

Verification, validation and transfer

Background

Analytical service providers are focusing on supporting pharmaceutical companies with the necessary documentation and verification of product quality.

Analytical methods are the basis for this task and need to deliver reliable, correct and reproducible results. In order to fulfill regulatory requirements, these methods need to be validated or verified.

Verification

A verification correlates with a suitability test or a part validation of an already existing, valid pharmacopeial method. It is necessary to ensure that the method in question can be conducted under the existing conditions of the executing laboratory.

Usually, simple methods such as pH value measurements do not require verification. With increasing complexity of the analytical method or sample preparation, the probability and extent of a verification increases.

However, whether or not verification is necessary will always be decided after consultation with the customer.

Method transfer

Method transfer implies relocation of the analytical method to another laboratory verifying that the executing laboratory is able to successfully conduct the transferred method.

Validation

Method validation ensures that the analytical method is suitable for the intended purpose and delivers reliable and reproducible results at any time, independent of the person carrying out the analysis.

Validation is necessary whenever an analytical method is intended for routine measurement, cleaning validation or quality control in a pharmaceutical laboratory or whenever the execution of the method needs to be modified.

Guidelines such as the ICH Q2 specify the necessary parameters for the validation process.

Essential parameters of a validation include:

- Accuracy
- Precision
- Specificity
- Limit of detection and quantification
- Linearity
- Range
- and robustness.

The experts at Reference Analytics can provide substantial know-how in the field of verification, validation and method transfer and will support you with consulting services related to your individual analytical challenges.