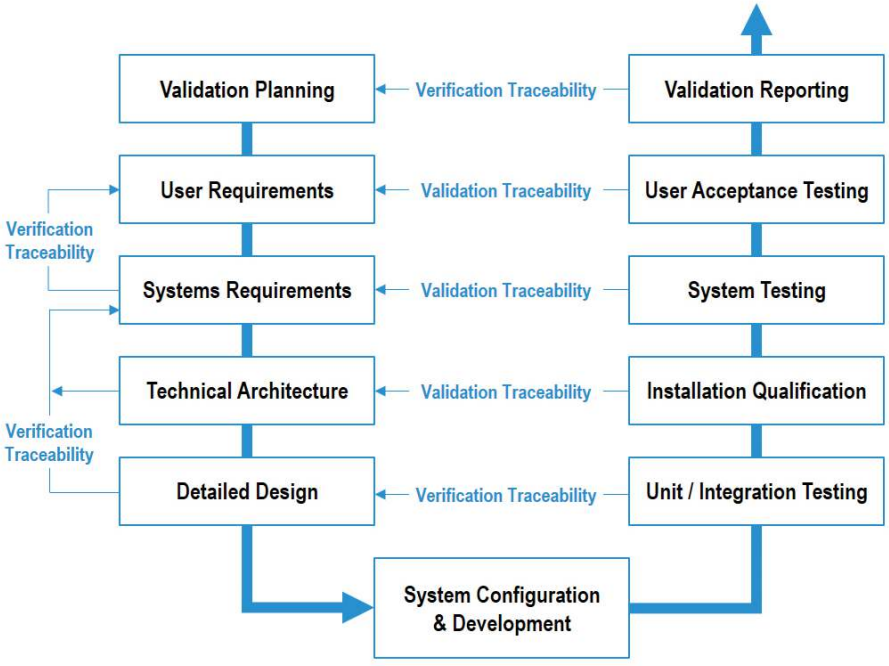
Best Practices for Validation Methodologies & Quality Management Systems

Validation is specialized testing to demonstrate regulatory compliance in addition to the traditional testing that is part of any software development life-cycle methodology—from sequential waterfall to iterative agile ones. Life sciences companies are required by health authorities to validate the impacts of their software on product quality and integrity as they relate to consumer health. Health authority regulations include current good manufacturing, clinical, laboratory. and documentation practices (collectively called "GxP"), the use of electronic signatures, and maintenance of regulated records (called "Part 11"). North American and European health authorities and life science companies generally accept GAMP 5 as the industry standard guidance for developing and maintaining compliance applications in a validated state.

Validation V-Model



The validation v-model starts in the upper left with validation planning and proceeds down the left side of the V through requirements and designs to configuration and development. It then proceeds up the right side of the V with traditional and validation testing processes that trace back to the elements on the left side of the V. This v-model supports quality assurance with traceability from test scripts to user and functional requirements.

Glemser TECHNOLOGIES

Validation Activities

The following activities are typically involved in validating and maintaining the validated state of a compliance application used in a life sciences company.

- Validation planning
- Risk and compliance assessments
- Validation protocol development
- Test script writing and execution
- Validation report writing
- Standard operating procedure development
- Change control procedures and execution
- Validation training

Validation Documentation or Artifacts

The following documents are developed, executed and retained as artifacts to demonstrate to a quality auditor that a compliance application was properly developed, tested and validated.

- Validation Plan
- Validation Strategy
- User Requirements
- Functional Requirements
- Traceability Matrix
- Installation Qualification
- Test Protocol, Test Script(s), and Test Report
- System Testing (Operational Qualification) Test Protocol, Test Script(s), and Test Report
- User Acceptance Testing (Performance Qualification) Test Protocol, Test Script(s), and Test Report
- Validation Summary Report

Glemser TECHNOLOGIES

Validation Best Practices

Detailed User Requirements

Often user requirements are defined at too high of a level and left for the technical team to decipher. This can lead to misunderstandings and gaps when translating to functional requirements. User requirements should be clear and detailed enough to not leave any room for interpretation.

Early Risk Assessment

Sometimes the assessment of risks can be an afterthought or completed last just to satisfy the validation process. The delayed risk assessment can lead to extra work as medium- or high-risk items can affect the validation process. It is key to engage both the technical and business teams after functional requirements are developed to assess which requirements have a medium or high risk. These requirements must be validated with more rigor. Deferring this step often occurs since it can be a lengthy process and requires time from the business stakeholders. If validation scripts are developed before this is completed, however, they may not include enough focus on areas that involve medium or high risk.

Validation Dry Runs

Executing dry runs of operational qualification (OQ) and performance qualification (PQ) scripts is essential to reducing the probability of validation execution discrepancies.

Executing at least one if not multiple passes of the OQ and PQ scripts is critical in reducing lengthy validation cycles due to defect resolution. The cost of resolving defects during a dry run is many times less than that of resolving these defects during formal execution of OQ and PQ scripts. This is also an opportunity to train or reinforce the training of the OQ and PQ executors. The technical professionals executing the OQ and the business users executing the PQ may not be experienced with using the system, especially if it is a new system deployment. Dry runs allow the team that will be formally executing the scripts to become familiar with both the system being validated, the OQ and PQ scripts themselves, and the execution process and tools used to execute the scripts. This familiarity will reduce the time needed to formally execute the scripts because participants have performed the execution during a dry run already. The dry run also helps project planning as it provides an estimate of how long the formal execution will take and how much time is required of the technical and business teams executing the scripts.

Technical Training and Expertise

Training and expertise in the system being validated is key to a successful validation. While not explicitly required, the familiarity and expertise in a system by both the technical and business teams help reduce gaps in user and functional requirements and reduces OQ and PQ script development and script execution times. If these teams understand the software, they can write more detailed requirements that support how the system will function to meet their needs. This understanding will also allow OQ and PQ scripts steps to focus more on verifying the requirements and less on how to navigate the system. These streamlined scripts can then be executed with more efficiency by users who are familiar with the system—reducing overall execution time during dry runs and formal execution.

Early Validation Lead Engagement

Engaging the validation teams at the right time during the project is key. If the validation effort is started too early when requirements are in flux, validation deliverables may require rework. It is important for validation teams to understand the outcomes of the business and functional requirements. If validation teams are involved in requirement gathering discussions too early, draft and intermediate requirements may stick with them and cloud their understanding of the final requirements. It can be beneficial to the project schedule to have the validation team begin development of their deliverables while the final requirements are being reviewed and approved. However, care must be taken to ensure the requirements are in a stable state when the validation team is tasked with developing validation deliverables against them.

About the Author

Ray Glemser, Ph.D.

Ray Glemser is the CEO and executive consultant of Glemser Technologies. His experience developing technologies for pharmaceutical, biotech, medical-device, and consumer-healthcare industries allow them to improve quality, comply with regulations, and gain operational efficiencies. Ray's effective approaches help life sciences professionals solve complex regulatory and quality control challenges.

About Glemser Technologies

Glemser's IT solutions to life science companies enable smooth operations and resolve technical challenges so clients can ensure better patient outcomes and lower cost of ownership.

Glemser TECHNOLOGIES

Phone: +1 (610) 317-9400 | E-mail: inquiry@glemser.com | Website: glemser.com