

CASE STUDIES



Guardtech











www.guardtechgroup.com

CLIENT CASE STUDY

CNC QC LABORATORY





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THE CLIENT

Noumed Life Sciences a newly formed UK-based Pharmaceutical manufacturing company producing generic drugs on a large scale that serve a wide range of therapeutics for the worldwide market. Additionally providing a variety of services from IP Licensing to Contract Manufacturing to R&D.

THE BRIEF

After successfully delivering a suite of cleanrooms for the owner of a generic Pharmaceuticals company, we were commissioned to design and construct a large scale manufacturing facility for his new UK generics brand. Phase one of this project was the construction of a QC Lab to house the research and development activities and the testing of product batches.







21C+/-2 & 30-70% RH



"As good a facility as the inspector has been in..."

een set high for our next project ogether which will be in the very

Operations Director, Noumed Life Sciences





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

Structural:

GT Shell Pro PIR Wall Panels, GT Shell Lite Wall Cladding, GT Access Plus Powder Coated Steel Doors, GT Deck Pro ESD Vinyl Floor Capped & Coved, GT Lid Lite Powder Coated Aluminium Ceiling Grid & PVC Tiles.

◆ **Electrical:** 13-amp power and Cat 5e network flush-mounted sockets, containment buried within the wall panels in channels and housed in basket in service channels in the ceiling void.

Mechanical:

Refurbished and new VRV high-level split systems, plumbing & drainage for a number of sinks, RO water system,

fume extraction equipment and ductwork.

- ◆ **Equipment:** LEV extraction arms, environmental stability chambers, fume hoods & workbenches, emergency shower.
- ◆ Furniture: Bespoke Trespa workbenches with integrated shelving and sinks, Trespa cabinets, stainless steel utility sinks, chemical storage cupboards, roller racking.



THE RESULT

Noumed's Operations Director said: "I'm happy to inform you that our MHRA inspection went very well over this past week. The site passed its inspection for packaging, warehouse and QC testing. We expect to receive formal certification in the next 45 days.

"One of the notes made by the inspector was that this was as good a facility as he has been in, which is indicative of your team's hard work and quality of work. For that I would like to thank you both and your teams. It only means that the standard has been set high for our next project together which will be in the very near future."



GRADE D PACKAGING





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Noumed Life Sciences – a newly formed UK-based Pharmaceutical manufacturing company producing generic drugs on a large scale that serve a wide range of therapeutics for the worldwide market. Additionally providing a variety of services from IP Licensing to Contract Manufacturing to R&D.

THE BRIEF

After delivering a suite of cleanrooms for the owner of a generic Pharmaceuticals company, Guardtech were commissioned to design and construct a large-scale manufacturing facility. Phase two of this project was the construction of Grade D cleanrooms to house separate blister packaging lines for bulk packaging of a number of different pharmaceutical products.







aceutical 21°C / 45% RH ±10%





"I'm happy to inform you that ou MHRA inspection went very well. The site passed its inspection for packaging, warehouse and QC testing. We expect to receive formal certification soon.

"One of the notes made by the inspector was that this was as good a facility as he has been in, which is indicative of your team's hard work and quality of work.

"For that I would like to thank you both and your teams. It only means that the standard has been set high for our next project together which will be in the very near future."

> **Operations Director,** Noumed Life Sciences





THE TECH SPECS

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

- Structural: GT Shell Plus PIR Wall Panels, GT Lid Max PIR Ceiling Panels, GT Shell Lite Wall Cladding, GT Access Pro GRP Doors, GT Deck Plus Vinyl Floor Capped & Coved, GT Lid Lite Powder Coated Aluminium Ceiling Grid & PVC Tiles.
- ◆ Electrical: 13-amp & 3Ph Power and Cat 5e Network flush mounted sockets, containment buried within the wall panels in channels and housed in basket in service channels in the ceiling void.
- Mechanical: Separate bespoke AHUs serving each packaging line, laydown and sampling areas served by a chiller with a shared AHU for common areas. Compressed Air pipework, Process Chilled

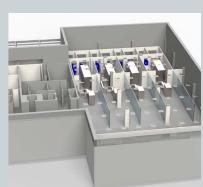
Water, Central Vacuum System.

- Monitoring: GT Scan Max CF21R compliant Environmental Monitoring System with in-room displays, alarm beacons and software . BMS connectivity for all plant and services.
- ◆ Furniture: Bespoke Trespa Workbenches with integrated Shelving and Sinks, Trespa Cabinets, Stainless Steel Utility Sinks, Chemical Storage Cupboards, Roller Racking.

