Cleanroom solutions

www.cleanroom-solutions.co.uk

Guardtech group

CLEANROOM SOLUTIONS
ENQUIRY FORM

Name: **Company:** **Position:**
Location: **Telephone:** **Email address:**

Installation address	
How did you hear about us?	Google: ☐ Bing: ☐ Email: ☐ Word of mouth: ☐ Facebook: ☐ Twitter: ☐ LinkedIn: ☐ Magazine advert: ☐ Event or exhibition: ☐ Business directory: ☐ Other: ☐
Function	Cleanroom: ☐ Laboratory: ☐ Biosafety Lab: ☐ Containment Suite: ☐
Classification	ISO8: ☐ ISO7: ☐ ISO6: ☐ ISO5: ☐ Level One: ☐ Level Two: ☐ Level Three: ☐ CNC (Unclassified) ☐
External cleanroom dimensions	Length: Width: Height:
Personnel airlock (PAL)	Length: Width: Height:
Materials airlock (MAL)	N/A: Length: Width: Height:
Internal rooms (quantity)	☐ rooms
Panel system	Fully Flush: ☐ Semi Flush: ☐
Doors (quantity)	Rapid Roll: ☐ Single Doors: ☐ Double Doors: ☐
Windows (quantity)	900 x 900mm: ☐ 1500 x 900mm: ☐
Flooring	N/A: ☐ Vinyl: ☐ ESD Vinyl: ☐ Resin: ☐
Temperature control	No: ☐ Yes: °C +/- °C
Humidity control	No: ☐ Yes: °C +/- °C
Heatload	Max Occupancy: operators Equipment: kW
Lighting	500 Lux: ☐ 750 Lux: ☐ 1000 Lux: ☐ 1250 Lux: ☐
13-amp sockets (quantity)	Flush mounted: ☐ Three-compartment trunking mounted: ☐
CAT6a data sockets (quantity)	Flush mounted: ☐ Three-compartment trunking mounted: ☐
3-phase power (quantity)	N/A: ☐ 16-Amp: ☐ 32-Amp: ☐ 63-Amp: ☐
Other mechanical requirements	Compressed Air: ☐ Extraction: ☐ Process Gases: ☐ Central Vacuum: ☐ Drainage ☐ Purified Water: ☐ Town's Water Supply: ☐
Environmental monitoring	Analogue – Pressure Only: ☐ Digital – Temperature, Humidity & Pressure: ☐ Full Environmental Monitoring System – With Sensors & Software: ☐
Furniture (quantity)	Stepover Bench: ☐ Trespa Work Bench: ☐ Ergonomic Chairs: ☐ Storage Cabinet: ☐ Sink: ☐ Garment Rail: ☐ Coat Hooks: ☐ Bin: ☐
Equipment (quantity)	Laminar Flow Unit: ☐ Biosafety Cabinet: ☐ Transfer Hatch: ☐ Trolley Hatch: ☐ Autoclave: ☐

CLICK HERE to download your Microsoft Excel enquiry form

Please email your completed enquiry form to sales@guardtech.com

- BESPOKE DESIGN
- RAPID TURNAROUND
- FULLY VALIDATED TO ISO 16444-3

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TURNKEY CONSTRUCTION

THE GUARDTECH GROUP'S turnkey design & construction specialists Cleanroom Solutions are providers of bespoke controlled environments for large-scale manufacturing applications.

Installing expansive cleanrooms that balance the operational requirement for volume production with the compliance demands of high-specification controlled environments, Cleanroom Solutions have a legacy of delivering high-performance facilities for clients in a wide range of industries, including:

- Universities and R&D
- Pharmaceutical and Biotech
- Healthcare and Hospitals
- Aerospace and Automotive
- Semiconductor and Micro-electronics
- Optics and Microscopy
- Medical Device and Diagnostics
- Food and Cosmetics

Cleanroom Solutions is founded on the principles of detailed technical consultation; deeply understanding client requirement and challenges whilst presenting a range of options from best practice to value-engineered solutions.

A complete turnkey approach to delivery, with tight project management, detailed design and comprehensive documentation ensures that clients feel well supported, valued and empowered to construct facilities that will meet the demands of their process and stand the test of time. A truly collaborative experience which results in a mutually beneficial long-term partnership.

CONTENTS

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CONSULTATION

DURING an initial consultation with Cleanroom Solutions, you will be dealing with dedicated industry professionals who pride themselves on listening, understanding and unearthing your exact needs and requirements, prior to advising on and recommending a solution, or more commonly a variety of solutions.

Whether you have a fully developed brief, a URS (User Requirement Specification) or just a broad idea of what you need to achieve and the space available to you, Cleanroom Solutions support you to derive the best value solution for your application; balancing specification with budget whilst considering the restrictions imposed by the host building.

