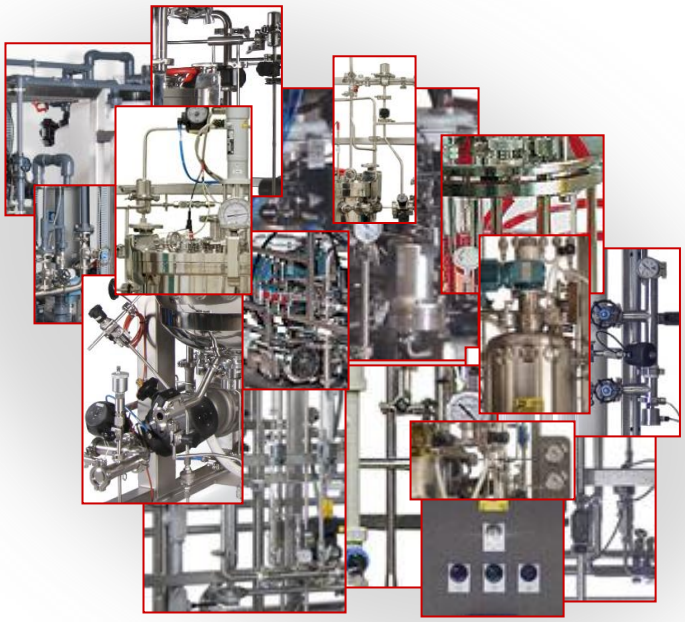
Validation in Partnership Ltd.

EQUIVAL

- for the process and packaging equipment manufacturer -

“Life-cycle testing, verification and qualification documentation … at the touch of a button.”



Although this brochure principally targets suppliers to the health science industries, **EquiVal** can be used to document the testing of equipment supplied to any industry.

What is EquiVal?

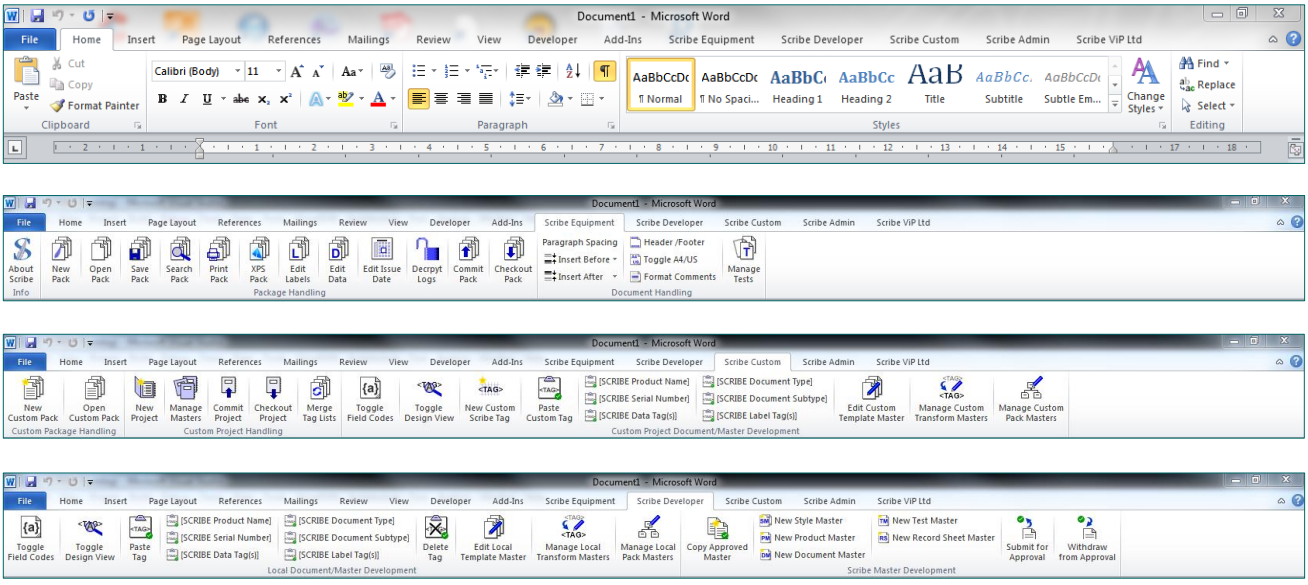
It is an off-the-shelf, state-of-the-art solution to the automated generation of unbeatable quality life cycle testing, verification and qualification documentation for any company selling process or packaging equipment to bio/pharmaceutical product manufacturers.

