A leading provider for blood services in Australia

A leading provider for blood services in Australia is a pharmaceutical manufacturing organisation and as such must comply with the Good Automated Manufacturing Practice (GAMP). GAMP is a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry and describes a set of principles and procedures that must be adhered to ensure quality and traceability of pharmaceutical products.

GAMP covers all aspects of production; from the raw materials, facility and equipment to the training and hygiene of staff. Standard operating procedures (SOPs) are essential for processes that can affect the quality of the finished product.
Particularly complex within GAMP is the definition of Validation vs. Testing.

Approach

The organisations Quality Management System needed to be aligned with the GAMP requirement for validation and testing. A new Computerised System Validation Master Plan (CSVMP) was designed and generated.

Objective

Validation of a computerised system encompasses more than testing the software application, though this is an important component of computerised system validation. Validation provides the framework for testing and qualifying a system as suitable for use. The objective of each system validation exercise is to deliver a high level of assurance that all parts related to the use of the computerised system work correctly and consistently in accordance with the system's documented requirements. This includes demonstrating control during the project, ensuring compliance to requirements and regulations, and generating system knowledge.

The validation objectives for computerised systems embodied in the CSVMP are aligned with the Good Automated Manufacturing Practice (GAMP) - A Risk-Based Approach to Compliant GxP Computerised Systems.

In addition to documentation and testing of the system (software application and the infrastructure), the computerised system required additional and ongoing controls such as:

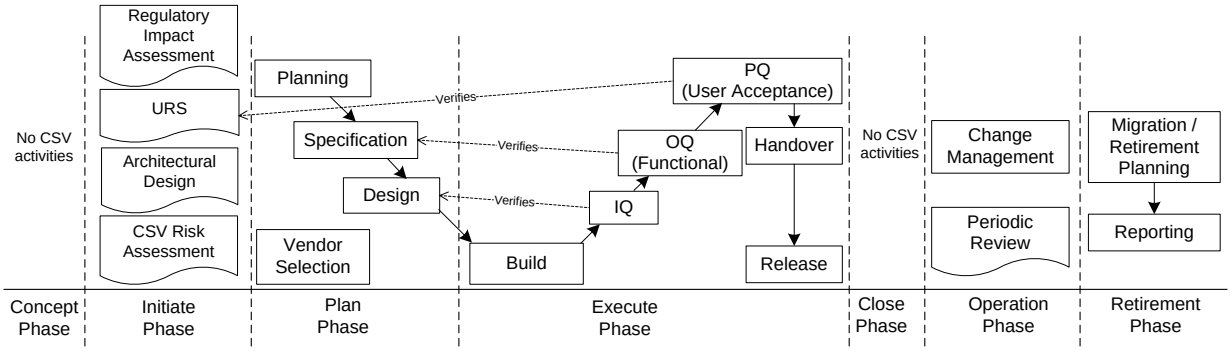
- Current operating procedures or manuals
- Adequate physical and logical security measures to protect the integrity of the system's software programs and its associated critical data, including the prevention of unauthorised changes to electronic data
- Built in checks of critical data entered into the system (either by the operator or by comparing instrument readings)
- Audit trails to identify the critical data entered or changed, when and by whom.

- Ability to generate retained data in human readable form electronic or printed, including audit trails
- A validated archival and retrieval system that is designed to maintain data for the required retention period.
- A disaster recovery or contingency plan which is regularly verified.

Prospective validation for each system follows the V Model SDLC that is depicted in the diagrams below (Figure 1 V Model). System development and verification are activities that are intertwined throughout the lifecycle and provide checkpoints for formal inspections.

The major phases within the SDLC are:

- Concept
- Initiate
- Plan
- Execute
- Close
- Operation
- Retirement



V Model Life Cycle

This is an overview of the V Model life cycle (SDLC) and shows the key validation activities and GAMP aligned deliverables in each phase.

Deliverables

- Architecture documentation
- CSV Risk Assessment
- Data Migration Protocol
- Decommissioning Report
- Design Specification
- Functional Specification
- Installation / Operational Qualification documentation

- Installation Qualification documentation
- Integration testing documentation
- Operational Qualification documentation
- Performance Qualification documentation
- Traceability Matrix
- Unit testing documentation
- User Requirements Specification
- Validation Plan
- Validation Summary Report
- Vendor Assessment

Outcome

A major portion of the quality documentation has been reviewed and updated in full alignment with GAMP principles. The remaining documentation is being updated as part of the continuing improvement quality process. The new CSVMP system meets all the specified outcomes and delivers to the organisational strategic intent.