Engineering Consultants

Piramal Healthcare, Suite 4

Description

- £2.5m investment to extend production capacity at Grangemouth for hormonal products, including contraceptive pills and hormone replacement therapies in order to increase production capacity
- Cleanroom suite for the production of Antibody-Drug-Conjugates at multiple commercial scale
- Separate rooms for personnel gowning; equipment & materials staging; mAb thawing; component cleaning and large scale buffer preparation (up to 2,000L volume) utilising single use disposables
- Processing rooms for non-cytotoxic operations such as pooling and modification or reduction or purification of the antibody
- Suite to facilitate cytotoxic operations such as drug toxin handling; conjugation and purification
- Final filtration and fill area included for bottling off the Bulk Drug Substance (BDS).

Involvement

- Detailed design of systems to client User Requirement Specification to deliver new cleanrooms to ISO 7 (Class 10 000) and ISO 8 (Class 100 00)
- Services to deliver door interlocking to maintain appropriate room pressure cascades and airflow directions
- A dedicated Air Handling Unit (AHU) with mechanical pressure stabilisers and duct mounted motorised dampers in the extract system for room pressure control and duct mounted attenuators to control room noise to an acceptable level
- Terminal supply air HEPA filter in all ISO 7 & ISO 8 cleanrooms with safe Change HEPA filters serving the production cleanroom
- Automatic control of room temperature and humidity via the BMS. Automatic fan speed control for the AHU supply air fan to maintain constant airflow during filter 'blinding'
- An Environmental Controls System (EMS) for monitoring of critical room temperature, humidity and pressure, all validated to 21 CFR 11.

£2.5m extension of MHRA approved ISO class 7 and ISO 8 class medical production facility for the manufacture of Antobody Drug Conjugates

Benefits Delivered

- Detailed design information in Autodesk Revit MEP coordinated Building Information Model to a level of development consistent with level 2
- Provide detailed Contractor guidance on standards of installation to deliver cleanroom standards
- Undertake a capacity assessment of existing electrical distribution and secondary supplies and develop an resilient electrical distribution infrastructure
- Undertake full surveys of existing building infrastructure, identify points of interface for connection of new services, and to identify necessary upgrade works to accommodate the extended facility
- Worked collaboratively with the contractor and integrated design team to deliver highly technical clean room spaces within tight budget constraints
- Close communication and co-ordination with Piramal Engineering Project Manager to develop the Client brief into a full technical design proposal
- Provision of additional support during the project with regular site visits, communication to ensure the Building Services Engineers had full technical understanding of the complex issues associated with constructing laboratory facilities.