

ASEPTIC PHARMACY CLEANCUBE



Grade C

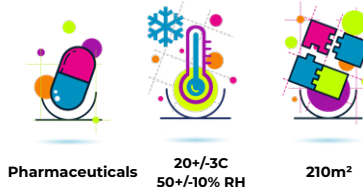


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THE CLIENT

Gloucestershire Hospitals NHS Foundation Trust – formed from Gloucestershire Hospitals NHS Trust, which was established following a reconfiguration of health services in Gloucestershire in 2002. The Trust provides acute hospital services from two large district general hospitals, Cheltenham General Hospital (CGH) and Gloucestershire Royal Hospital (GRH). In this instance, it was the Trust’s aseptic pharmacy team that required a cleanroom solution.



Pharmaceuticals 20+/-3C
50+/-10% RH 210m²

THE BRIEF

The client had an urgent and rapid requirement for a GMP Grade C aseptic compounding cleanroom environment for the production and handling of chemotherapy pharmaceuticals. After a thorough consultation with the client and site survey of a proposed location, Guardtech recommended a Cleancube Maxi-4 base footprint with three annexed 20ft Mini units to serve as ancillary areas for material access lobby and store as well as a separate Cleancube Plant Skid.



This aseptic pharmacy Cleancube connects to the main Cheltenham General Hospital to support the Trust’s process.

“A complex project to help deliver critical medicine...”

Guardtech Project Manager Florence Whitehead said: “The project undoubtedly challenged us from every angle – there were so many complexities to the design, engineering innovations to ensure compliance and peak operational functionality, as well as the requirement to deliver a solution as quickly as possible. “I want to pay tribute to everyone involved in making this happen – it was a huge project to undertake but the Guardtech family really pulled together to overcome a number of hurdles along the way.”

Florence Whitehead
Guardtech Project Manager



cleancube
mobile cleanrooms

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GT Shell official panel system partner:



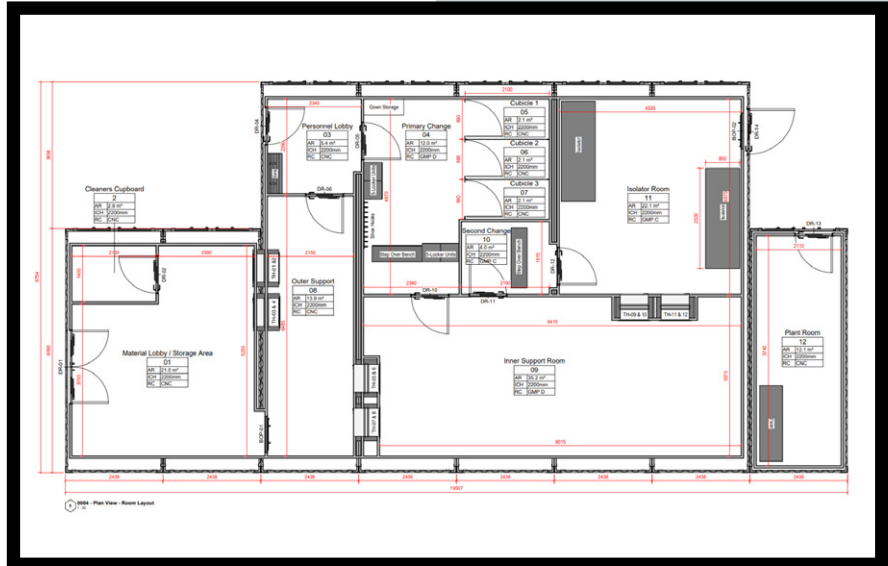
Partner

THE TECH SPECS

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

◆ **Structural:** GT Shell Pro 60mm Kingspan Quadcore insulated panels Cleansafe 120, Panels Hollow core and low-level exhaust grille for transit back to plenum, GT Lid Pro 60mm Kingspan Quadcore insulated Cleansafe 120 powder coat ceiling panels, GT Deck Pro vinyl flooring system covered 100mm from floor level – sealed to panel underside, GT Access Plus Kingspan single doors with vision panels, GT Access Lite Kingspan leaf-and-a-half powder-coated steel doors with vision panels.

◆ **Electrical:** GT Lux Lite LED lighting units flush-mounted in ceiling panels with PIR activation, 13amp double sockets wired back to the corresponding module sub DB, 32amp outlets, Isolator outlets wired back to the corresponding module sub DB, 3-compartment curved profile trunking around room perimeter and columns, RJ45 ethernet



sockets fed back to 18-way network switch, fire alarm, smoke heads in each room feeding back to fire alarm panel, electro-magnetic interlock system on Grade D and C doors.

◆ **Mechanical:** GT Air Plus 30kW and 20kW upflow air handling units (AHU), wall-mounted recirculating units with condensers for air conditioning, GT Flow max 1200 x 600mm low profile fan filter units (FFUs) with H14 HEPA filters, 3 x grade 316

stainless steel trolley interlocked active H14 HEPA filtered transfer hatches, 5 x regular.

◆ **Monitoring & Controls:** GT Scan Pro Environmental Monitoring System (EMS) with seven digital touchscreen display transmitters with alarms – fed by temperature, humidity & pressure probes. AHU controller digital display for setting target temperature, humidity and fan speed.

