



CLIENT

JAG

LOCATIONS

Melbourne, Australia

CORE CAPABILITIES

- Project and stakeholder Management
- Factory Acceptance Testing
- Validation and Compliance services
- GMP compliance

PROJECT SUMMARY

Synertec was engaged by JAG to deliver the independent validation and qualification for the automation control system for a number of major production plants including:

- The new Privigen Module IV plant
- An upgrade the existing Module III system
- The AlbuRx Facility Phase 3 project.

THE CHALLENGE

JAG required an independent, experienced partner who not only understood automation control systems and the complex processes of a pharmaceutical facility, but also one who was experienced in GMP validation services.

SYNERTEC'S SOLUTION

Synertec's role was to work with both JAG and CSL to develop testing strategies for the various required Operational Qualification protocols and to execute them on the live site.

In order to validate JAG's software, GMP procedures were followed, as per CSL's requirements. Developing and executing the Operational Qualification protocols included gaining a detailed understanding of the existing Module III plant for Privigen and implementing it into the Module IV testing.

Operational Qualification covered the following types of testing:

- Normal operation
- Negative testing
- Infrastructure
- Peripheral devices and remote terminals
- Electronic batch records

Synertec also developed and executed FATs for Process Control software with CSL and JAG. This involved checking CSL approved recipes, P&IDs and flow-paths.