

CELL & GENE THERAPY



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THE CLIENT

4basebio – manufacture and sell proprietary, synthetic DNA and mRNA products for applications in Cell & Gene Therapies and vaccines. 4basebio offer RUO AAV manufacturing services for partners developing gene therapies, offering targeted non-viral vectors for partners wishing to deliver therapeutic nucleic acid or proteins to specific cells and tissues.

THE BRIEF

The client was looking to expand their manufacturing capacity with the introduction of two floors of new Grade C modular cleanrooms, including process rooms, solutions preparation areas, change areas, cleanroom corridors, several personnel and materials airlocks and separative devices, in an existing office park premises in Cambridgeshire.



Cell & Gene Therapy



21 ± 2C
45% ± 10% RH



400m²



“All the client’s requirements were catered to by the team...”

Guardtech Group Operations Director Conor Barwise said: “This project presented the team with a variety of challenges due to the relatively large number of process spaces and change areas in a restricted overall footprint.

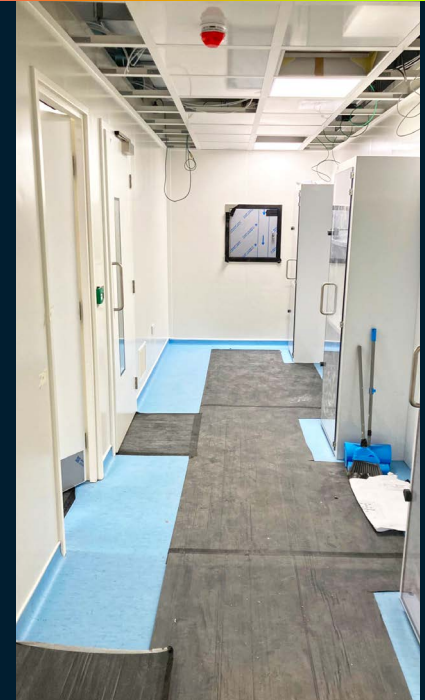
“However, over the past 20 years, Guardtech Cleanrooms have encountered a wide variety of different projects with space, access and operational limitations and the Design and Install teams worked brilliantly together to ensure all of the client’s requirements were catered to.”

Conor Barwise
Guardtech Group
Operations Director



Guardtech
cleanrooms

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THE TECH SPECS

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

- ◆ **Structural:** GT Shell Plus QuadCore wall panel system, GT Lid Plus T50 ceiling grid, GT Access Plus semi-flush single and double doors with electromagnetic interlocks, status indicators and break glass, GT Deck Plus vinyl flooring in Sapphire Blue, capped & covered.
- ◆ **Mechanical:** GT Flow Plus H14 HEPA Fan Filter Units with G4 Pre-Filters, GT Air Pro 30kW Upflow Air Handling Units (AHUs), DX pipework between AHUs and condensers, ductwork to DW 144 and insulated.
- ◆ **Electrical:** 13amp double sockets, electromagnetic interlocks, PVC conduit in panel core, basket in the void, GT Lux Plus LED luminaires achieving

an average of 500 lux at Bench Level.

- ◆ **Environmental Monitoring:** GT Scan Pro Environmental Monitoring System (EMS), featuring in-room LED panels measuring Pressure, Temperature, Humidity connected to client PC utilising Akivision software, with digital display & sounder and text & email alerts.
 - ◆ **Furniture & Equipment:** H14 HEPA filtered goods lift, clear perspex enclosure, electro-magnetically interlocked, mechanically interlocked polypropylene transfer hatches, waste hatches & chute, electro-magnetically interlocked polypropylene transfer hatches.
- Biological Safety Cabinets, Trespa Toplab workbenches, stainless steel steppover benches with shoe compartments, stainless steel Pigeon Holes for Shoe Storage, powder-coated steel lockers, wall-mounted stainless steel dispensers, stainless steel sinks with motion sensor taps, point-of-use heater plumbed in to water supply and connected to drainage, Contamination Control Flooring laid on the 'dirty' side of the Primary Change Areas.

THE CHALLENGES

- Tight squeeze:** Most of the major challenges with this project related to the tight nature of having multiple process rooms in a relatively constricted space, coupled with the fact the facility would operate over two floors. Squeezing as many process rooms into the building as physically possible while working out how they all interfaced together was a tricky task for the Guardtech Cleanrooms Design and Installation teams, but it was a challenge they were equal to. The team was also challenged by the fact the client required separate change areas for each of the seven process rooms. Again though, the Guardtech engineers found a solution to ensure the client was able to make the most of every inch of available space.
- Floored layout:** The team were tasked with providing a separated waste transfer system for incoming product and outgoing goods via a split hatch and a dedicated bespoke waste chute. The Design Team also had to take fire break and pressure regime considerations into the overall equation. Overcoming incoming goods from the ground floor to the first floor with the HEPA-filtered

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transfer hatch was a test – and on top of that, the team had to construct the top floor while the lower floor was fully operational. But the Guardtech Cleanrooms Installation Engineers have a great deal of experience in constructing environments in conjunction with ongoing client process and so extra care was taken to ensure their work was never compromised in any way.

THE RESULT

Guardtech Group Operations Director Conor Barwise said: “This project presented the team with a variety of challenges due to the relatively large number of process spaces and change areas in a restricted overall footprint.

“However, over the past 20 years, Guardtech Cleanrooms have encountered a wide variety of different projects with space, access and operational limitations and the Design and Install teams worked brilliantly together to ensure all of the client’s requirements were catered to.”