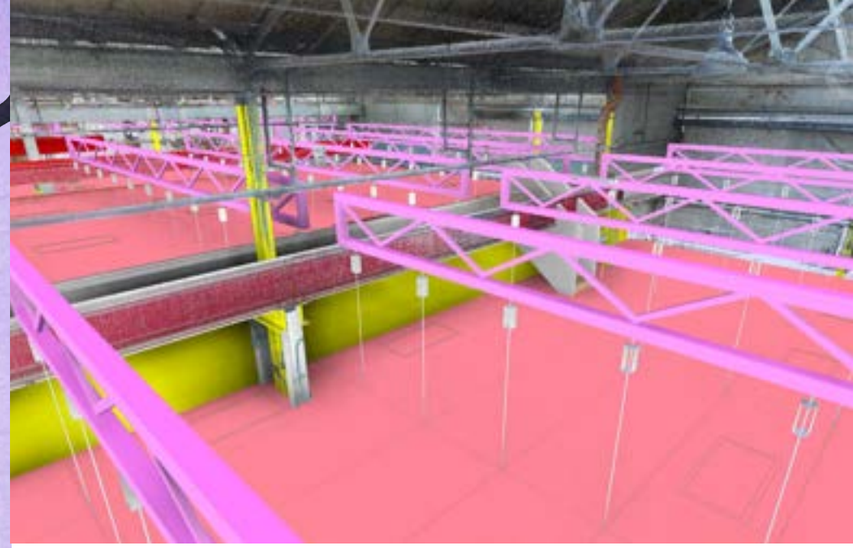
A comprehensive and in-depth needs analysis is initially conducted to determine the most appropriate process flow, classification and configuration of room layout. Understanding your process requirements, including equipment and supporting utilities is an essential part of the concept design process and early identification will ensure that the most appropriate choices are made.

Determining room performance specification is a vital part of consultation and balancing the needs of process, product and operators is a critical starting point, whilst considering ongoing running costs, maintenance and redundancy also form part of the assessment.

Cleanroom Solutions will support in the specifying, design and installation of all plant and process utilities, such as extraction, process gases, compressed air, drainage, purified water, vacuum and plumbing and can even supply all bespoke specialist furniture to facilitate a complete turnkey experience.

Understanding the future needs of the business and development plans will also factor into the conversation and influence the methodology of construction. Building Control, CDM and Fire Strategy are all important parts of consultation, and at the heart of all decision making will be compliance and adherence to ISO14644 and in some cases EU cGMP guidelines.

Following consultation, concept drawings will be produced with a fully detailed proposal for review and discussion.



LASER SCAN & SURVEY

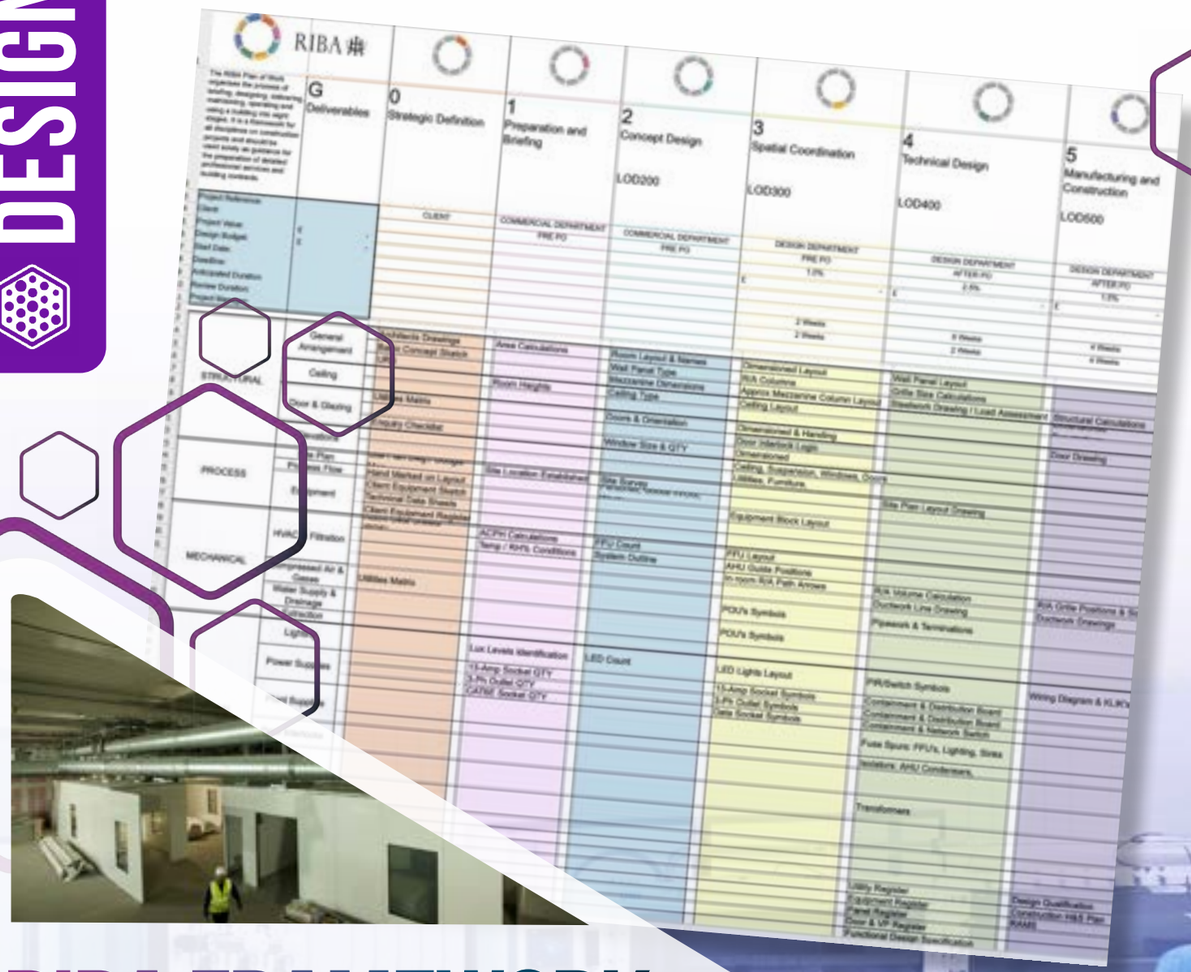
CLEANROOM SOLUTIONS have embraced the next level of design technology by incorporating 3D laser scanning into the beginning of their process as a detailed room information data capture.

