



API Process Upgrade Project, 9106-01
Aesica (Queenborough) Ltd

RBPC was awarded design works November 2012
 Facility shutdown for the start of upgrade May 2013.
 Partial handover to make product 1, July 2013.
 Final handover to make product 2, December 2013

API Potent Drug Facility

Equipment, facility and utility upgrades to make products for a new customer

Detail design, HAZOP, Construction Management, Validation

Requirements

- The requirement was to upgrade an existing Potent drug facility such that it could make a new product which is both a Schedule 3 controlled drug and also is a potent drug with an OEL of 1.5 µg/m³ 8 hour TWA (Safebridge level 3 potent compound).
- Materials of construction of equipment had to be compatible with HCL. The existing stainless steel Filter dryer had to be removed in a sympathetic way such that it could be sold on the second hand market and replaced with a new Hastelloy Filter dryer.
- Containment systems were to be upgraded to handle a product with an OEL of 1.5 µg/m³
- HVAC systems were upgraded to meet ISO 14644-1 class 7
- Installation of a new HTF package
- Works to be carried out such that there was minimum impact to other production operations.

Scope

- The initial concept including the purchase of the new Filter dryer was completed by Aesica
- RBPC designed and costed the remaining equipment, facility and utility upgrade.
- HAZOP assessment
- RBPC then managed the construction of the upgrade.
- RBPC completed all equipment, facility and utility validation.

Delivery

- The upgrade was delivered in a 2 stage process. Initially a shutdown was required to relocate existing equipment and a contained construction area was created. The remainder of the facility was then handed back over to manufacture existing products.
- The remaining upgrades and validation were then completed as planned

Outcome

- The upgrade was delivered on time and within budget

Approved quote:

RB Plant delivered a logistically difficult project in a flexible and professional manner.