Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

Compliance and Validation Services for Waters Informatics Solutions

For Workstation, Workgroup, or Enterprise

DEPLOYING AND MANAGING A NEW COMPUTERIZED SYSTEM IN A REGULATED ENVIRONMENT

To achieve critical scientific and business objectives, organizations from diverse markets continuously seek out the latest analytical instrumentation. Realizing the full potential of these innovative technologies often requires changes in the accompanying software – changes that may precipitate a wide range of challenges, including:

- Training users on new software applications and learning how to maintain new systems.
- Managing multiple software solutions and processes in the lab.
- Addressing the validation burden that accompanies implementing a new analytical system.

The Waters™ Informatics Professional Services team provides a comprehensive suite of Compliance and Validation Services designed to get your system into production as quickly and cost-effectively as possible. Not only can our highly trained and experienced software professionals help you to accelerate the installation, configuration, and testing/verification of the application, we can also facilitate your entire process – from critical planning to validation reporting.

THE COMPUTERIZED SYSTEM VALIDATION PROCESS

Many regulators and regulated laboratories value the advice given by the industry organization International Society for Pharmaceutical Engineering (ISPE) GAMP when developing an approach to Computerized System Validation (CSV). The objective of a good CSV process is to establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

According to a typical V Model from GAMP (see Figure 1), after referring to their own Validation Planning SOPs, the regulated laboratory must determine their laboratory specific requirements and specifications, often in a document called a User Requirement Specification. Part of this specification will be to define a process to address, test, or challenge those requirements. Once the application is installed and configured in their laboratory, these tests must be executed to verify that the specifications can be met, and the executor must document any deviations.

WHAT DO REGULATED LABORATORIES VALUE MOST IN THEIR CGXP SERVICE PARTNERS?

A recent global survey of regulated laboratories identified key criteria for choosing a compliance services vendor:

- Partner knowledge of regulations, systems, and technology.
- Expertise and quality of services provided.
- Cost efficient services that expedite the validation process and improve the up-time of software and instruments.

With Waters, you have a dedicated partner that can address these needs and who is truly focused on your success.

This documentation must be reviewed and approved before formally releasing the computerized laboratory solution for regulated work in the laboratory. Once the system is in use, a change control process needs to be established to manage upgrades and planned changes, as well as ensuring that automated instrumentation is regularly maintained and rechecked.

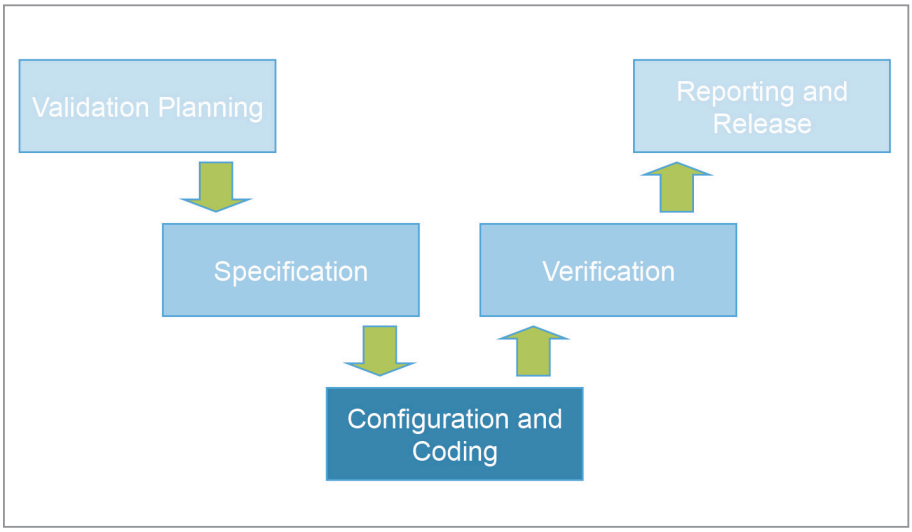

Figure 1. Simplified V Model: "A General Approach for Achieving Compliance and Fitness for Intended Use" as described in the GAMP Good Practice Guide for Compliant Laboratory Computerized Systems.

CURRENT APPROACHES TO CSV: GAMP 5

Demonstrating that a Computerized System is validated remains the responsibility of the regulated laboratory. However, the current edition of GAMP (GAMP 5) recognizes that most automated laboratory solutions are Commercial Off-The-Shelf (COTS) solutions rather than bespoke computer applications. This reduces the overall risk of the solution and influences the extent of testing expected. Commercial solutions are rigorously tested by reliable vendors before release and the vendor can additionally provide qualification services and validation expertise to support the regulated company. Specifically GAMP 5 and two subsequent GAMP Good Practice Guides from the ISPE encourage the regulated laboratory to "leverage supplier testing and services" when developing their own CSV plan.

This approach can significantly reduce the time, cost, and effort of validating a GxP computerized laboratory system but does require regulated laboratories to demonstrate they have reviewed, assessed, and approved the services provided by vendor or partner. Guidance about supplier assessment can be found in the GAMP Good Practice Guides from ISPE.