Using cutting-edge technology from industry leaders Leica, a full 680,000-point-per-second scan with spherical images can be captured within 20 seconds, incorporating a maximum scan distance of 60 metres at an accuracy of 4mm tolerance.

Entire facilities can be transferred into an accurate 3D model from a site survey that can be completed in as little as one hour.

The information that this provides is invaluable to the design process and enables for full clash detection to be initiated whilst always considering the exact confines and restrictions of the host building.

This detailed scan identifies issues far earlier in the process, prior to manufacturing of components or attendance on-site. The benefits to the client are cost assurance and time-frame confidence, as challenges are encountered and overcome at the design stage rather than disrupting construction.



RIBA FRAMEWORK

THE RIBA Plan of Work was initiated in 1963 to provide a framework for architects to use on projects with their clients, bringing greater clarity to the different stages of a project.

Cleanroom Solutions have developed their own framework that closely mirrors the stages of RIBA, as many of their construction projects will interface with commercial architects, M&E designers and main contractors.

This document outlines expected deliverables in line with the main construction project and provides a common language for this area of specialist subcontractor works.

Each individual stage details the exact design outputs that will be produced and the expected drawings or models, calculations and documents provided.

As the design progresses through each stage of development, the complexity becomes greater and the clarity of information improves, resulting in a final design pack that has identified and resolved clashes and facilitates an effective installation.

The Cleanroom Solutions RIBA Plan of Work includes the following:

0 – Strategic Definition
Client-provided drawings, URS, equipment & utilities register, process flow, enquiry checklist

1 – Preparation & Briefing
Concept layout sketch, area calculations, performance criteria, host building information

2 – Concept Design
Developed general arrangement – structural, mechanical, electrical, room data sheets

3 – Spatial Co-ordination
Dimensioned drawing pack with developed master specification and site plan

4 – Technical Design
Full 2D issued drawings for each specific area of construction, registers, calculations, schematics

5 – Manufacturing & Construction
Signed off approved drawings for installation

6 – Handover
O&M's, commissioning documentation reports

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2D & 3D MODELLING

CLEANROOM SOLUTIONS' in-house Design team consists of specialist 2D (AutoCAD) and 3D (SolidWorks) Engineers; led by Directors with more than 100 years' combined experience in the sector, their comprehensive design offering includes:

- General arrangement layouts; structural, mechanical & electrical
- Process flow diagrams
- Elevations and sectional drawings
- HVAC P&ID, ductwork schematics, lighting layouts and wiring diagrams
- Pressure cascade diagrams
- Furniture & equipment layouts
- 3D models and animations
- Virtual reality facility walk-throughs

The Level of Design (LoD) and the software in which the design is developed will depend on the complexity of the detail required to inform the design in accordance with the budget allocated. LoD may also progress alongside the development of the project to deliver further clarity at future stages.

Panel Layout: All components fully dimensioned. Individual wall panels, glazing, single, double and rapid rise doors, return air columns and vents, wall-to-wall coving (if being used). Panel elevations included.

Ceiling Layout: Ceiling panels or grid, including points of suspension, LED lights, HEPA filters, smokeheads, CCTV cameras.

HVAC Layout: AHU(s), CRAC Unit(s), Fan Coil Unit(s) and/or Fan Filter Units detailed. Supply and return air ductwork in different colours with diameters shown, including heater batteries, VCDs and cleaning hatches. Filter size and positions, DOP ports and diffuser types outlined. Exhaust vents identified and dimensioned, power supplies shown for HVAC plant.

Electrical Layout: Distribution boards positioned, numbered and sized, 13-amp, 3-Ph and CAT6 sockets positioned, numbered and sized, containment runs identified, circuit logic detailed.

Lighting Layout: LEDs numbered relating to the lighting schedule in the MRS, Klik boxes positioned, wiring between LED and Kliks shown, emergency lights identified, PIR or switches shown.

Mechanical Layout: Compressed air, process gases, extraction, vacuum, purified water, town's water, drainage. All pipework runs displayed with diameters, termination points detailed including fitting type and size. Plant identified and dimensioned.

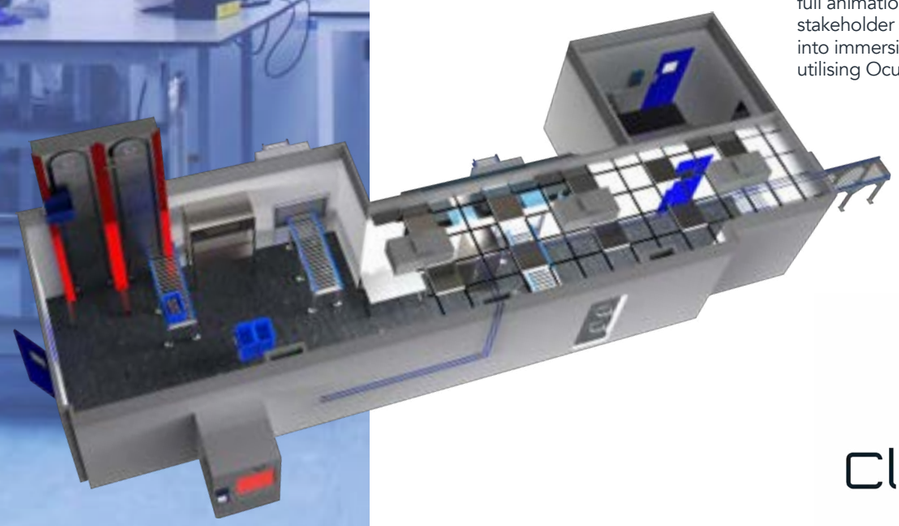
Furniture & Equipment Layout: Process equipment identified and dimensioned. Changing room furniture and transfer equipment, workbenches and furniture.