EquiVal delivers incredible time- and cost-savings and has empowered a multi-million dollar increase in turnover for one major multinational supplier by reducing its document generation times from a typical eight hours per support pack to just 45 seconds. That's an increase in efficiency of over 64,000%. What's more, the improvement in quality has resulted in customer complaints about documentation falling from almost 30% of unit sales to less than 1%.

are the primary factors in any decision affecting product quality and patient safety, and EquiVal provides an invaluable contribution to their compliance strategy (see below for more information).

Although ingenious, the automation powering EquiVal is nothing more than an add-in to Microsoft Word, so there is no complicated software to worry about. It takes just a few seconds to install and all its functionality is readily accessed via additional tabs on the standard MS Word ribbon bar.

It really is so intuitive that you will find it second nature in no time. You will be completely self-sufficient and need no ongoing support from us.



EquiVal is entirely compliant with the requirements of all major regulatory agencies (FDA, EMA, etc.) and is just one of a number of modular verification documentation systems we have developed, based on the knowledge and experience we have gained in the field providing hands-on validation services since 1996.

With the universal regulatory adoption of ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality System), your customers now have to demonstrate that science and risk

EquiVal can even be provided with an interface to your document management system for that added customer assurance of quality and control.

What are the benefits to you?

The following are just a few of the more salient advantages of using EquiVal, each of which will become more apparent as you read further:

- Reduced document generation times and higher output

- Increased profits
- Optimised head-count
- Improved consistency
- Reduced errors, rework and customer complaints
- Enhanced image and reputation
- Supports the rapid and compliant expansion of your business
- Release of more skilled resources for more demanding duties
- Documentation packs can be provided in the customer's own in-house styling
- Document management system interface enables:
  - tighter control
  - rapid expansion
  - more perceptible Quality System
  - improved compliance
- Developed by an experienced validation service provider
- Option to offer eleventh hour transfer of tests between protocols to prevent deviations being caused by others
- Tried and tested since 2011
- Ability to develop totally new documentation offerings without our involvement

What are the benefits to your customers?

These are equally as numerous and include:

- Ability to specify unique documentation packs
- Availability of documentation in their own style
- Assurance of document quality prior to procurement
- No needless deviations
- Guaranteed document delivery times
- DHS, if included, provides assurance of quality
- Valued contribution to ICH Q10 Quality System
- Developed by an experienced validation service provider
- Proven system - many happy customers since 2011

Why was EquiVal developed?

To enable equipment manufacturers targeting the health science industries to offer verification documentation of the highest quality and yet readily accommodate the wide-ranging demands of customers, who invariably have their own unique requirements for verification documentation.

During the course of our validation projects, although sympathising with the 'one size fits all' attempts of process and packaging equipment vendors, the tendered quality often fell far short of the mark and we had no alternative but to encourage our clients to insist on changes or enhancements to the standard documentation support offerings. We decided it might be time to create an alternative and be more proactive in easing these customer/vendor relationships, hence EquiVal.

Not only does EquiVal enable vendors to agree to the provision of the precise life cycle documentation support pack each customer wants, while being secure in the knowledge that delivery times and costs will not be adversely affected, but it also gives customers the confidence that the end product will be of unsurpassed quality and stand up to any regulatory scrutiny.

Depending on the particular customer, a typical equipment life cycle can involve the vendor in some or all of the following stages:

- User Requirement Specification (URS)
- Functional Design and Test Specification
- Assembly/System Build
- Factory Acceptance Test
- On-site Installation
- Commissioning
- Site Acceptance Test
- Installation Qualification/Verification
- Operation(al) Qualification/Verification
- Ongoing Servicing
- Requalification/Reverification
- Decommissioning/retirement

At most of these stages, various checks and tests have to be performed to verify the static and dynamic attributes of the equipment. More

often than not, these verifications are undertaken by different individuals using different document sets.

