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## 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 - A Risk-Based Approach to Compliant GxP Computerised Systems. (GAMP).

GAMP is a set of regulatory guidelines for manufacturers and users of automated systems in the pharmaceutical industry. It covers all aspects of production; raw materials, facilities and equipment, training and hygiene of staff.

### Objective

1. Develop a new Computerised System Validation Master Plan (CSVMP) that aligns to GAMP
2. Review all quality management system documentation and align to GAMP

GAMP regulatory guidelines ensure a high level of assurance that all parts of the system work correctly and consistently in accordance with the system's requirements.

In addition the system required additional and ongoing controls. e.g.

- Current operating procedures or manuals
- Physical and logical security measures to protect the integrity of critical data.
- Ability to generate extensive audit trails
- A disaster recovery and contingency plan which are regularly verified.

System development and implementation activities utilised both PMBoK and ITIL methodologies.

### Outcome

All deliverables were aligned to ISO 9001-2008, ISO 27000 Security and GAMP principles.

The new system met all the specified regulatory requirements and delivered to the organisational strategic intent.