COMPUTER SYSTEMS VALIDATION

The use of computerised systems within the pharmaceutical, biotech and regulated industries is increasing day by day to leverage repeatability, consistency, efficiency and to derive faster quicker more accurate business intelligence to aid key decision making.

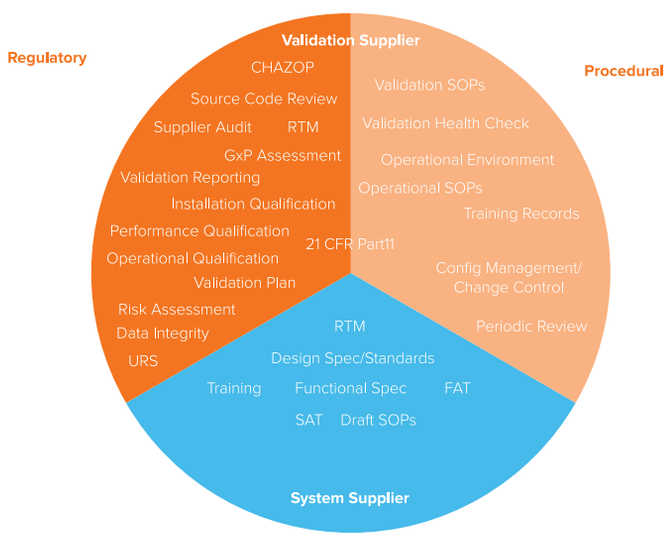
The majority of computerised systems being implemented today include many elements of GxP criticality and as such are being exposed to increasingly intensive regulatory (FDA, MHRA) scrutiny with resultant regulatory exposure and significant business risk and impact.

Clarity Compliance Solutions can lead you through the whole Computer Systems Validation activity; from user requirements and system selection, through build, test, go-live, operations and to system retirement. We can provide cost-effective, pragmatic solutions delivered by our highly experienced and professional team. Our consultants not only know the industry well but several of them have been heavily involved in the development of GAMP® - all of which we can leverage to your advantage.

Effective Computer Systems Validation requires the incorporation of three components that together ensure your system is designed, built, tested, operated and maintained in manner ensuring it is fit for purpose. These components being:

Regulatory – We will ensure you have all the required regulatory documentation for the design, build and testing of your system.
Procedural – We will ensure you have all the required procedures in place within your overall Quality Management System and system specific procedures to operate and maintain your system.
System Supplier – We have years of experience working with suppliers on their Quality Management Systems, Design and Test documentation and ongoing system support. Clarity Compliance Solutions actively bridge the compliance gaps to minimise any impact on the project and system delivery.

Computer Validation Operational Environment



Project Support

During the delivery of CSV projects Clarity Compliance Solutions can be your compliance partner enabling you to leverage the expertise, market experience and professionalism to deliver cost benefits through pragmatic and compliant solutions.

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Vendor Selection and Evaluation

Reliability and fitness for purpose of systems procured into the regulated industries will often be dependent on the approach to their development lifecycle. The vendor evaluation and selection process for high risk items is vital to their validation and justification for use. We have extensive experience in the application of GAMP and GxPprinciples and can tailor a vendor evaluation/audit as appropriate. The output can be generated in the form of a comprehensive report making recommendations regarding vendor selection and the nature and extent of testing and validation based upon audit findings.

Validation Policy and Procedures

We help our clients with interpretation of regulations and formulation of pragmatic policies and procedures, resulting in minimal expenditure to reach acceptable levels of residual risk.

Validation Master Planning

We apply your SOP's and generate clear/concise validation master plans stating the validation approach, rationale, scope of the validation, roles and responsibilities, and applicable procedures and guidance documentation.

Risk Assessment

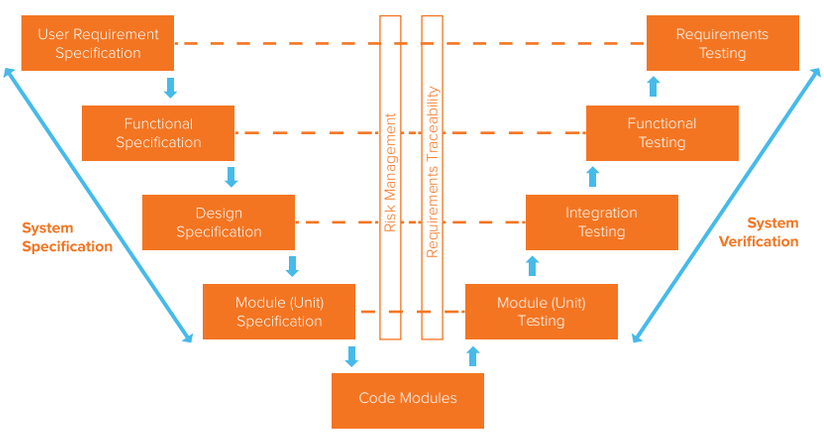
We have developed formal documented risk assessment processes. These can be used to tailor the validation method and extent for each element. Using this defendable approach we target the validation effort where it can make a real impact on critical process reliability and patient safety.

Design, Build, Test Protocol Development and Execution

We draw upon our knowledge and international guidelines to ensure that critical systems are designed and tested to meet their design purpose and the wider requirements of the regulated industry.

We have experience of many types of development lifecycle including V-model (see diagram below), we can leverage this experience throughout the project lifecycle.

V Model Lifecycle



- Data Integrity Assessments
- Audits and GAP Analysis
- Spreadsheet Validation
- Access Database Validation
- Electronic Data Archiving

Why Clarity Compliance Solutions?

Our risk based approach to criticality assessments and associated validation strategy ensures a cost effective approach to CSV system compliance. We focus effort and resources on critical areas resulting in reduced validation costs for the project. With an integrated approach to validation Clarity Compliance Solutions can deliver the greatest business benefit in terms of business operation, project outcome, audit exposure, and ensure you have beneficial operation from day 1.

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www.clarity-compliance.com | enquiries@clarity-compliance.com

Consulting: +44(0)7725 744636 | Enquiries: +44(0)7735 204233
Clarity Compliance Solutions Ltd • PO Box 1965 • Newport • NP19 1BQ