



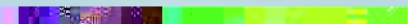
Introduction to method validation

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Overview

- What is method validation?
- Why is method validation necessary?
- When and how do you validate a method?
- Method performance parameters
- How do you assess fitness-for-purpose?



What is validation?

'The **confirmation**

Why is method validation necessary?

- Ethical

Who validates a method?

- The analyst
 - in-house development and validation of new methods
 - verification of the performance of previously validated methods
- The laboratory
 - method development and validation section
- Sectoral/professional/standardization body
 - validation of methods via interlaboratory study

How do you validate a method?



Method performance parameters

Providing evidence that the method produces results that are fit-for-purpose

- Precision (repeatability, reproducibility)
 - how close are the results of replicate measurements made on the same sample?
- Bias, recovery
 - how close are the results to the 'right' answer
- Working range (LoD, LoQ, Linearity)
- Ruggedness/robustness
 - control necessary for each stage of the procedure
- Selectivity/specificity
 - are there any interferences?

Measures of quality Precision, bias and accuracy



