How to Validate a Chromatographic Method: A Practical Course

Course description

How to Validate a Chromatographic Method: A Practical Course is a solid, one-day, introductory level course focusing on the practical aspects of validating chromatographic methods in regulated analytical laboratories. The course materials are based on ICH and FDA guidance documents and current best practices of the pharmaceutical industry. The course is augmented with real world examples recently encountered by the instructor. This is an excellent means to introduce analytical chemists to chromatographic methods validation and the concepts of validation in a CGMP environment in general. It's also an excellent means to "brush up" on chromatographic methods validations skills.

Target Audience

Analytical chemists preparing to validate analytical methods, particularly HPLC methods, for the first time, chemists who need a refresher in the technique, or managers involved in the supervision of methods validation will benefit from this course. QA personnel who review data from validations will also find this course very useful.

Course Outline

1. Introduction: Overview of Chromatographic Methods Validation
   1.1. Common Methods Validation Terms
   1.2. Before Getting Started: Practical Aspects
   1.3. Method Categories and Required Analytical Performance Characteristic or Validation Test
2. Accuracy (Recovery)
3. Precision
4. Specificity
5. Detection Limit
6. Quantitation Limit
7. Linearity
8. Range
9. Robustness Testing
10. System Suitability Determination
11. Forced Degradation Studies
12. Solution Stability Studies
13. Filter Retention Studies
14. Extraction Efficiency Studies
15. Reporting the Results
16. Review of Selected References
17. Where to Get Help
18. Questions and Answers