THE CHALLENGES

The Floor: A resin floor was required – however, the area that was to be covered extended over two separate slabs. Extensive surveys and core samples were required to determine the type of slab and the most appropriate substrate to overlay, which was eventually specified as a high-build two-part epoxy resin with quartz and sand mesh base layer.

Automatic doors: Programming the logic between the manual and automatic doors and their



interlocking function was a time consuming and difficult exercise.

HVAC balancing: Each of the process rooms were designed at a high pressure and are served by a common central corridor – this, along with the use of calibrated weighted Pressure Relief Valves (PRVs), meant that balancing was a very delicate exercise that required a great deal of care and technical skill.

Heat exchanger: A heat exchanger was required to stop the pipes from freezing, so this was installed to provide two loops – one glycol-enriched to prevent pipework freezing and the other with H2O only serving the process equipment.

OPTICAL MANUFACTURING





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THE CLIENT

Contamac – the world's largest independent manufacturer of contact and intraocular lens materials. The business produces bespoke ocular formulations using their clients' own specifications and is the leading innovator in the development of specialist polymers and biocompatible materials for medical applications.

THE BRIEF

Guardtech were tasked with the design and construction of an ISO7 optical cleanroom in an existing building that required repurposing. This included a full, comprehensive design of all mechanical & electrical services for the building as well as the related process equipment.







21°C+/-2°C / 45%+/-10%



"One of our most stunning iobs to date..."

Mark Wheeler, **Guardtech Group Commerical Director**





THE TECH SPECS

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

- ◆ Structural: GT Shell Plus PIR Wall Panels, GT Lid Plus Ceiling Grid & Tiles, GT Access Pro GRP Doors, GT Deck Plus Vinyl Floor Capped & Coved.
- ◆ Electrical: 13amp double sockets flush mounted. Three-phase
- ◆ Mechanical: Filtration provided by H14 HEPA filters powered by bespoke air handling units, chiller and low temperature hot water.
- ◆ Monitoring: Environmental monitoring system measuring pressure, temperature and humidity.
- ◆ Transfer equipment: Bespoke HEPA-filtered cleanroom goods lift and trolley hatch.
- **Extraction:** Process and in-room fume and heat extraction from hard-pipe connection and LEV arms.

◆ Furniture: Bespoke Trespa workbenches on grade 304 stainless steel frames, 16 laminar flow workbenches, stainless steel stepover benches, laminar flow garment stocker, stainless steel sink unit with Dyson Airblade taps.

THE CHALLENGES

Ceiling void: This project saw Guardtech develop a two-storey building that was originally an office block. The whole of the second floor had to be raised to accommodate a ceiling void capable of facilitating all of the services required.

HVAC & filtration: Contamac had severely restricted space for the plant, which would need to be housed externally. In addition, strengthening of the floor significantly restricted the ceiling voids of both the upstairs and downstairs cleanrooms. A specific design study was commissioned to evaluate the most appropriate form of air handling equipment to meet the temperature and humidity conditions required by the client, while also meeting the airflow demands of the ISO7 classification of the cleanrooms.

Cleanroom staircase: The client needed to access both the upstairs and downstairs cleanrooms without having to undress and then dress again in cleanroom clothing, so the two controlled environments needed to interface without compromising one another. Guardtech created a changing room that housed a staircase leading to the upstairs area this allowed a single change area to serve both cleanrooms.

Guardtech pressurised the staircase in such a way that it maintained classification, yet did not compromise the differential between the changing room and the two levels of cleanroom. They achieved this using balance pressure dampers and creatively configured air supply to the staircase and adjoining lobbies. This required extensive design work which had to be factored into the HVAC design study that was conducted.

Structural: Within the design study Guardtech undertook, structural calculations were conducted to assess the load of the cleanroom and the process equipment. This highlighted that the existing floor would not sustain the load imposed, therefore the floor had to be strengthened before the cleanrooms could be installed. Significant design planning was conducted around the process flow, as this was a new process and space planningwas essential to ensure that the cleanroom being on two levels actually worked for the process that would be housed.

Bespoke cleanroom lift: The client required heavy product to be moved from floor to floor in a non-compromised condition, but without manual handling no such solution was readily available. Guardtech worked with Felcon to design, install and commissioned a cleanroom-compatible goods lift which did not compromise cleanliness or pressure cascades. This HEPA-filtered cleanroom lift needed to maintain a positive pressure during transition. An upstairs and downstairs lobby was therefore fashioned to ensure that the pressure regimes of the lower and higher cleanrooms was not compromised by the opening and closing of the lift doors.

