



CLIENT
CSIRO

LOCATIONS
Melbourne, Australia

CORE CAPABILITIES

- Project Management
- Concept and detailed design
- Multidisciplined engineering: process, mechanical, electrical, control and automation engineering
- 3D modelling
- Commissioning
- GMP validation and compliance services
- V-model engineering lifecycle
- Tender packages and evaluation
- Construction support services

PROJECT SUMMARY

Synertec was engaged by CSIRO to deliver the schematic design for a new multiproduct facility to produce a variety of biological therapeutic goods through cell culture (utilising monoclonal antibodies).

THE CHALLENGE

CSIRO required a partner who had GMP expertise coupled with experience in designing and implementing facility expansions on brownfield sites without interruption to normal operations.

The project also required engagement with the Therapeutic Goods Administration of Australia for in-principal approval of the facility, as this facility is a first in Australia for single use technology for multi-product biologicals for both API and Final Product Manufacture including sterile filling.

SYNERTEC'S SOLUTION

Synertec's team of experienced GMP engineers worked closely with CSIRO to ensure all of the Australian standards were adhered to – not only in the design – but also throughout the tender and equipment supply packages. The project involved rigorous user requirements gathering, development of block layouts, process flowcharts and a basis of design. Synertec managed all design sub-consultants including architectural, structural, hydraulic, mechanical, electrical and quantity surveying.

In order to ensure the site was not adversely affected by the new facility, the team performed an assessment of the existing site conditions.

The final facility design included the following:

- Grade B and C cleanrooms with associated HVAC systems
- Personnel change locks, materials storage areas and materials transfer locks
- WFI and Pure Steam Generation and Distribution Systems
- Sterile Compressed Air and Sterile Gases supply and reticulation
- Clean and Waste Autoclaves
- Sterile Filling Isolator