Large amounts of information are usually transcribed manually into test protocols from core engineering documents, or cut and pasted from previous versions. Such practices inevitably lead to errors, rework, customer complaints and time delays. Slight variations in wording can lead to, what should be, an identical test at different stages in the life cycle (e.g. a performance test at FAT, OQ and annual servicing), being performed to varying compliance standards.

These practices also pose a real challenge to version control, which can result in inconsistencies in information and standards of documentation, and worse … needless deviations during protocol executions.

EquiVal makes all such eventualities a thing of the past.

What makes EquiVal so different?

Now, this might sound a bit complicated but a brief online demonstration will soon convince you otherwise.

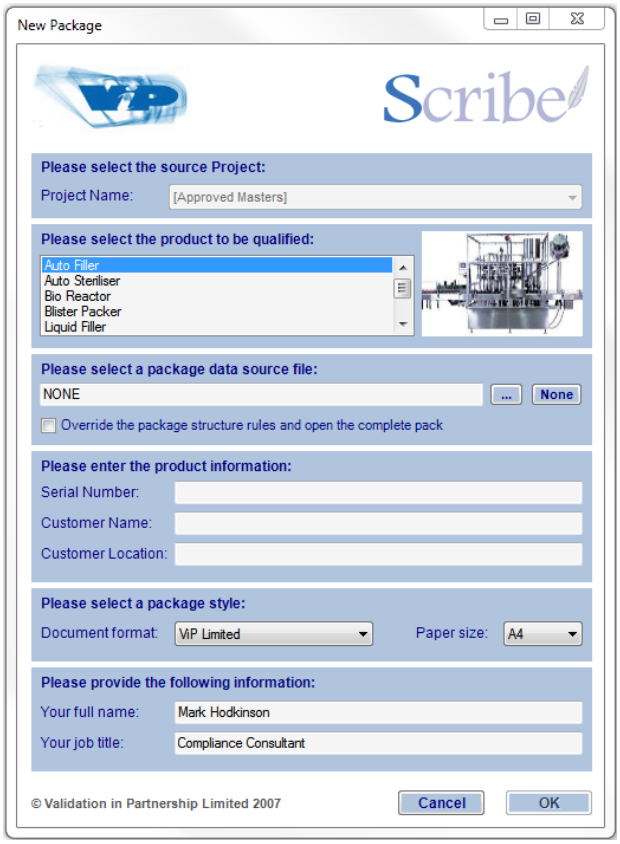
In EquiVal, all your verification documentation exists as a library of individually approved standard master components, e.g. document types, tests and record sheets, which you assemble via highly intuitive interface panels into whatever life-cycle verification pack you want, or your customer desires.

Each component contains a 'data tag' wherever purchase-specific information is to be inserted, such as configuration particulars, tag references, operating parameter set-points, tolerances, etc. User interfaces enable these 'data tags' to be assigned specific text or numerical values, and formulae can be applied to manipulate the final value to appear in the document.

Further interfaces enable 'rules' to determine the automatic inclusion or omission of particular test and record sheets, based on the purchase-specific equipment configuration.

The complete content of each document is swiftly defined and the entire life cycle test/ verification document pack is compiled before your eyes.

A later change to the document pack, such as the addition or removal of a prerequisite, check or test, or an amendment to the order of tests can be effected in seconds.



Any subsequent modification to the equipment configuration or to any of the verification acceptance criteria, such as a set-point or tolerance adjustment, is easily handled via the user interface, and the necessary update is automatically instantly injected wherever the applicable 'data tag' appears throughout the complete document pack.

Furthermore, as each pack can be adapted to a particular customer's preferences, should the customer wish to embrace a new industry initiative, with its inevitable change in terminology for life cycle stages or documents, the user-interface can insert all necessary

amendments instantly throughout the entire document pack.

This may not seem such an impending eventuality to have to cater for, but the '*verification to minimise validation*' message of ASTM E2500 is finally beginning to make its impact, as some of the 'big boy' pharma and biopharma companies have started to take it on board.

It is only a matter of time before everybody else follows suit and then the onus will be firmly put on the equipment manufacturers to dovetail their testing and verification activities into whatever specific life cycle approach and terminology each customer wants.

This is precisely the sort of scenario that EquiVal was designed to help you with. Each of your customers can have an individually tailored documentation pack for each particular purchase.