Flow Layout: Pressures in each room, flow (personnel, material, air, equipment), supply volume at each supply grille, exhaust volume at each return air grille.

Door Layout: Singles, doubles, rapid rise doors, emergency break-through panels, interlock logic, control panels or buttons for automatic openers, emergency break glasses and traffic light indicators shown.

Mezzanine Layout: Supporting steelwork columns, mezzanine deck layout, staircases, pallet gates, edge protection, fire boarding.

3D Models: Provide a detailed and spatially aware render of the facility, they can be particularly helpful when designing tight void spaces, plotting process equipment and illuminating abstract concepts such as plenum designs and complex utility integrations. These can be converted into full animation videos that can be used for stakeholder engagement and developed into immersive virtual reality experiences utilising Oculus VR headsets.



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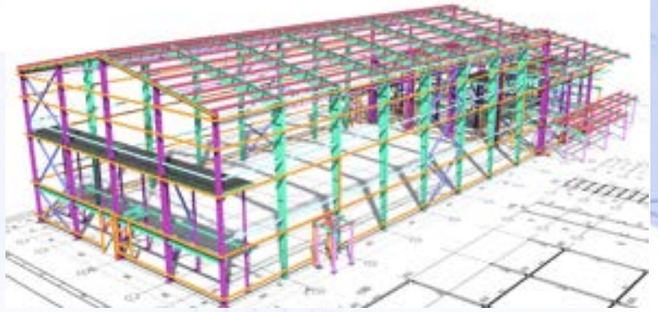


BIM: BUILDING INFORMATION MODELLING

THE CLEANROOM SOLUTIONS team are heavily invested in introducing exciting new technology to support client outcomes with the most expansive design process possible.

This led to the recent investment and incorporation of Revit – a digital platform for Building Information Modelling (BIM), in which the building is a live element which contains intelligent information.

BIM lies on a database and therefore shouldn't be conceived as a simple 3D visualisation tool. From a single model, infinite numbers of sections, plans, elevations, 3D views, schedules and material lists can be extracted.

Any revision is reflected simultaneously to all the extracted data representations. This connection is bidirectional, which means any revision made on plan, view or schedule is directly reflected to the database. It leads to full automation while removing the need for manual updates – which is the most time consuming operation of the traditional design and construction works.

Working alongside main contractors, BIM modelling provides a fast, effective and robust tool for managing multi-contractor projects, avoiding conflicts through clash detection of confederated models.

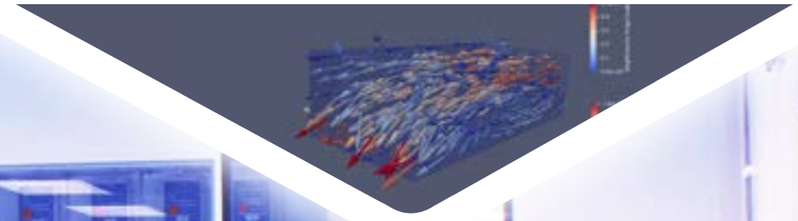
BIM also supports highly accurate Bill Of Materials (BOM) compilation, ensuring accuracy with on-site provisions and components, reducing waste and increasing productivity.

CFD: AIRFLOW SIMULATION

COMPUTATIONAL FLUID DYNAMICS (CFD) enables airflow within controlled environments to be simulated during the design phase, providing visualisation, insight and guidance into:

- Optimised airflow configuration, reducing dead spots and increasing uniformity and coverage
- Temperature and humidity mapping throughout the space, relating to heat sources within the room and their relation with conditioned supply air
- Reducing energy consumption by evaluating air changes required per hour
- Supply diffuser and exhaust vent positions
- Appropriate sensor positioning
- Comparative flow distribution for smoke test validation and room recovery testing

Air flow modelling acts as a virtual smoke test, enabling multiple configurations to be simulated, reducing costs and time whilst providing the most efficient design possible.



DOCUMENTATION

DETAILED and comprehensive documentation is produced to aid the design process and support cGMP compliance.

This information is compiled in response to the client brief and provides a contractual framework, a fully developed scope of works and a defined performance specification.

Master Room Specification: Excel documentation that captures specific parameters pertaining to the design – such as room data sheets, equipment and utilities register, schedules for panels, doors, glazing, furniture & equipment.

Functional Design Specification: Outline of the design concept for all structural, mechanical and electrical systems, a guide to all material specifications selected for key components, with full list of appendices containing data sheets and performance data.

Design Qualification (DQ): For all cGMP projects a full design qualification can be produced in response to the URS outlining compliance to the brief whilst initiating a framework for the later commissioning stages of Installation Qualification (IQ) and Operational Qualification (OQ).

Stakeholder engagement is key to the success of the documentation phase, setting expectations early and involving the appropriate people from initiation ensures a smooth process and a project file that meets the needs of the business from a compliance and audit perspective.