REAGENT MANUFACTURING





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THE CLIENT

Origin – manufacturers of versatile packaging solutions for the global pharmaceutical market. Origin take care of the design, manufacture and consolidated supply of a wide range of pharmaceutical packaging. In this instance, their leading aseptic filling expertise and large-scale manufacturing production lines were required to package reagents used in COVID-19 diagnostic kits.

THE BRIEF

In response to the upscaling of COVID-19 diagnostics across the UK, Origin were briefed with assembling a 'reagent-fill' facility in an extremely quick timescale. Origin turned to Guardtech to help condense a 24-week build schedule into half that time to meet the increasing demand of COVID-19 testing, with both firms keen to play







s 21°C

470m



their part in the national effort to fight the virus. Origin required six ISO5 cleanrooms for their aseptic filling processes and a larger background environment at ISO7 for packaging of materials and associated utilities to support the process equipment, such as power units, water and compressed air.

"Communication was continuous and effective..."

Guardtech Operations Director
Conor Barwise said: "With such
a challenging schedule and necessity
that the highest quality was achieved,
it was essential that the communication
between all project stakeholders was
effective and continuous. Guardtech
worked alongside the main contractor
and client with an openness and
proactiveness that ensured all
stakeholders and teams onsite worked
together in a positive manner. Any
issues or disruptions to the schedule
were reviewed collectively and
managed pragmatically. A fantastic
project we were proud to deliver."

Conor Barwise, Guardtech Group Operations Director





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

Structural:

GT Shell Plus PIR Wall Panels - including glazed panels, GT Lid Plus Ceiling Grid & Tiles, GT Access Pro Rapid Roll Doors.

Electrical:

13-amp small power, flush-mounted with embedded containment within the panel core, three-phase power sockets ceiling mounted, electromagnetic door interlock system, automatic swing-arm door closing systems on large double doors with infrared activation, digital touchscreen HMI group fan speed controller.

Mechanical:

GT Flow Plus Fan Filter Units including H14 HEPA filters provided a total air supply of 115,500m³ per hour, GT Air Plus – four off 25kw VRF units ducted throughout the plenum, stainless steel sinks installed with point-of-use heater and associated plumbing.

Monitoring:

GT Scan Max CF21R Part 11 compliant Environmental Monitoring Software with connected temperature, humidity and pressure probes serving all cleanrooms with additional in-room LCD displays and three 49-inch display screens in ISO7 packaging hall.

• Furniture: Stainless steel stepover benches, wall-mounted dispensers, stainless steel pedal bins, stainless steel sink unit, bespoke stainless workbenches.

THE CHALLENGES

Schedule: Due to the nature of the client's business model being focussed on immediate COVIDresponse, time was of the essence and a lot work was done up front to identify the appropriate materials and resources to condense a standard 24-week building schedule to a compressed 12-week operation. This also included working around other contractors operating in the main hub and facilitating the client's process equipment installation and commissioning while the cleanrooms were being fabricated.

Christmas and COVID: The 12-week schedule

The 12-week schedule overlapped the Christmas break, so Guardtech had to facilitate holiday working amidst a landscape that was already difficult due to general COVID complications, travel restrictions and virus management onsite.

HVAC: Due to time constraints, Origin's HVAC system had to be installed using 'off-the-shelf' components – therefore the design had to be well thoughtout by Guardtech's team to ensure the best possible results.

Brexit: With the UK leaving the EU at the turn of year, a number of key components had to be tightly managed in terms of the shipping and importation process to avoid delays.



THE CLIENT

University of Cambridge –

between floors, air shower,

specialist E-beam close

control room (+/- 0.1 C),

ISO5 & 6 areas, plus wet

process benches with

and localised ISO5.

extract set back facility

GRAPHENE RESEARCH FACILITY

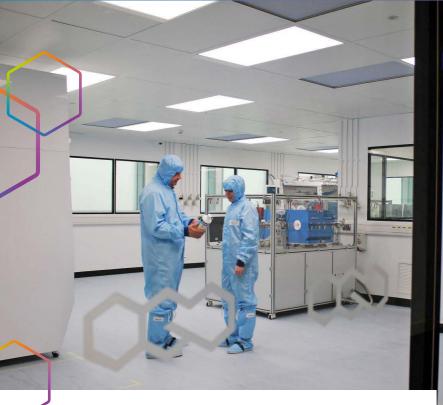




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21°C+/- 0.1











UNIVERSITY OF CAMBRIDGE

n Gaylard said: "This project was in a ew building, split over two floors ift shaft to take people between the two ors. When designing the cleanroom eanroom Solutions Director] Jan ies had to create a bespoke 'clean ople coming in from the other floor The E-Beam, which sits in the ISO5 oom, is an expensive piece of equipmen - and when it's fully operational, it has to run at 0.1 of a degree. So to control that had to come up with a unique desig ntrolling humidity and temperatu We did it through a combination of chilled and hot water and sensible cooling coils. It was a very intricate llers, a very detailed design. challenged us, and we were delighted

