METHOD VALIDATIONS

By Natasha Samsunder

- **Definition:**

- Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice.

Analytical methods need to be validated or revalidated:

- before their introduction into routine use;
- whenever the conditions change for which the method has been validated (e.g., an instrument with different characteristics or samples with a different matrix); and
- whenever the method is changed and the change is outside the original scope of the method

The USP has published specific guidelines for method validation for compound evaluation (7). USP defines **eight steps for validation**:

- Accuracy
- Precision
- Specificity
- Limit of detection
- Limit of quantitation
- Linearity and range
- Ruggedness
- Robustness

Validation steps

- Develop a validation protocol, an operating procedure or a validation master plan for the validation
- For a specific validation project define owners and responsibilities
- Develop a validation project plan
- Define the application, purpose and scope of the method
- Define the performance parameters and acceptance criteria
- Define validation experiments
- Verify relevant performance characteristics of equipment
- Qualify materials, e.g. standards and reagents for purity, accurate amounts and sufficient stability
- Perform pre-validation experiments
- Adjust method parameters or/and acceptance criteria if necessary

- Perform full internal (and external) validation experiments
- Develop SOPs for executing the method in the routine
- Define criteria for revalidation
- Define type and frequency of system suitability tests and/or analytical quality control (AQC) checks for the routine
- Document validation experiments and results in the validation report.

Validation Plan

- 40 samples in duplicate on both platforms to measure accuracy
- Additional runs for precision
- Additional runs for linearity.....

New VQA method for PCR