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PROJECT MANAGEMENT

EACH AND EVERY Cleanroom Solutions project is assigned a dedicated Project Manager, skilled at transferring the fully worked up design into a complete project plan and schedule.

The Project Manager will be assigned after client Purchase Order placement. A comprehensive project handover meeting will take place with the Commercial Department to ensure that the full brief and scope of works are adequately outlined and understood by all internal project stakeholders.

The PM will co-ordinate the detailed design process to ensure approvals are in place before proceeding to project initiation, planning, purchasing and implementation; communicating with the client at all stages.

Co-ordinating all aspects of the project, from design to installation, commissioning to validation, supported by the Guardtech's Group Operations team, Cleanroom Solutions' Project Managers provide on-site presence and client co-ordination to assure your schedules are being met.

Cleanroom Solutions Project Management packages include:

- Weekly Programme Meetings and Project Reports including progress photos
- CDM & Building Control co-ordination
- Design process management
- Supervision and management of installation and commissioning resource
- Responsibility for site Health & Safety – including compilation of H&S Construction Plan
- RAMS provided for all significant activities

CDM: CONSTRUCTION, DESIGN & MANAGEMENT REGULATIONS

THE CONSTRUCTION (Design & Management) Regulations (CDM 2015) are the main set of regulations for managing the health, safety and welfare of construction projects.

CDM applies to all construction work and includes new-build controlled environments, as well as demolition, refurbishment, extensions, conversions, repair and maintenance of cleanrooms and laboratories.

The Construction Industry Training Board (CITB) has produced the industry guidance written by industry volunteers appointed via the Construction Industry Advisory Committee (CONIAC).

CDM aims to improve health and safety in the industry by helping construction companies like Cleanroom Solutions sensibly plan our work so the risks involved are managed from start to finish.

CDM ensure Cleanroom Solutions:
- Have the right people for the right job at the right time
- Co-operate and co-ordinate our work with other parties involved in the project
- Have the right information about the risks and how they are being managed
- Communicate this information effectively to those who need to know
- Consult and engage with workers about the risks and how they are being managed.

CDM is an inclusive duty-of-care process involving the client, Principal Designer and the Principal Contractor, as well as all Sub-Contractors and Operatives associated with the project.

Principal Designers and Contractors

It is the clients' duty to appoint a Principal Designer and Contractor – and it is advisable that the client appoints the Principal Designer role to protect both them and Cleanroom Solutions; to act as an intermediary between both parties.

The Principal Contractor (in most cases, Cleanroom Solutions) plan, manage and monitor throughout the process – the Principal Designers work to reduce risk, inform others and eliminate hazards.

The Principal Designer produces the PCI (Pre-Construction Information), which then allows Cleanroom Solutions, as Principal Contractor, to produce a Construction Phase Plan.

Co-ordination and communication between the Principal Contractor and Principal Designer is critical throughout the process. Cleanroom Solutions provide O&M (Operations and Maintenance) information to the Principal Designer who then compile a Health & Safety file for the client on completion of the project.

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STRUCTURAL

DOORS

Cleanroom Solutions offer a comprehensive choice of cleanroom-grade doors to meet the needs of any application. From powder-coated steel or GRP single or double doors to motion sensor-activated rapid rise doors, all of the options in the range can be electronically interlocked and offer tight control against leakage and ingress/contamination.

RETURN AIR

The return air path is factored in to structural components, either via bespoke panels with hollowed channels to accommodate sufficient airflow or as columns produced from the same materials used for wall construction. These columns can also be used as service chases to conceal process and plant utilities.

GLAZING

Fully flush or semi flush glazing options available. A range of sizes from standard viewing panels to full height gallery windows. Fish tank glazing is also available in the Cleanroom Solutions range.

WALLS

Composite panel construction with different thicknesses and types of insulation, panel faces manufactured from powder-coated steel varying in coating application, dependent on chemical and scratch resistance required. Semi flush and fully flush systems available, wall-to-wall and wall-to-ceiling coving as standard.

GRADING SYSTEM

Cleanroom Solutions are focused on providing the best value solution for every project. To support this aim a grading system has been developed for each major component of construction. Rather than adopting a quality level across the board, a combination can be applied to ensure the correct level of material specification matches the application, industry, process and client. Important factors when designing this blend are: quality level, timeframe, budget and regulatory requirements.

- **Elite level of components, adopting industry best practice, highest performance, usually combined with most significant cost.**
  Applications: Grade B Pharmaceuticals
- **High-quality components offering a comparable level of performance to GT Max with specification compromises.**
  Applications: Semiconductor, Aerospace
- **Mid-range product offering specifically suited for laboratory and biosafety applications and lower grade cleanrooms.**
  Applications: Medical Device, Diagnostics
- **Entry-level components – ideal for applications where control requirements are less stringent and budget is the determining factor.**
  Applications: Automotive
- **A range of components specifically designed to facilitate fire rating and fire safety systems.**
  Applications: Various

CEILING

Depending on the level of control your operation needs, Cleanroom Solutions have every base covered, starting with ceiling grid & tile grid systems before moving into more robust alternatives including panelled ceilings and heavy-duty walk-on aluminium nodal grid layouts.

