

Guide To Method Validation For Quantitative Analysis

This supplement is intended to be used in conjunction with "The Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics (2nd ed.)" Availability. This supplementary guidance is available in the following languages: Download the guide in English (published 2019-10-06) (pdf, 1.0 Mb). Citation

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Method Validation Vs. Verification: What's The Difference?

When it comes to validation, analytical test methods used for medicinal products based on biological molecules can be a bit 'tricky' to deal with. Coming up with a suitable design for the validation protocol can be quite difficult. In particular, the choice of what parameters to investigate, and the design of the associated experiments.

Brief Guide to Tricky 'Bio' Method Validation

Method validation is the process by which it is established, through laboratory studies, that the performance characteristics of the method meet the requirements for its intended purpose (1-5). It is a part of the overall validation process that also includes software validation (6), instrument qualification (7,8), and system suitability (9).

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