TRAINING COURSE

Validation of Analytical Methods for Pharmaceutical Analysis

Validated analytical methods are essential for testing pharmaceuticals to ensure that the quality of the data generated by these methods can be assured. This two day training course will enable you to design suitable experiments for the validation of an analytical method, taking into account all the relevant guidelines, such as ICH Q2(R1), and then interpret and document the results obtained using appropriate statistics. It is ideal for anyone who is involved in the design, implementation, reporting or review of validation studies for methods used to analyse pharmaceuticals.

The course is delivered using a combination of presentations and exercises in which extensive use of case studies provides real life experience in designing and interpreting validation studies. Chromatographic techniques, such as HPLC, will receive particular attention. After attending this course you will be able to:

- Understand the purpose of analytical method validation.
- Define the parameters used for method validation, i.e. validation characteristics.
- Plan a validation protocol.
- Perform the required analysis in the most efficient manner.
- Interpret the results of validation.
- Generate a suitable report on completion.

This course is available in three 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); you can opt for our live web based training option where the training is delivered over a series of 8 sessions at a time to suit you; or we can deliver the course at your site including any required customisation to meet your specific requirements.

Comprehensive course handouts, access to training resources via e-MTS, certificate of training, post training support, and a copy of the MTS training book, *Validation of Analytical Methods for Pharmaceutical Analysis*, are all included in the course fees.

Course Outline

Day 1

- Introduction: the purpose of validation; Guidelines for method validation, e.g. ICH & FDA, and the types of methods that they apply to; Definition of analytical method validation characteristics.

MOURNE TRAINING SERVICES • 14 Burren Road • Warrenpoint • Co. Down • BT34 3SA
Tel: + 44 (0) 28 41773724 • Email: info@mournetrainingservices.co.uk
Web: www.mournetrainingservices.co.uk

- Statistics for method validation: The mean, the standard deviation and confidence intervals; Student's t-distribution; Statistical significance and comparative studies in method validation; Test for outliers in method validation.
- Validation characteristics, as defined in ICH Q2(R1): Specificity; Linearity; Range; and Accuracy.

Day 2

- Validation characteristics continued: Precision (repeatability, intermediate precision & reproducibility); Detection limit; Quantitation limit & Robustness.
- Designing the validation protocol: Choosing validation characteristics; Designing experimental procedures for validation studies; Setting appropriate acceptance criteria; Method validation during drug development; Verification of pharmacopeia methods; and analytical method transfer.
- Preparation of the validation report: Contents of the validation report; Reporting of the required results for each validation characteristic.