FLOORING

Cleanroom Solutions builds cater for all your flooring needs, beginning with homogeneous vinyl reinforced with cross-linked polyurethane that is UV-cured and features hot-welded joints, coved 100mm up the wall over underlay former and capped. Copper-grounded anti-static ESD vinyl is also available. Alternatively, a flexible epoxy resin or urethane floor screed can provide protection for more heavy-duty environments or clients can opt for raised access flooring – in the form of solid, grating or perforated panels.

ANCILLARIES

To optimise your available space and support the cleanroom structure, we offer full mezzanine design and installation, including edge protection, staircases and cat ladders.

For applications where the host building cannot be used to support the cleanroom structure, steelwork erections may be necessary – these can also be used to facilitate plant gantries and maintenance access.

Fire & ATEX Ratings

We are able to offer fire rated and ATEX rated components for all structural, electrical and mechanical parts of the build. These ratings are often dependant on review from insurers or building control.

AIR HANDLING UNITS (AHUs)

The heart of any controlled environment is its ventilation system.

Bespoke air handling units (AHUs) provide a central point for air supply and distribution ducted to terminal H14 HEPA filters.

In addition to powering the filtration system, heating and cooling can be provided by alternative utilities such as direct expansion (DX), chilled water (CHW) and low pressure hot water (LPHW).

Ancillary components to be considered within the air management system include trim heaters, volume control dampers, flow switches, fire dampers, insulation and pressure release valves.

Determining temperature and relative humidity are the deciding factor in not only plant selection but also controls philosophy, which may also include consideration for integration with a Building Management System (BMS).

Full psychometric charts and coil condition date is produced when determining the AHU and associated componentry.

UPFLOW UNITS

A popular alternative means of providing air conditioning to controlled environments is by using smaller package upflow/downflow units either directly ducted to Fan Filter Units (FFUs) or ducted to a plenum where FFUs draw a common supply.

This solution is highly efficient and provides a great level of redundancy as well as facilitating operation during maintenance. Typically used in applications where relative humidity demands are not as tightly controlled, these standardised units can be available ex-stock which make them an attractive solution for quick turnaround projects.

FILTRATION

For ISO 14644 compliant environments, H14 HEPA filtration is required. This can be delivered via terminal filters connected to air handling units (AHUs) via ductwork or as individual Fan Filter Unit (FFU) modules directly ducted or drawing supply air from a shared plenum. HEPA filtration can also be placed on the exhaust via plenum boxes or specialist safe change units to facilitate containment or eliminate cross contamination.

PURIFIED WATER

For volume manufacturing of Pharmaceuticals and Semiconductor products, purified water is often required. We can install a variety of systems for process integration, including all plant, distribution systems, pipework and fixtures and fittings. Ranging from low grade DI water systems with localised distribution all the way through to US Pharmacopoeia compliant closed loop 316L stainless steel FWI systems.

EXTRACTION

Fumes such as solvents and acids, particulate – such as powders and fibres – and heat can all be directly extracted at source from the controlled environment. Extraction ductwork material is selected based on the characteristics of the by-product extracted, powered through fans and exhausted at a high level, in some cases via filtration media such as HEPA, ULPA or carbon. Alternatively, extract can be filtered via scrubbers and returned to the supply air stream.

MECHANICAL

VACUUM

House vacuum for cleaning activities can be provided via a centralised vacuum system. This enables a number of rooms to have a wall-mounted connection to a central pump that is housed externally to the controlled environment with filtered exhaust. Vacuum pumps and pipework can also be provided for process applications.

FAN COIL UNITS

For smaller applications or support areas where humidity control is not required a cost effective and energy efficient solution can be provided via appropriately sized fan coil units. These can be ducted to Fan Filter Units (FFUs) or simply to diffusers in unclassified areas.

PROCESSED GAS DISTRIBUTION

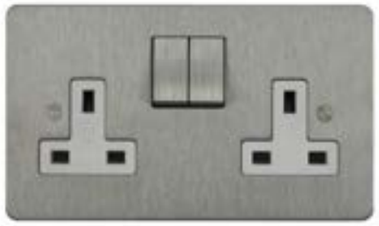
Highly filtered compressed air can be provided with compressors, filtration, transair pipework and a range of fittings for process requirements. In addition, a vast range of gasses, either from cylinder or generator, can be integrated into the facility design with appropriate pipework, valves and manual or digital control systems with appropriate alarms where required.

WATER SUPPLY & DRAINAGE

Hot and cold water supply can be installed to handwash and utility sinks as well as process equipment that may have a demand. Drainage can be accommodated either via pump or gulleys – for Pharmaceutical applications 316 stainless steel drainage and traps can be provided.

ELECTRICAL

SMALL POWER



Cleanroom Solutions are an NIC EIC accredited electrical contractor and conduct full electrical installations for all cleanroom plant, as well as providing power sockets for client equipment. Containment can be implemented simply with cleanroom compatible antimicrobial three-compartment trunking or with smarter integrated solutions such as concealed service channels and flush sockets.

CONTROL PANEL

Touchscreen HMI provides the interface for the controls and monitoring systems for your cleanroom. The EMS feeds back to give real-time data on temperature, humidity and pressure. The BMS can link back data concerning the operational status of all plant, including fan speeds, coil condition, run data and other connected utilities.

LIGHTING

Powder-coated steel light units, flush mounted into the ceiling panels with drop-down hinged diffuser. Also available as surface-mounted aluminium LED batten luminaires for laboratories. Activation by switch or PIR (passive infrared) sensor. Lights can be UV filtered for photo-sensitive processes.