> Sean Gaylard Design Engineer





Fresh air to the cleanroom(s) provided via a roof mounted Air Handling Unit (AHU) complete with frost coil, cooling coil and reheat coil, incorporating full Trend BMS controls. A specialist process gas system, complete with extract and abatement system, plus a monitored leak detection and O2 depletion monitoring, DI water system.

Electrical installation: Full installation, including sub main distribution, 230v sockets, 3-phase power, data cabling, CCTV, fire detection/aspirator and gas leak detection wiring.

ISO7 second floor areas:

Conventional air flow design incorporating a plenum and FFUs, complete with sensible cooling coils utilising chilled water and trim heaters to provide more stable room temperatures. Conventional low level return air grills returning to the plenum areas via external service

chase/corridor areas.

ISO5 ground floor areas: Full laminar flow design incorporating a plenum & FFUs. complete with sensible cooling coils utilising chilled water and trim heaters to provide more stable room temperatures. A raised access floor with air grills provided the air flow path back to the plenums via the service corridor areas and built-in room return air ducts. Access to the ground floor cleanrooms was provided by a passenger lift with HEPA filtration at high level, cleaning the sealed lift shaft, as well as an air shower prior to entering the ISO5 areas.

ISO5 area (E-Beam room):

Ground floor area with full laminar flow design, incorporating a plenum & FFUs, complete with sensible cooling coils utilising chilled water and trim heaters to provide more stable room temperatures (+/-0.1 degree C). A raised access floor with air arills provided the air flow path back to the plenums via built-in room return air ducts.



THE RESULT

Cleanroom Solutions Project Director Sean Gaylard said: "This project was in a brand-new building, split over two floors. The first floor was offices and we had a lift shaft to take people between the two floors. When designing the cleanroom, [Cleanroom Solutions Director] Jan Pyrgies had to create a bespoke 'clean shaft' to ensure that the work being done in the cleanroom wasn't compromised by people coming in from the other floor. "The E-Beam, which sits in the ISO5

room, is a very expensive piece of equipment - and when it's fully operational, it has to run at 0.1 (achieving 0.05) of a degree. So to control that Jan had to come up with a unique design for controlling the humidity and temperature. We did it through a combination of chilled and hot water and sensible cooling coils. It was a very intricate control system - AHUs on the roof, chillers, a very detailed design.

"Using heating and cooling at the same time often surprises people, but it was critical to control the temperature in this way.

"It was a complex project, which really challenged us, and we were delighted with the final result."



CLIENT CASE STUDY

MEDICAL DEVICE SOFTWALL ISOPOD





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THE CLIENT

Oval Medical Technologies Ltd – a world class drug delivery business specialising in the development of autoinjector platforms with a strong patient focus. Oval designs, develops and industrialises autoinjectors that include integrated, customised primary drug containers. Oval's enabling autoinjector technology provides consistent delivery performance for a wide range of formulation viscosities.

THE BRIEF

Oval were looking to enhance the capability of their development lab to incorporate a new upgraded part of their process, opting for two conjoined 6m² Softwall Isopods. Oval had specific challenges within the room that precluded them from opting for a standard Isopod, therefore we were charged with designing two bespoke connected units.



Medical Device

12:



"A valuable project for an exciting new product..."

Mark Wheeler said: "The team enjoyed tackling the various challenges that this bespoke Isopod build presented. "Many of the lessons we learne on this project, and the new ideas we implemented for thes bespoke Isopod models, have been incorporated into our ongoing development plans for the standard product range. "This should prove to be extremely valuable in helping us to develop the best possible product for the widest range of future users."

Mark Wheeler, Guardtech Group Commerical Director





THE TECH SPECS

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

Structural:

Grade 304 stainless steel frame with anti-static PVC strip curtain.

- Electrical: LED lighting panels to provide an average of 500 lux at bench level.
- ◆ Mechanical: Filtration provided by H14 HEPA filters powered by Fan Filter Units.

Monitoring:

Pressure monitoring from magnehelic gauges.