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◆ **Furniture & Equipment:** 2-tier cleanroom 304 stainless steel trolley with braking castors, grade 304 stainless steel waste bin with swing lid and removable top adjustable levelling feet, grade 304 stainless steel wired storage racking, eye-wash station, foot-operated 75-litre pedal bin with lid and bag-clamping band, full length grade 304 stainless steel polished finish mirror, mild steel lockers with sloping roof, internal shelf and lockable doors, 304 stainless steel multi-purpose dispenser with vision slots, grade 304 stainless steel stepover bench with 6 compartments and adjustable levelling feet, grade 304 stainless steel wall-mounted clog rack, 304 stainless steel wall-mounted coat hook rack, grade 304 stainless steel cubicle bench with box section frame and adjustable levelling feet, hazardous substance COSHH cupboard with 3 perforated shelves, 13 x fitted work benches (two with fitted extraction) with grade 304 stainless steel frame and Sealwise WCB top with upstands, stainless steel grade 304 high back wash trough with 2 sensor taps, high back floor standing wash trough with sensor operated hand dryer, sensor soap dispensers and sensor taps.



THE CHALLENGES

Annex No.1: This was the first-ever NHS Cleancube aseptic pharmacy that Guardtech had been contracted to manufacture – which brought a number of different challenges and requirements in order to meet EU GMP Annex 1 compliance. The design of the facility had to demonstrate robust control of contamination through

a carefully considered process flow. This meant that Cleancube Design Engineers had to work closely in collaboration with the client to ensure a methodical, robust, compliant and user-friendly layout was developed. A great deal of effort went into ensuring we made the most of every inch of space in a footprint that was extremely tight due to the limitations imposed by the hospital car park area designed by the client.

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Critical solution: The client's previous aseptic pharmacy suite had been condemned due to severe structural damage caused by a pressure issue. This meant that production of vital chemotherapy medicine had to be postponed until the new facility was up and running. Cleancube's versatile make-up, as well as the host of benefits it brings through being an off-site, pre-fabricated option, made it an ideal solution for a super-busy hospital Trust that simply couldn't allow for any prolonged downtime or disruption that a typical traditional construction project would've brought.

This also meant that certain aspects of the project veered away from what Guardtech would usually deliver on an NHS project. One of those concerned ventilation – where a derogation was agreed with the client to proceed with the installation without meeting HTM 03-01 compliance. Health Technical Memorandum 03-01: Specialised Ventilation for Healthcare Premises sets out the standards for design, installation, validation, operation and maintenance of ventilation systems in Healthcare facilities – such as aseptic pharmacies. Because it was so critical to get this facility online as soon as possible, and because Guardtech had such



a long and trusted history in delivering elite sterile cleanrooms, it was felt that a derogation would speed up the process in helping to get the vital unit back online as soon as possible.

Well documented: Despite that time-saving derogation, the Guardtech team still had to ensure they delivered a world-class facility that met all the expectations of a GMP Grade C Annex 1 compliant facility, backed up water-tight project management

and documentation. A full DQ, IQ and OQ were conducted on the facility, as well as rigorous post-installation commissioning, including Stroma leakage testing and a comprehensive validation process.

Changing scope: Because the delivery of any cleanroom facility is an evolving process, Guardtech engineers try to be as flexible as possible to ensure clients get exactly what they want.

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The scope of this project changed throughout the design and installation of the Cleancube – for example, EMS (environmental monitoring) probes to measure pressure were added to the facility’s transfer hatches, as well as over HEPA filters in critical areas.

Bacons were added late on in the installation for alarms, fridge temperature probes were connected to transmitters and an extra room even had to be created within the footprint – MAL (materials airlock) – as the Trust required a dividing wall to safely contain a specialised LEV extraction zone, as the back end of the facility connected to the existing hospital building. As ever, Guardtech did everything they could to meet an ever-changing brief from a client who needed to ensure they ended up with a facility to match their critical workflows and operational procedures.



Top hats: This was also a first for Cleancube in terms of ‘top hat’ connection for isolators. Whilst the Guardtech team have engineered the technology for countless microbiological safety cabinets over the past seven years, this was the first occasion – of what is now likely to be many – when the solution was

required for an isolator suite. This required special design and engineering work to be conducted on the container shell to ensure a practical, robust and compliant solution.

A thimble connection was utilised with the isolators to ensure that pressure is always balanced, as maintaining that consistent pressure in the

room is critical for safe operation.

More firsts: This Cleancube featured a string of other newly established processes and innovations, including the installation of relatively small in-bench grille extraction units for cleaning products that pull away clean fumes to protect operatives.

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It was also the first time the team had installed airborne insect traps in a Cleancube, as well as a dedicated N+1 redundancy Cleancube Plant Skid – a back-up 30kW upflow unit housed in a specially engineered container to cover the main air handling unit (AHU) in case of emergency power loss/disruption.

This was also the maiden introduction for edge protection on the container facility roof – which was specially designed for this cleanroom. Because it's not a typical industrial flat roof and instead features corrugations, Guardtech engineers had to utilise the container corner castings to install the edge protection safely and securely.

THE RESULT

Guardtech Project Manager Florence Whitehead said: "Being part of such a major project for our beloved NHS – and helping provide this Trust with a solution to support their critical work for cancer patients – was an incredibly rewarding experience for me personally.

"The project undoubtedly challenged us from every angle – there were so



many complexities to the design, engineering innovations to ensure compliance and peak operational functionality, as well as the requirement to deliver a solution as quickly as possible. "I want to pay tribute to everyone involved in making this happen – it was a huge project to undertake but the Guardtech family really pulled together to overcome a number of hurdles

along the way.

"Naturally, with such a huge institution as the NHS, the client was extremely diligent – in the best possible way – and their passion and commitment to drive this project on to fruition was so admirable. Thank you to them as well for their part in conducting an amazingly well co-ordinated and collaborative effort to bring this dream to reality."