

Good Manufacturing Practice Facility Design



SYNERTEC



CLIENT

CSIRO

LOCATION

Melbourne, Australia

CORE CAPABILITIES

- Project management
- Concept design and detailed design
- Specialist multidiscipline engineering including process, mechanical, electrical, control, and automation engineering
- 3D modelling
- Commissioning
- Good Manufacturing Practice (GMP) validation and compliance services
- V-model systems engineering lifecycle analysis
- Tender packages and evaluation
- Construction phase support

PROJECT SUMMARY

Synertec was engaged by CSIRO to design a new multiproduct facility to produce a variety of biological therapeutic goods through cell culture, utilising monoclonal antibodies.

THE CHALLENGE

CSIRO required a partner with strong expertise in Good Manufacturing Practice (GMP) 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 (TGA) of Australia for in principle approval of this first in Australia facility for single use technology of multi-product biologicals for both active pharmaceutical ingredient and final product manufacture including sterile filling.

SYNERTEC'S SOLUTION

Synertec's team of experienced GMP engineers worked closely with CSIRO to ensure compliance with all relevant Australian standards in the design and throughout the tender and equipment supply packages.

The project involved the development of rigorous user requirements, block layouts, process flowcharts, and basis for design. Synertec managed all the design consultants including architectural, structural, hydraulic, mechanical, electrical, and quantity surveying.

To ensure the existing operations were not adversely affected by the new facility, the team conducted a detailed assessment of existing site conditions.

The final facility design included the following:

- Grade B and Grade C cleanrooms with associated heating, ventilation, and air conditioning systems
- Personnel change locks, material storage areas, and material transfer locks
- Water for injection and pure steam generation and distribution systems
- Sterile compressed air and sterile gases supply and reticulation
- Clean and waste autoclaves
- Sterile filling isolator