Inhaled Pharmaceutical Manufacturing Facility

CLIENT
Medical Developments International

LOCATIONS
Mulgrave & Rowville, Australia

CORE CAPABILITIES

- Project Management
- 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 Management

PROJECT SUMMARY

CSIRO was contracted by the Medical Developments International (MDI) to develop a novel synthesis for the manufacture of an inhaled pharmaceutical treatment. A bench scale process was developed that produced product that exceeded all the requirements of the US Pharmacopoeia.

THE CHALLENGE

The bench scale process needed to be scaled-up to a commercial scale facility, which complied with TGA and FDA requirements. As the product success grew, expansions and new facilities where required.

SYNERTEC'S SOLUTION

Initially, Synertec was contracted by MDI to work with CSIRO during this phase primarily as an advisor for the development of the process to ensure what was being undertaken on the bench could be scaled up to a commercial process with minimal safety and regulatory hurdles. Once the basis for the process had been established, Synertec undertook a detailed Front End Engineering Design (FEED) exercise. The exercise involved investigating all the issues surrounding the design, construction, validation and operation of a pharmaceutical manufacturing facility.

To enable product export, Synertec was contracted to Project Manage the compliance of the existing Clean Rooms to meet TGA and US FDA requirements. These efforts resulted in a successful US FDA Audit for MDI and the issue of a license to sell product into the US market.

Most recently, Medical Developments International (MDI) required a new pharmaceutical manufacturing facility with ISO 14644 Class 8 clean rooms for the dedicated manufacture of Methoxyflurane. Synertec designed and managed the build of a new pharmaceutical manufacturing facility. Using the V-Model, Synertec developed validation documents for the design and qualification phase (up to operational qualification) and performed qualification of the new facility.