Tribiosys

Scientific Consulting Services

Expediting Decision-Making in R&D

Regulatory Compliance and Validation Offerings

Tribiosys is a scientific consulting company that designs and develops solutions for analyzing and managing R&D data and processes for pharmaceutical, biotechnology and medical device companies. We employ proven methodologies and best practices around quality and project management, with an experienced staff that has developed and refined these practices over many years via complex projects. Our solutions are designed with multi-tier open, adaptable architectures that leverage existing investments and integrate best-of-breed COTS solutions.

Tribiosys resources work in multi-disciplinary teams that combine scientific and informatics expertise. Tribiosys project teams are experts in the efficient use of IT methodologies to support effective R&D processes. Tribiosys' scientific staff, including Ph.D. level scientists and informaticians has expertise in bio, chemical, process and clinical informatics. Our highly skilled technical staff, including architects and software engineers, has experience in a wide variety of technology platforms, tools and technologies.

Tribiosys has aligned its offerings into four key Practice Areas:

- Scientific Computing
- Clinical Data and Information Management
- Laboratory Data and Information Management
- Regulatory Assessment and Validation

Tribiosys Validation Offerings

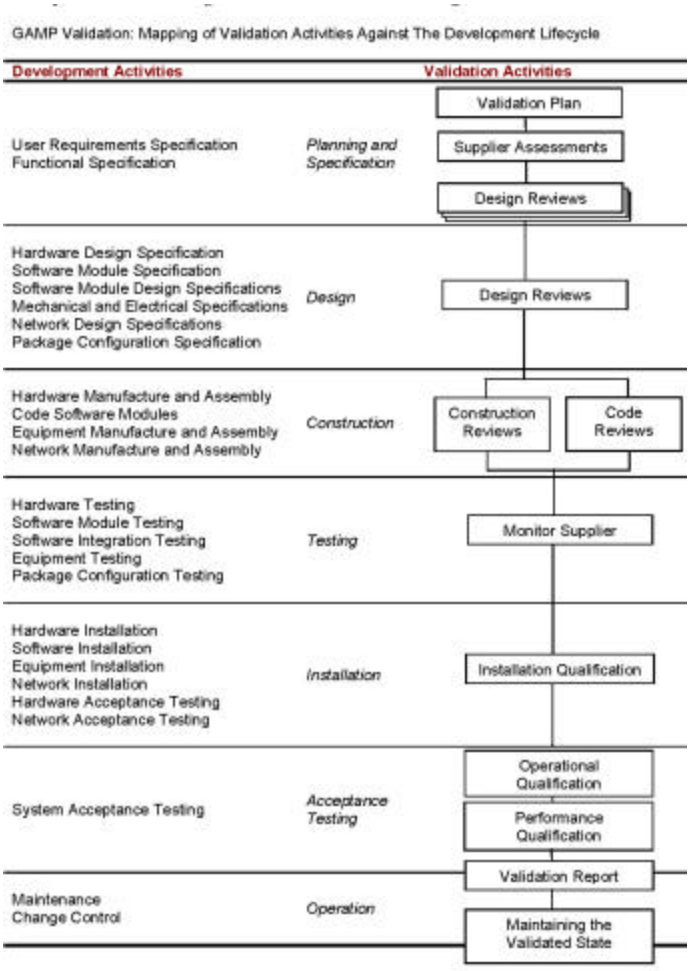
Tribiosys provides technology-based services pertaining to international regulatory compliance (e-submissions, Computer System Validation, 21CFR Part 11/ HIPAA, ICH guidelines, Common Technical Document). Services include validation and 21 CFR Part 11 gap analysis, mitigation / redeployment / remediation, master and system-specific planning, training and SOP development, and archival, storage and retrieval solutions for current and legacy software environments.

The Tribiosys computer systems validation approach integrates industry standard software development life cycle (SDLC) and software quality assurance (SQA) methodologies with relevant validation compliance best practices. Specifically, Tribiosys has experience planning and managing validation projects, including:

- Validation to GLP, GCP, GMP standards
- Gap Analysis and Risk Assessment
- Development of Validation Documentation Suites including Validation Master Plan, URS and FRS, Traceability Matrix, Policies, SOPs, Work Instructions, Validation Protocols & Reports (IQ, OQ, PQ)
- Change Management and maintaining a continuous validated state
- Rollout of validated applications to additional sites

Tribiosys Validation Approach

Tribiosys follows the GAMP recommended guidelines for mapping validation activities to the system development life cycle.



