

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?

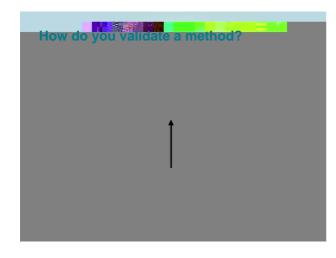
'The confirmation

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



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?