NETWORK

CAT6, 6A or 6E data outlets flush mounted or installed within trunking, cabled back to network patch panel for client connection to host building server. Can also be incorporated into the EMS and BMS.

3-PHASE POWER

Often highly technical client process equipment requires a three-phase power supply, 16A, 32A or 63A outlets for this need to be factored in to the equipment layouts to establish best positioning and to accommodate concealed cable runs.

BACK-UP POWER

All cleanrooms require a power connection from an external source. The rating of this will depend on the power demand of each room. UPS (uninterruptible power supply) battery back-up can also be provided and a changeover switch can be installed to alternate between a mains and generator supply.

ENVIRONMENTAL MONITORING SYSTEMS (EMS)

Cleanroom Solutions provide a fully integrated Environmental Monitoring System that can also be 21CFR Part 11 compliant.

With a range of high-performance multi-function sensors, temperature, humidity, pressure and particle monitoring can all be monitored in real time and recorded for an audit trail. Fully flush or semi flush LED display gives in-room feedback.

BUILDING MANAGEMENT SYSTEMS (BMS)

Full integration with client BMS or a separately commissioned Building Management System can be provided. Typical integration includes HVAC, filtration, lighting, power management, extraction and any other utilities associated with the cleanroom. Typical software application provided by Trend.

ELECTRICAL REGISTER

Determining electrical requirements of the cleanroom in conjunction with the diversified load of client process equipment is conducted at design stage via a detailed electrical register. This will identify a total load assessment for comparison against the incoming building supply as well as outlining estimated heat load to be factored in to the HVAC design.

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INSTALLATION

INSTALLATION is performed by experienced Cleanroom Solutions engineers supported by approved, fully trained sub-contractors for specialist services.

The Installation Engineers are specially trained in controlled environment construction and have years of experience, not only installing critical environments but also servicing and operating within them. Cleanroom Solutions' building techniques benefit clients with quick, clean and consistent installations, conducted by a flexible and friendly team who thrive on problem solving, high-quality presentation and exceeding client expectations.

With in-house Structural and Electrical teams, backed up by the wider Guardtech Group support team, Cleanroom Solutions take tighter control of projects, with a quicker and more consistent installation which presents substantial cost savings. Cleanroom Solutions co-ordinate all aspects of every build they undertake, including:

Electrical: Lighting, small power & 3-phase, data, plant connections and door interlocks
HVAC & filtration: From full-scale, bespoke Air Handling Units (AHUs) to Upflow units and small split systems including all ductwork
Gas services: Process gasses, compressed air, extraction and vacuum including all pipe/ductwork and ring mains
Monitoring: Fully networked Environmental Monitoring System (EMS) with IT integration with 21 CFR Part 11 compliance, BMS
Water: Purified and process hot water, drainage, plumbing connections

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COMMISSIONING

THE COMMISSIONING phase begins post-construction and concentrates on qualifying all systems and their functionality.

For a Pharmaceutical application this will form part of the Installation (IQ) and Operational Qualification (OQ). For all other industries a standard commissioning plan will be drafted and test certificates will be produced alongside a detailed Operational & Maintenance (O&M) manual.

The commissioning plan will cover a series of verification checks on key components, systems and plant – such as HVAC, electrical, network, lighting, EMS, BMS and other critical utilities. The cleanroom performance will be verified through ISO 14644 validation and associated testing.

HVAC
- Airflow supply and velocities
- Chilled water flow rates, temperatures and valve set points
- Room temperature and humidity check
- Air on and air off coil temperatures
- Frost protection checks
- Heater loading tests
- Probe calibration, location and offset
- Fan speed, inverter and electrical checks
- System pressure testing

ELECTRICAL
- Continuity testing
- Insulation resistance testing
- Polarity
- Resistance testing (measuring Zs)
- RCD checks

NETWORK
- LAN continuity testing

BMS
- Software validation
- Hardware verification and calibration

EMS
- Transmitter/probe calibration (UKAS)
- CF21R Part 11 compliance (if required)

LIGHTING
- Lux level verification
- Emergency lighting testing

PLUMBING
- Pipework pressure & drainage testing

COMPRESSED AIR & GASSES
- Air purity & oil-free test ISO8573-1:2010
- Pressure, micro-organism, moisture testing

EXTRACTION
- Airflow & velocity measurements

SEPARATIVE DEVICES
- Particulate, airflow, filter integrity testing
- Optional: temperature, KI-discus, velocity

FIRE ALARM
- BS5839-1 operational testing

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SERVICES

DECONTAMINATION

THE GUARDTECH GROUP Decontamination Team are specialists in restoring control to critical environments and supporting clients in maintaining compliant facilities.

The Decontamination Team offer a comprehensive range of periodic deep clean contracts, and with more than 30 years of experience combined among our two most senior operatives alone, our hard-working team have the knowledge, skill and expertise to deliver high-performance cleans to ensure your operations are never compromised.

The Guardtech Decontamination Team work to GMP standards for Pharma and Medical Device facilities, ensuring the removal of gross and micro particles to maintain ISO standards as per agreed SOPs and good practice.

All cleans are supported by a pre-clean contamination assessment and a post-clean efficacy verification stage to demonstrate the effectiveness of the clean. All operators are specially trained and work to extensive SOPs and checklists.

