Manufacturing Facility for Inhaled Pharmaceuticals

PROJECT SUMMARY

CSIRO was contracted by Medical Developments International (MDI) to develop a novel synthesis for the manufacture of an inhaled pharmaceutical treatment. A bench-scale process was developed to make product that exceeded all the requirements of the United States Pharmacopeia, one of the pharmaceutical industry's most recognised standards.

The next stage of the project was commercialisation.

CLIENTS

CSIRO

Medical Developments International

LOCATION

Mulgrave and Rowville in Melbourne, Australia

CORE CAPABILITIES

- Project management
- 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 management

THE CHALLENGE

The bench-scale process needed to be scaled-up to a commercial scale facility that complied with the requirements of the Australian Therapeutic Goods Administration (TGA) and the United States Food and Drug Administration (FDA).

Expansion of existing facilities and construction of new facilities were required as the success of the product grew.

SYNERTEC'S SCOPE

Synertec was initially contracted by MDI to work with CSIRO during the scale-up phase primarily as an advisor on process development to ensure the bench-scale process could be scaled up to a commercial process with appropriate safety and regulatory compliance.

Once the basis for the commercial process had been established, Synertec conducted a detailed Front End Engineering Design (FEED) exercise. This involved investigating all issues surrounding the design, construction, validation, and operation of the pharmaceutical manufacturing facility.

To enable product export, Synertec was contracted to project manage the compliance of the existing clean rooms to meet TGA and FDA requirements. This work resulted in a successful FDA audit for MDI and the issue of a license to sell product into the US market.

Synertec's partnership with MDI continued with the construction of a new pharmaceutical manufacturing facility for the dedicated manufacture of Methoxyflurane, utilising clean rooms certified to ISO 14644 Class 8. Synertec designed and managed the build of the new pharmaceutical manufacturing facility. Using the V-Model systems engineering lifecycle analysis, Synertec developed validation documents for the design and qualification phase (up to operational qualification) and completed the qualification of the new facility.