In a similar way, a request for the documentation to be compiled in the customer's in-house style and format can be readily accommodated, with changes to logos, colours, fonts, layout, etc., taking just a matter of minutes.

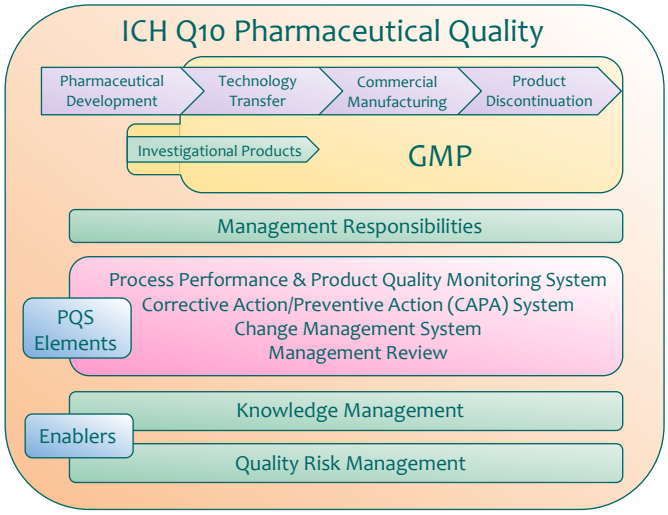
Because the generation process is so swift, a document such as a Factory Acceptance Test Protocol need not be produced until just before it is required for execution. This means it can be amended to reflect any last minute alterations, such as a late customer-requested configuration change, without any deviations having to be encountered and documented.

Your customers will always be appreciative of you simplifying their dealings with the regulatory agencies by ensuring there are no preventable deviations to attract unwanted scrutiny.

Why the earlier references to ICH Q9 and Q10?

Because all of your pharmaceutical and biopharmaceutical customers, who wish to sell their products in the USA or Europe, have no option but to comply with these guidelines, and EquiVal can help you to help them in this.

As the following diagram from ICH Q10 illustrates, the 'Enablers' for the obligatory Quality System are seen as Knowledge Management and Quality Risk Management, which is why the FDA, in particular, has been emphasising the need for science- and risk-based verification.

