



Project Summary



Client:

Medical Developments International (MDI)

Location:

Rowville, Victoria, Australia

Design and Construction of new Pharmaceutical Manufacturing Facility

<p>Project Summary:</p>	<p>Medical Developments International (MDI) required a new pharmaceutical manufacturing facility with ISO 14644 Class 8 clean rooms for the dedicated manufacture of Methoxyflurane.</p> <p>Synertec designed and managed the build of a new pharmaceutical manufacturing facility for MDI. The facility consists of ISO 8 clean rooms. Synertec designed and managed the build of the HVAC system and the necessary process services. 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. The scope of the work delivered by Synertec for the cleanroom validation included:</p> <ul style="list-style-type: none"> • User Requirement Specification (URS) • Functional Specification (FS) • Design Specification (DS) • Design Qualification (DQ) • Installation Qualification (IQ) • Operational Qualification (OQ) • Validation Summary Report (VSR)
<p>Technologies:</p>	<p>ISO14644 Class 8 Cleanroom</p>