



## Analytical Method Validation

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This one day course covers all of the basics required to produce an analytical method validation protocol, implement the validation studies and report to FDA standards.

Analytical Best Practices will also be discussed and described and statistical treatments introduced.

## Course Contents

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### Validation Parameters

- Selectivity (Specificity)
- Linearity
- Accuracy (Trueness)
- Precision
- Sensitivity
- Robustness (including experimental design and statistical analysis)

### Experimental Design for Analytical Method Validation

- ANOVA, Plackett-Burman, full factorial methods etc. Statistical Methods and Tests for Validation
- When and how to use t-tests / f-tests to provide rigour to validation results
- Overview of Equipment Validation

### The following topics will be considered for each of the major validation parameters

- Definitions
- Applicability
- ICH guidelines
- Eurachem guidelines
- ISO / IUPAC guidelines
- Important Comments and Considerations
- Procedure
- Statistical Analysis (where applicable)
- Validation Protocol Statements and Reporting
- Conclusions
- Workshop / Tutorial Exercise (where applicable)



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