

MEDICAL DEVICE CLIENT CASE STUDY





THE CLIENT

Advanced Medical Solutions Group (AMS) – specialising in the design, development, manufacture and distribution of novel, high-performance tissue-healing technologies, including advanced wound care products, surgical dressings and medical grade materials as well as medical adhesives and sutures for closing and sealing tissue.

THE BRIEF

The client was in the process of extending their existing premises to expand their capability for manufacturing an innovative new Medical **Device product. Cleanroom** Solutions were engaged as a sub-contractor on behalf of AMS to initially deliver dual ISO6 and 7 cleanrooms, as well as Personnel and Materials Airlocks.







Medical Device

19+/-2°C / 30-60% RH



"They delivered precisely what we expected..."

Peter Davies, Group Engineering Manager at Advanced Medical Solutions, said: "From worksite safety, timekeeping and productivity to communication and value for money, Cleanroom Solutions have been excellent across the board.

"I have found Cleanroom Solutions to be a most knowledgeable and professional organisation who worked with us on the design requirements and then delivered precisely what we expected."

Peter Davies AMS Group Engineering Manager



Advanced Medical Solutions



MEDICAL DEVICE





THE TECH SPECS

A controlled environment designed, installed, cleaned and commissioned by Guardtech built to the following specification:

- ◆ **Structural:** Structural: GT Shell Pro wall panels, 3 x GT Access Plus single doors (interlocked), GT Rise Max rapid roll doors (interlocked), GT Lid Plus aluminium grid ceiling system, GT Deck ESD vinyl flooring capped & coved, steelwork C-channels creating a plenum using brackets and panels, GT Vision Plus glazing panels.
- Electrical: GT Lux Plus LED light panels, 13-amp sockets and CAT6a network data points in three compartment dado trunking, 12amp 3-phase power, Uninterrupted Power Supply (UPS) back-up, electromagnetic doors interlocks.
- Mechanical: GT Airt Pro upflow unit, GT Flow Plus H14 HEPA Fan Filter Units with speed control, CAREL mimic screens providing room conditions and air conditioning status, beacon indicators, fully compliant fire alarm system with aspirator pipework and additional smoke detectors and sounders, return air duct probes.

- ◆ **Utilities:** Compressed air pipework system finished in isolation valves, plumbing with mains hot & cold water to twin wash trough.
- Environmental Monitoring: GT Scan Lite Magnehelic gauges to monitor pressure.
- ◆ Furniture & Equipment: Stainless steel stepover benches, stainless steel garment holder, stainless steel shelving, stainless steel lockers, stainless steel twin wash trough with Dyson Airblade taps.

THE CHALLENGES

Generally, this project went extremely smoothly, with all interested parties working together diligently, efficiently and effectively to produce an excellent build on time and on budget. The only particularly tricky challenge to overcome involved issues with having two big teams on the same site conducting separate works.

Dual works: Ground conditions were not ideal for cleanroom construction when we arrived on site – with the Principal Contractor excavating the ground outside. Due to the external excavation works that were in progress the ground conditions were uneven and presented a daily challenge in getting materials in and out. As a CDM site, it was critical

that the co-ordination communication between the Principal Contractor and Cleanroom Solutions was on point, with a particular focus on the movement of materials in a safe and practical manner. The teams all worked together seamlessly to achieve this, ensuring neither build was compromised in any way.

ISO6 room: Originally, one room was to be ISO6 so naturally had additional FFUs to provide the air change rate. Part way through, AMS decided that the ISO6 room could be downgraded to ISO7. We made no changes to the FFU design and left the room as per the original design, thus presenting the IQ & OQ as ISO7. This room will naturally achieve ISO6 due to the amount of FFUs but would need to be revalidated.

THE RESULT

Peter Davies, Group Engineering Manager at Advanced Medical Solutions, said: "From worksite safety, timekeeping and productivity to communication and value for money, Cleanroom Solutions have been excellent across the board. "I have found Cleanroom Solu-

tions to be a most knowledgeable and professional organisation who worked with us on the design requirements and then delivered precisely what we expected."