

## Method validation advice (mVadvisor)

### Customer

The UK Department of Trade and Industry (DTI) funds many programmes aimed at helping industry. One of these is the 'Valid Analytical Measurement' programme (VAM), aimed at fostering best practice in the field of analytical chemistry.

### 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.

The VAM project aimed to develop software that would aid chemists in the creation of validation protocols. In a previous project for VAM, LGC (Europe's leading independent provider of analytic and diagnostic services) had contracted Tessella to develop software to set up analytical protocols and process the results of method validation studies based on those protocols. Tessella developed mVal, a software package for analytical method validation, which is now available from VAM. mVal is, however, software for the expert user. On this occasion the DTI were looking for a system aimed at a wider user base.

### Tessella Solution

For the new project, DTI solicited bids for the development of a web-based system. The aim of the system was to allow the user to describe their validation problem.

A consortium of Tessella and LGC were awarded this work; Tessella would develop the website, and LGC would supply the expertise in analytical measurements.



After a stage clarifying the requirements, development work started. The target platform was Microsoft's Internet Information Server and the software used a number of technologies; static web pages were written in HTML, whereas dynamic pages – the content determined by the protocol selected by the user and the data entered – used a combination of ASP, HTML and JavaScript. Some of the 'calculator' pages for determining false acceptance and rejection rates were written as Java applets.

### Results and Benefits

The web pages are arranged in the form of a 'Wizard', thus the user is able to follow a well-defined path through the website. The user is asked about their problem, and allowed to create either a custom validation protocol or one based on internationally recognized standard protocols such as ICH or MCERTS. Links to help-pages provide further explanation of any given web page as necessary. Features such as a glossary and statistics advisor are available to answer more detailed questions. After working through the pages, the user produces a validation protocol that they can then save or print. The information can also be downloaded as a protocol file for loading into mVal.

The resulting system, mVadvisor, is available on the VAM website. It forms another service to the analytical measurement community, assisting analysts with the design of method validation studies. Further information about mVal and mVadvisor can be obtained from [www.vam.org.uk](http://www.vam.org.uk)