

Project Summary



Client:

Australian Red Cross Blood Service

Location:

Brisbane / Alexandria / North
Melbourne, Australia

Validation Consultancy for 3 ARCBS Sites

Project Summary:	<p>Synertec was engaged to undertake the rework existing validation protocols, write validation protocols for systems/areas that had no existing protocols and coordinate validation temperature mapping of Cold Rooms, Freezer Rooms & processing areas. The scope included the provision of technical expertise during the TGA Audit.</p> <p>NAPS & VTPS Facilities:</p> <p>The project feature included the following:</p> <ul style="list-style-type: none">○ Facilitated and prepared site URS○ Prepared Validation Master Plans○ Prepared and executed Design Qualification○ Executed design traceability○ Developed Trade Packages for critical services○ Reviewed all Installation and Operational Qualification documents○ Developed and executed Performance Qualification protocols○ Prepared Validation Summary Reports for systems and the facility○ Reviewed the design of GMP critical services including HVAC, Cool
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	<p>Rooms, Freezer Rooms, Building Management System, Environmental Management System, Security Management System and Laboratory Gases.</p> <ul style="list-style-type: none">○ Supported and presented in TGA Licensing Audit <p>Brisbane Facility:</p> <p>Synertec was initially contracted to assist with the validation of the new processing facility. Synertec provided personnel and expertise which:</p> <ul style="list-style-type: none">○ Completed the facility validation packages within 2½ months to meet the TGA Audit date.○ Were able to work around the ongoing building works to achieve this outcome.○ Co-ordinate activities/communicate requirements across a wide range of departments and contractors to enable compliance and to meet deadlines.○ Enabled compliance not only within the specific requirements of validation but associated systems.○ Succeed in a high pressure environment (failure to achieve a processing license would have resulted in a major, negative impact on the blood supply Australia wide). <p>Ultimately resulted in the ARCBS Brisbane being awarded a full processing license by the TGA following the audit.</p> <p>NAPS & VTPS Facilities:</p> <p>Synertec provided continuous validation and consulting support to the ARCBS in the development of the new NAPS & VTPS site. The Synertec team supplied final review, assessment and approval on all GMP-related documents, protocols and site technical issues.</p> <p>All documentation generated was designed to be applicable to this site but also future sites to enable consistency of approach and minimisation of effort.</p>
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