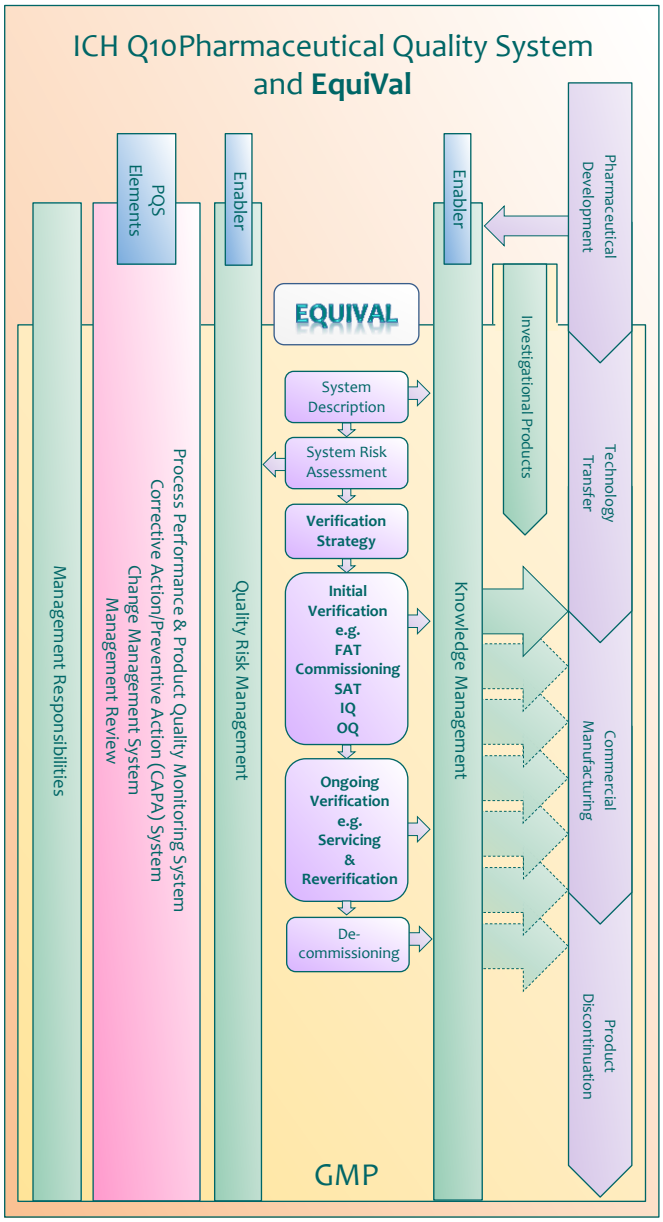


As shown on the next page, if we turn this diagram through 90 degrees and insert EquiVal, you can see what a considerable contribution it makes.

Some equipment manufacturers now offer customers a Risk Assessment, which identifies all generic risks associated with the static and dynamic elements of their equipment. EquiVal goes the extra mile.

It presents each customer with a Risk Assessment for their particular purchase and a Verification Strategy depicting precisely where each identified risk will be mitigated in the projected verification testing.

Moreover, it also provides for the customer to expand these documents to assess, and mitigate, any other specific risks your equipment may pose to their product(s) and critical process parameters due to factors beyond your control, such as simultaneous site operations, power outages, etc.



How much does EquiVal cost?

EquiVal will cost you just a mere fraction of the man-hour cost-savings it will make for you. Imagine being able to generate hundreds more product test documentation packs, of a higher quality, with no additional resources.

As the second paragraph on page 2 states, that's an increase in throughput of anything up to 64,000% using the same headcount … and EquiVal's user-friendliness means more experienced personnel can be made available for more challenging activities.

Rather than pay the annual licence fee in advance, you can pay by instalments or even opt to pay a price per documentation pack, as and when the packs are generated.

With the last option, you pay nothing until you actually have a purchaser.

If you would like to receive a quick indication of the potential cost-savings and increased profits EquiVal could make for your company, please send a brief email to Kieran.Sides@vipltd.co.uk indicating:

(1) the approximate number of life cycle testing/verification/qualification document packs you will produce this year for sale to pharma and biopharma customers, and

(2) the average number of man-hours it takes you to produce a pack for sale. You will receive a response within 24 hours.

Please contact us directly for more definitive cost details.

We can also provide you with cost details for us to develop an interface between EquiVal and your document management system, and advice can be offered to anyone considering installing a document management system for the first time.

How do we find out more?

We could include another couple of pages telling you about how EquiVal's software pieces together the individual components of specific documents, how variable data tags are used, how data is automatically inserted and record sheets are generated based on 'rules' associated with the equipment configuration and components … but there is only one way to really appreciate the power of EquiVal and that is to see it in action.

Please contact Kieran Sides using any of the means identified below and we will be only too happy to arrange a short online demonstration for you, so that you can see EquiVal working on your own desktop.

For further information, please contact:

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- **ModuVal-PRO**

  This complete life cycle version of ModuVal is available in five options.
  www.vipltd.co.uk/ModuValPRO.pdf

- **ModuVal-INTRO**

  The ModuVal 'front end' for those who wish to retain their current qualification and validation protocol structures.
  www.vipltd.co.uk/ModuValINTRO.pdf

- **ModuVal-RETRO**

  This cut-down version of ModuVal assesses the validity of existing validation project.
  www.vipltd.co.uk/ModuValRETRO.pdf

Other products available from ViP include our range of science- and risk-based modular verification solutions for pharmaceutical and biopharmaceutical product manufacturers. The verification approach and the options available are introduced in the following documents, which can be downloaded by pasting the accompanying links into your browser:

- **ModuVal - The Methodology**

  A full explanation of the science- and risk-based modular verification approach that is ModuVal.
  www.vipltd.co.uk/ModuValMethodology.pdf

- **ModuVal - The Product Range**

  A brief summary of ModuVal and the range of ModuVal products currently available.
  www.vipltd.co.uk/ModuValProductRange.pdf

- **ModuVal Contents/Price List**

  The complete contents and price for each option of ModuVal-PRO, ModuVal-INTRO and ModuVal-RETRO.
  www.vipltd.co.uk/ModuValContentsPrice.pdf

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