All methods used in analytical chemistry are subject to error. Therefore it is vital that each method should be evaluated and tested to ensure that it produces results which make it suitable for the intended purpose. Due to the demand for reliable and comparable methods, performance requirements have been established at a national and international level for implementation of official methods, e.g. by European legislation, by the CEN or European Pharmacopoeia, the Association of Analytical Communities (AOAC) International, and worldwide by Codex Alimentaris (CAC). Thus any method proposed that is used for official purposes must be validated in a collaborative trial study, resulting in defined method performance characteristics.

Validation of analytical methods is based on a series of experimental procedures to establish: selectivity, sensitivity, repeatability, reproducibility, linearity of calibration, detection limits and limit of determination, and robustness. It is well known that these headings become more difficult to apply as the complexity of the analysis increases. Method validation is the process in which every stage of a new analytical method is subjected to rigorous series of tests to ensure that the method will be able to deliver all the outcomes required of it. The confidence that the method can deliver these outcomes is expressed in terms of statistical probability over the whole analyte concentration range established during the validation process.

Verification of a method involves the testing of a series of method parameters to ensure that a previously validated analytical procedure performs as reported when it is introduced into a new environment where, at the very least, equipment may not be identical to that employed in the initial validation. Established methods must, as a minimum requirement, be verified when introduced into a laboratory for the first time. Verification, strictly speaking, is also necessary if the method is modified or applied to a new situation, for example a different sample matrix. A new method must be subject to a much more searching series of validation procedures, each one of which ads further confidence in the analytical results obtained. While method validation is mandatory for assurance of analytical quality, the cost to a laboratory is significant. It is therefore important for the financial well being of a laboratory that validation should adopt no more than those procedures necessary to ensure the analytical quality demanded by a client.

An important question now is does a validated method automatically give a validated result? And to that question the answer must be: no. There can never be a mechanism or recipe for producing automatically valid results because one can never eliminate the skills, the role and the responsibility of the analyst.