THE TECH SPECS

Internal ceiling height:

Space may have been at a premium – but this wasn't a major



obstacle for Guardtech. The team opted to use slimline Fan Filter Units in order to create the tallest internal ceiling that could be achieved for the Isopods.

Structural: The client wanted the units to be mobile, and so wheels were fitted. As a result, we needed to put structural reinforcement in place to reduce the risk of splay.

Structural calculations were made to ensure the outward force was offset by adequate bracing.

Equipment transfer: The client needed to move equipment between the two Isopods, which meant the Installation team needed to incorporate a removable bar at the bottom of the Isopods. This enabled us to retain the structural bracing while accommodating the need for equipment transfer.

THE RESULT

Guardtech Commercial Director Mark Wheeler said: "The team enjoyed tackling the various challenges that this bespoke Isopod build presented. "Many of the lessons we learned on this project, and the new ideas we implemented for these bespoke Isopod models, have been incorporated into our ongoing development plans for the standard product range. "This should prove to be

extremely valuable in helping us to develop the best possible product for the widest range of future users."

CLIENT CASE STUDY

CLEANCUBE MOBILE SOLUTIONS





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THE CLIENT

Cignpost Diagnostics – providers of COVID-19 screening and other healthcare services. They combine operational agility with leading gold standard test technologies. Cignpost Diagnostics provide healthcare services to a range of industries including media and sport.

THE BRIEF

Develop rapid response unit for the COVID-19 pandemic. CleanCube shipping containers and modular buildings created for oil and gas industries were developed quickly with Cignpost Diagnostics to find COVID-19 solutions. From conception to delivery, the first Luton Box Van mobile cleanroom was produced in three weeks. As of June 2021, we'd produced one tour bus conversion, seven vans, three modular buildings and 18 shipping containers, as well as two permanent laboratories.



Analysis/

2205 - / 2

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Numero units





"Guardtech made a complicated process very easy..."

"We started working with Guardtech soon after the pandemic hit in the UK. Cignpost Diagnostics was focused on providing screening services to allow people to get back to work safely and securely.

"To enable this, we needed mobile laboratories manufactured to BSL2 safety standards.

"We engaged with Guardtech and they made what could have been a complicated process very easy. We can recommend Guardtech unequivocally."

Cignpost Diagnostics





THE TECH SPECS

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

- ◆ Structural: GT Shell Plus PIR Wall Panels, GT Lid Max PIR Ceiling Panels, GT Shell Lite Wall Cladding, GT Access Lite GRP Doors, GT Deck Plus Vinyl Floor Capped & Coved.
- ◆ Electrical: 13amp double sockets contained in three-compartment PVC trunking ran around all perimeter walls. Safety isolation transformer provides earthing for all units. 32amp single phase hook-up.
- Mechanical: Filtration provided by H14 HEPA filters powered by fan filter units, recirculating wall-mounted air conditioning cassettes, mobile sinks with self-contained supply and effluent containers.
 - Monitoring: Magnehelic pressure gauges.

◆ Furniture: Bespoke Trespa workbenches on grade 304 stainless steel frames, Trespa seating benches, stainless steel coat hooks.

THE CHALLENGES

Timeframe: A rapid turnaround was required to protect both potential COVID-19 sufferers and staff working in the units. Guardtech managed to produce fully fitted-out Biosafety Level 2 labs in just two weeks per CleanCube. Sourcing vehicles, finding appropriate materials and factoring in installation time presented numerous challenges. The Guardtech team worked around the clock to fulfil orders for these vital CleanCubes.

Space optimisation: The benefit of being able to have compact BSL2 labs in places where space was at a premium was crucial for firms tussling with the COVID-19 pandemic. But this also meant that the footprint in each unit was severely restricted. In fact, the biggest footprint in some labs was just 4.5m x 2.5m – but Guardtech engineers somehow managed to fit an entire lab in

that space, including external plant equipment such as air con condensers. The team were tasked with fitting the units with bespoke Trespa workbenches, which lined the perimeter, that couldn't be as deep as standard benches. Attention to detail was key – every millimetre needed to be diligently planned out.

Electrical connection: Our skilled technicians installed safety isolation transformers to give the units independent earthing points – ensuring the supply was safe. The initial design featured the use of a standard 32amp single phase supply, but we have since developed an alternative domestic connections solution using two 13amp plug sockets.

Fitting in: In one tricky case, the client wished to add a Bio Safety Cabinet to their unit after it had been sent into the field. The BSC might have been too tall to fit, but a restrictive ceiling is not the kind of thing that derails Guardtech – and so with some inspired tinkering from our Installation experts, the van's plenum was cut into and totally reworked so the tall standing unit could be included.



