Training Course

Transfer of Analytical Methods for Pharmaceutical Analysis

Transferring an analytical method from one laboratory to another should be straightforward but unfortunately it is a process which is often problematic. Recognition of this has resulted in a new USP chapter <1224> Transfer of Analytical Procedures, and an update to chapter 6 of the EU GMP regulations. In this one day course the different approaches to transfer are explored fully and case studies are used extensively to follow the process from review of the method prior to transfer, to creating a suitable protocol with relevant acceptance criteria, and evaluating the results generated to assess whether the transfer has been successful.

This course is ideal for anyone involved in the transfer of analytical methods. For example: Analytical chemists, laboratory managers/supervisors, quality control analysts/managers, quality assurance managers, and regulatory affairs managers.

Please note: Familiarity with the characteristics studied during analytical method validation is necessary for this course since these are used for method transfer. The MTS course, Validation of Analytical Methods for Pharmaceutical Analysis, is recommended.

The course is delivered using a combination of presentations and exercises. After attending this course you will be able to:

• Understand the different possible approaches that may be used for analytical method transfer.
• Review analytical procedures in terms of transfer to another laboratory and identify potential problems.
• Prepare a transfer protocol including relevant experiments and acceptance criteria.
• Interpret the results of method transfer using appropriate statistics.

This course is available in two options: You can attend one of our open enrolment training courses at an external location (dates of upcoming events are available on the MTS website); or we can deliver the course at your site including any required customisation to meet your specific requirements.

Comprehensive course handouts; Certificate of Attendance; access to training resources via e-MTS; optional post training assessment (leading to Certificate of Training); and post training support, are all included in the course fees.
Course Outline

• The requirements for method transfer in the pharmaceutical industry.
• Different approaches to transfer:
  ➢ Comparative testing,
  ➢ Co-validation between two or more laboratories,
  ➢ Revalidation,
  ➢ Transfer waiver.
• Review of available regulatory guidance for method transfer, e.g., USP <1224> Transfer of Analytical Procedures, EMA, WHO, FDA.
• The steps for transfer of analytical methods:
  ➢ Pre-transfer assessment:
    ▪ Review of methods by both sites,
    ▪ Review of requirements for receiving unit.
  ➢ Training at the receiving unit.
  ➢ Preparation of the transfer protocol, to include methods, materials, experiments, acceptance criteria, etc.
    ▪ Defining the transfer experiments,
    ▪ Defining the acceptance criteria.
  ➢ Carrying out the method transfer experiments.
  ➢ Evaluation of the data generated against the protocol.
  ➢ Preparation of the transfer report.
• Comparative statistical tests which may be used for method transfer data, e.g., Student's t-test, Equivalence testing, etc.
• Common problems encountered during method transfer and how to resolve them.