

Validation of analytical measurement (mVal)

Customer

Planning validation studies is a difficult topic, especially for *ad-hoc* requirements and where fitness-for-purpose is the principal issue.

LGC, Europe's leading independent provider of analytic and diagnostic services, contracted Tessella to develop mVal, a new method validation software that provides all necessary statistical tools for fast and efficient validation in analytical laboratories. This product was commissioned under the Valid Analytical Measurement programme (VAM), funded by the Department of Trade and Industry.

Business Problem

Modern analytical laboratories must be able to prove that the results they report are obtained using valid methods. The first step in performing a method validation study is the production of a protocol. This defines the features on which the method should be validated (the performance characteristics), as well as the pass/fail criteria for each characteristic. This task requires an appreciation of the implications of the choice of performance characteristics, in addition to an understanding of statistics.

Tessella Solution

LGC commissioned Tessella to develop an application to support in-house method validation. Working closely with LGC, Tessella consultants defined and designed the structure and statistical content of the application. The result, mVal, facilitates detailed, structured testing of an analytical method's specified performance characteristics. A protocol is set up defining the characteristics (such as 'precision' and 'ruggedness') to be studied. The protocol also identifies the experiments that will be

performed and defines how the data will be interpreted.

Once the protocol has been defined, a study can be carried out on a method. Data is entered for each analyte measured in the test, and mVal carries out all necessary statistical calculations. The user is then presented with a report of the summary statistics and critical values, such as correlation coefficients. On the basis of this, pass/fail decisions are made for each result for each analyte. The user can then make an overall judgment as to whether the study has successfully validated the method, and this decision is documented by mVal in the database file.



Results and Benefits

mVal is able to export and import protocols as XML files. This feature was particularly useful to LGC, who has implemented standard industry protocols in mVal and made the protocol files available to mVal users.

The technologies used to develop mVal were chosen to provide a user-friendly, standalone Windows application that runs on most desktop PCs. The software was developed and tested in two separate phases, enabling LGC to perform a thorough in-house beta test before returning to Tessella for some enhancements. The architecture has also been designed to allow for possible future expansion of the product features, such as migration to a client-server database system.

Further information about mVal can be obtained from www.vam.org.uk

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