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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.

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Method validation and verification
The guide “The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics” (2nd ed. 2014) is the principal Eurachem Guide on validation. The guide is available in multiple languages and includes information on: The concept of method validation; The background and rationale for method validation; How a method validation study should be performed and how much should be done (validation/verification); A thorough explanation of the various ...

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A Practical Guide to Immunoassay Method Validation
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Consequently, this Guide uses the commonly recognised term ‘method validation’ although ‘procedure validation’ would be more correct. The terms ‘ruggedness’ and ‘selectivity’ are preferred to ‘robustness’ and ‘specificity’ since the former are used by IUPAC.

The Fitness for Purpose of Analytical Methods
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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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