



WEB-BASED TRAINING COURSE:

THE VALIDATION OF ANALYTICAL METHODS FOR PHARMACEUTICAL ANALYSIS

This analytical method validation training course is aimed at analysts involved in the validation of methods used for the analysis of pharmaceuticals. The training is delivered using live web-based training, where the MTS trainer and the learner communicate over the internet. The method validation training course is split into 8 sessions, each of between 60 to 90 minutes in length. The timing for the delivery of the sessions is arranged to suit the learner. For example, a popular choice is to deliver two sessions in a day over a total period of four days. MTS will make every effort to fit in with the schedule that suits you.

Every attendee on a MTS course is asked to fill in a brief survey on their previous experience and training expectations to ensure that the training is optimised for their learning needs.

The standard cost for this training course, charged per person, is £600 + VAT.

SYNOPSIS:

The pharmaceutical industry is very heavily regulated due to the nature of its products. This method validation training course provides a thorough treatment of analytical method validation following current regulatory guidelines. The validation process of planning a study, executing the study, and interpretation and reporting of the results is described fully. The theory regarding the purpose of validation and the practical aspect of performing a study are combined in this course.

The definitive reference for this topic is the guideline produced by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Q2(R1) 'Validation of Analytical Procedures: Text and Methodology'. Sections of the guideline have

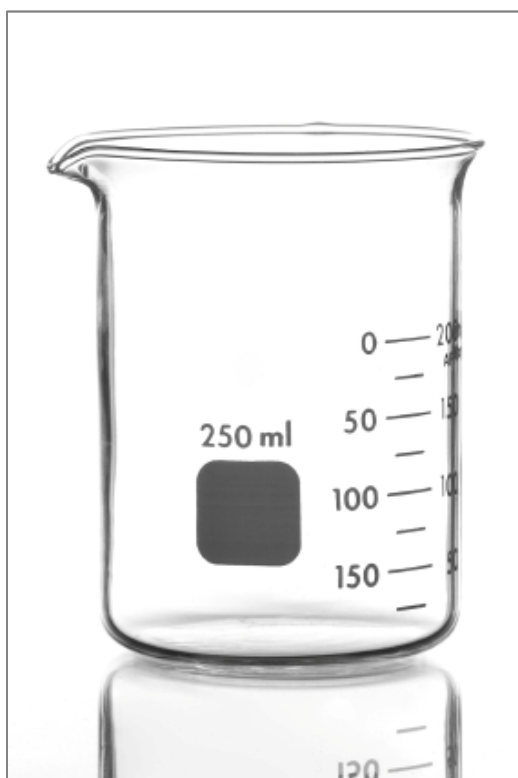
been reproduced in the training materials associated with this course with the kind permission of the ICH Secretariat. All ICH guidelines are available via the website, www.ich.org.

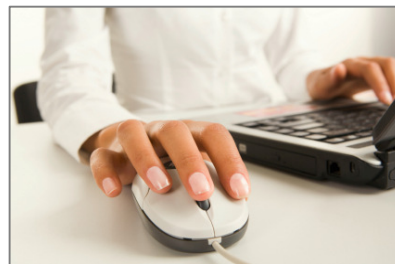
The learning objectives and full agenda for this training course are provided below.

LEARNING OBJECTIVES:

After taking this course the learner will be able to:

1. Understand the purpose of analytical method validation.
2. Define the parameters used for method validation.
3. Plan a validation protocol.
4. Perform the required analysis in the most efficient manner.
5. Interpret the results of validation.
6. Generate a suitable report on completion.





AGENDA

SESSION 1 – IN WHICH WE COVER:

INTRODUCTION TO TRAINING WHAT IS VALIDATION?

- i. Introduction to the purpose of validation
- ii. Guidelines for method validation, e.g. ICH, FDA, and the types of methods that they apply to
- iii. Analytical method validation characteristics – definition

SESSION 2 – IN WHICH WE COVER:

STATISTICS FOR METHOD VALIDATION

- i. The mean, the standard deviation, and confidence intervals
- ii. Student's t-distribution
- iii. Statistical significance and comparative studies in method validation (Student's t-test)
- iv. Dixon's Q-test for outliers in method validation

SESSION 3 – IN WHICH WE COVER:

VALIDATION CHARACTERISTICS

- i. Specificity
- ii. Linearity

SESSION 4 – IN WHICH WE COVER:

VALIDATION CHARACTERISTICS

- i. Range
- ii. Accuracy
- iii. Precision

SESSION 5 – IN WHICH WE COVER:

VALIDATION CHARACTERISTICS

- i. Precision continued
- ii. Detection limit and quantitation limit
- iii. Robustness



SESSION 6 – IN WHICH WE COVER:

VALIDATION PROTOCOL

- i. Choosing validation characteristics
- ii. Designing experimental procedures for validation studies
- iii. Setting appropriate acceptance criteria
- iv. Designing a validation protocol

SESSION 7 – IN WHICH WE COVER:

VALIDATION REPORT

- i. Contents of the validation report
- ii. Reporting the results for each validation characteristic

SESSION 8 – IN WHICH WE COVER:

WHAT HAVE YOU LEARNED?

- i. Review of learning
 - ii. Assessment
 - iii. Generation of a Training Action Plan for implementation of learning in the workplace
 - iv. Evaluation of training.
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FOR MORE INFORMATION AND DETAILS OF OTHER COURSES, PLEASE CONTACT US.