems are in compliance with applicable regulations and in-house general laboratory procedures
- Thetransferring and receiving units should compare and discuss data and any deviations from the protocol

METHOD TRANSFER REPORT

When the TAP is successfully completed the scientistsinvolved should prepare a Transfer Report that describesthe results obtained in relation to the acceptance criteria,along with conclusions that confirm that the receivingunit is now qualified to run the procedure. Any deviationsshould be discussed and justified.The issues thatcontributed to failure to achieve the predicted acceptancecriteria should be corrected, including training orfurther clarification of the analytical procedure. Whenthe acceptance criteria are not met, the procedure cannotbe transferred.

DISCUSSION

EFFECTIVE IMPLEMENTATION OF TAP

- Develop a transfer plan. This includes activities, a time schedule, owners and deliverables. .
- Develop SOPs for executing the tests. The SOPs include preparation of the sample, reference material, and reviewing and documenting testresults.
- Train workers. Workers from the transferring laboratory train analysts from the receiving laboratories.
- Training includes protocol detail,methodology and all issues that have arisen in the past.
- Execute the protocol in both laboratories. Actual results are compared with expected results and acceptance criteria.
- Identify the root cause of any issues. If acceptance criteria are not met, the root cause is identified and the issue resolved.
- Generate documentation specified in the plan. All documents as specified in the plan are generated, reviewed and signed by laboratory and QA
- Management of the transferring and receiving units.

SUMMARY

Transfer of analytical procedures is an expectedpart of the lifecycle, and should be anticipatedand addressedaligned with validation and verification of procedures andrequires carefully documented analyticalprocedure, pre-approved protocol and transferreport. Itmay be accomplished in various ways, includingcomparative testing, co-validation, revalidationor transfer waiver.

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