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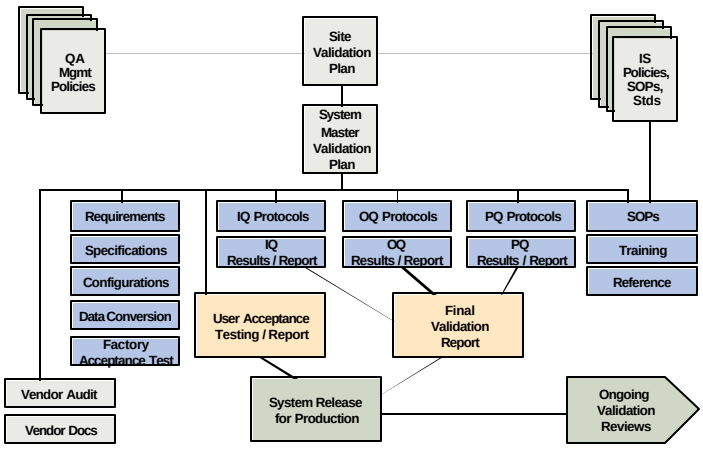
The validation documentation follows a well-organized hierarchy as described in the following graphic.



For a complete validation, documents include the following:

Computer System Validation

- Corporate Validation Policy
- Validation Guidelines
- Master Validation Plan
- Functional Requirements
- System Specs - Hardware
- System Specs - Platform Apps
- System Specs - Application
- System Specs - Design
- Vendor Qualification Audit
- Installation Qualification (IQ) Procedure / Protocol - Hardware
- IQ Procedure / Protocol - Software
- Operational Qualification (OQ) Procedure / Protocol - Hardware & Platform Applications
- OQ Procedure / Protocols - Application
- Performance Qualification (PQ) Procedure / Protocol - System
- Results of Installation Qualification
- Results of Operational, Performance testing
- Reports on IQ, OQ, PQ
- Final Validation Report
- User Acceptance / Release for Production

Computer System Management

- System Maintenance Procedures
- Validation Maintenance Procedures
- SOPs for Users
- End User Training Manual
- User Reference Manual
- Change Control Procedures
- Issues Management Procedures
- Document Management Procedures

All these documents are managed with change control which ensures that the system maintains its validated status.

Validation Tasks and Activities

Tribiosys performs the following general sequence of tasks within Validation.

- Document User Requirements (including regulatory requirements) for System,
- Identify Validation Requirements (e.g. Global Quality Guidelines)
- Assess Current Validation Status
- Identify cGMP impact and Perform cGxP risk assessment
- Develop a Validation Strategy
- Develop the Master Validation Plan
- Complete the collection / development / assembly of Validation Documentation including
    - Processes
    - Policies and Procedures
    - Plans
    - Protocols
    - Training Materials
- Evaluate Validation Procedures in different locations (i.e. Regions, Countries, etc.)
- Identify gaps
- Support Change Management to implement improved procedures
- Maintain Validated status

Tribiosys Validation Experience

Tribiosys has experience managing validation projects as well as developing SOPs, validation master plans, protocols, executing validation protocols and developing validation reports. The Tribiosys computer systems validation approach integrates industry standard software development life cycle (SDLC) and software quality assurance (SQA) methodologies with relevant validation compliance best practices.

Members of the Tribiosys team have experience with overseeing the complete validation of several custom-developed and commercial products. An example of such experience is the development and validation of an internet-based clinical trial and data management application, with integrated document and medical image management.

Similarly, over the past year, Tribiosys has worked with a medical device manufacturer to design, develop and test a 21 CFR Part 11 compliant clinical trial/data management system. As part of the engagement Tribiosys worked with the Quality Systems department of the medical device manufacture to develop and get approval on Systems Requirements Specification (SRS) and Systems Design Specification (SDS) documents per internally approved SOPs. These SRS and SDS documents were then used to develop Quality Systems approved Master Validation Plan and validation protocols. Tribiosys also participated in the User Acceptance testing and execution of the validation protocols and deployment of the system to end-users.