SCALABLE, EXPERT COMPLIANCE SERVICES TO MEET YOUR NEEDS

In an effort to assist customers with different levels of CSV expertise and/or resources, Waters has developed a suite of compliance and validation services that can accelerate the deployment your new analytical investment with the confidence it will meet regulatory expectations and prove the solution is fit for intended use.

WATERS' REGULATORY EXPERIENCE – A HISTORY OF INNOVATION AND SUCCESS

Organizations have come to rely on Waters for our keen understanding of regulatory expectations and a proven track record of helping customers successfully navigate a complex compliance landscape.

Waters Compliance Experts frequently contribute to ISPE GAMP Good Practice Guides on CSV and Data Integrity, and provide training and guidance document reviews to National Regulatory Authorities around the world.

A Robust Software Development Lifecycle Quality System: Waters software development process has been successfully audited by numerous regulated companies as well as Lloyds under their ISO accreditation.

Routine Software Qualification: These compliance services have provided the base-level qualification for customers' own CSV activities in many regulated environments and are based on successful delivery of IQ and OQ Software Qualification services. In addition to performing manual tests and paper workbooks, Waters pioneered the use of automated testing tools, such as Empower™ System Qualification Tool (SystemsQT™).

Computer System Validation: Waters has been providing comprehensive consulting services surrounding the validation process to our customers since 1999.

ROUTINE IQ AND OQ QUALIFICATION SERVICES FOR SOFTWARE

All Waters software can be deployed with routine Installation Qualification (IQ) and Operational Qualification (OQ) services and documentation, providing a base qualification platform and demonstrating that the deployment meets our expected performance requirements. This might be through Qualification Workbooks, Empower SystemsQT, or the unique Qualification Center capabilities of UNIFI™ Scientific Information System.

COMPUTER SYSTEM VALIDATION CONSULTING SERVICES

Waters will help develop a practical, risk-based approach to each one of the validation phases: planning, specifying, and verifying.

Prior to purchase of any Waters Informatics Solutions, an experienced Validation Consultant will provide a thorough explanation of our Computer System Validation Services, work with you to determine which option best fits your needs, and provide a detailed scope of work describing the validation documents and associated services. These services include:

Tier I Data Integrity CSV Services

- Tier I – Data Integrity focused CSV package includes the following:
  - Data Integrity requirements
  - Data Integrity focused operational qualification
  - Data Integrity requirements traceability matrix
  - Execution services

Tier II Advanced CSV Services

- Tier II – Advanced CSV package includes all of the Tier I – Data Integrity focused CSV package deliverables with the following additions:
  - Baseline risk assessment
  - Validation plan
  - System configuration specification
  - Extended operational qualification
  - Performance qualification
  - Validation summary report
  - Project management services

Tier III Premier CSV Services

- Tier III – Premier CSV package includes all of the Tier I – Data Integrity focused CSV and Tier II – Advanced CSV services package deliverables with the following additions:
  - Comprehensive risk assessment
  - Standard operating procedure development

THE CORE OF COMPLIANCE

Qualification

Testing an instrument system or software at a specific moment in time and verifying, with documented evidence, that it meets predefined specifications.

Validation

Verifying with documented evidence that an instrument system or computerized laboratory system continuously operates in a controlled and compliant manner throughout its life.

Service Offering	Prerequisite Core Qualification	Tier I Data Integrity CSV Services	Tier II Advanced CSV Services (Includes Tier I deliverables)	Tier III* Premier CSV Services (Includes Tier I and Tier II deliverables)
■ IQ workbook or IOQ by automated tool	✓			
■ Data integrity requirements ■ Data integrity testing ■ Data integrity traceability matrix		✓	✓	✓
■ Configuration and compliance advice ■ Configuration specification			✓	✓
■ Broad user requirements specification ■ Validation plan ■ Validation summary report			✓	✓
■ Tailoring requirements to customer workflow			✓	✓
■ Risk assessment ■ Risk-based testing ■ Risk-based traceability matrix			✓	✓
■ Validation of additional modules and/or additional customization				✓
■ Tailored system SOPs				✓

*For Tier III, discuss your exact needs with the Waters Professional Services team before placing an order.

Figure 2. Summary table of services and documents included in Computer System Validation Consultancy Services.

VALIDATION IS CRITICAL THROUGHOUT THE SYSTEM'S LIFECYCLE

Maintaining control of a Computerized Laboratory System is an on-going activity. A comprehensive system validation approach must include consideration for protecting and maintaining the system's validated state throughout its operational lifecycle. Key elements of this approach include:

- Change control management (including risk assessment, testing deploying changes)
- Regular analytical instrument qualification
- Configuration management
- System use and maintenance SOPs
- Backup and restore, archival, and business continuity SOPs
- Electronic data review processes
- Documented user training
- Periodic review of computerized systems

Under the expert guidance of Waters Informatics Professional Services team you can have confidence that your entire Waters Informatics system will be under control and its validated status preserved.

DEPLOYMENTS UP AND RUNNING FASTER

Waters' compliance professionals have the skills and expertise to make your implementation a success. With our help, the timeline for a user's validation process can be reduced by up to 50%. Talk to your Validation Consultant about how our unique suite of Compliance and Validation Services can get your regulated instrument or software deployment producing valuable results faster.

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