Our packages include:

- Builders' cleans
- Pre-validation cleans
- Biocidal/sporicidal cleans
- Microbiological/bioburden testing with TSA & SDA plates
- Pre-clean and post-clean contact plate testing
- Certified to work at height (IPAF PAL card holders)
- Working to GMP standards
- Cleanliness verification tests conducted – with full reporting
- Bespoke cleaning programmes
- Comprehensive multi-stage cleaning as and when required
- Will follow client SOPs and use specific validated chemicals and equipment when required
- Two most senior cleaners boast 30 years' experience in decontamination.

Press play for video content

Cleanroom solutions

SERVICE & MAINTENANCE

THE ONGOING operation and maintenance of your controlled environment is of paramount importance, therefore ensuring a service plan is in place to adequately facilitate this should form part of the strategy of implementation.

Cleanroom Solutions can provide a full turnkey offering with their in-house Service Department, with CITB-trained engineers and mechanical and electrical specialists, consolidating all utilities and plant maintenance to as few visits as possible. The selection of all plant and equipment will take into consideration the ongoing maintenance and associated costs as well as energy efficiency and warranty conditions, balancing these to achieve the best value solution for your application.

Service contracts can also include emergency call-out rates to ensure a rapid response for any potential future issues.

Press play for video content

VALIDATION & DOCUMENTATION

UPON CONCLUSION of all cleanroom builds an ISO 14644 validation is conducted to verify cleanroom performance and adherence to classification guidelines.

The critical testing point is to ensure that the airborne particle counts are in line with the allowable tolerances as set out in ISO 14644-1. All other testing is to provide supporting data to confirm the performance specification of the environment.

Validation testing could include any or all of the following:

- Air velocity and volumetric flow rate measurement
- Room differential pressure testing
- Airborne particle counting
- Temperature & humidity monitoring
- Light & sound level measurement
- Filter integrity testing
- Pressure & flow gauge calibration
- Room recovery rates
- Containment testing
- Airflow visualisation

DOCUMENTATION

For all non-cGMP-rated projects, standard commissioning documentation will apply (see Commissioning – page 19).

A far greater level of detail is required for qualification of cGMP facilities, following strict protocols and defined standards.

This portfolio of documentation includes the compilation and execution of a Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ).

These documents are produced as a call and response to the User Requirement Specification (URS) and aim to objectively answer all requests with supporting evidence.

Guardtech group

CLIENT CASE STUDY

GRAPHENE RESEARCH FACILITY

ISO Class 5, 6 & 7

THE CLIENT

University of Cambridge – the Cambridge Graphene Centre investigates the science and technology of graphene, carbon allotropes, layered crystals and hybrid nanomaterials. The innovation centre allows partners to meet and establish joint industrial academic activities to promote innovative and adventurous research with an emphasis on applications.

THE BRIEF

Cleanroom Solutions were tasked with building a cleanroom facility split over two floors, incorporating a unique passenger lift between floors, air shower, specialist E-beam close control room (+/- 0.1 C), ISO5 & 6 areas, plus wet process benches with extract set back facility and localised ISO5.

R&D

21°C+/- 0.1

UNIVERSITY OF CAMBRIDGE

"A very detailed design..."

Cleanroom Solutions Projects 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 an expensive piece of equipment – and when it's fully operational, it has to run at 0.1 of a degree. So to control that Jan had to come up with a unique design for controlling 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.

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

Sean Gaylard
Projects Director

Cleanroom solutions

CASE STUDIES

THE TECH SPECS

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 grills provided the air flow path back to the plenums via built-in room return air ducts.

Guardtech group

THE RESULT

Cleanroom Solutions Projects 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."

Guardtech group

CLIENT CASE STUDY

NANOFABRICATION FACILITY

ISO Class 4, 6 & 7

CASE STUDIES

JWNC James Watt Nanofabrication Centre

University of Glasgow

THE CLIENT

University of Glasgow – The James Watt Nanofabrication Centre undertakes fundamental, applied and commercial research, development and small-scale production using a vast array of developed process modules and background IP which can provide integrated processes to deliver circuits, devices, systems and solutions.

THE BRIEF

Cleanroom Solutions were asked to design and build a cleanroom facility for nanofabrication, comprising of an ISO4 E-Beam room with close temperature control to +/- 0.05 degree C & humidity control 45%RH +/- 5%, plus ISO6 service area & control room with temperature control to +/- 1 degree C & humidity control 45% RH +/- 5%.

R&D

21°C+/- 0.0.5 / 45%+/-5%

"An interesting build to be part of..."

Cleanroom Solutions Projects Director Sean Gaylard said: "This was another cleanroom build that required us to ensure an E-Beam could function effectively – a similar build to the Cambridge Graphene Centre controlled environment we produced.

"The team at Glasgow actually asked us to install a sophisticated noise cancellation system within the cleanroom – and that was really interesting to be a part of.

"The facility had the Glasgow underground to contend with, too – so that equipment was vital to ensure the E-Beam functioned correctly in writing nano lines on wafers. It's so sensitive to any noise or vibrations that any tiny change can make a big difference. To be responsible for ensuring the control in such extraordinary circumstances was really special for us."

Sean Gaylard
Projects Director

Cleanroom solutions

THE TECH SPECS

ISO7 corridor: Built to link the existing cleanroom to the new E-Beam facility. The lighting comprised of LED panel lights complete with yellow filters (LY5). A full Spicer Consulting noise cancellation system was designed and installed to reduce airborne electrical & vibration noise within the E-Beam room.

E-Beam Room: An Astra T50 ceiling grid system complete with FFUs was installed throughout. All FFUs installed within the E-Beam room are EC Low noise fan type and are controlled from a local Unitronics touch screen located in the service area.

Nitrogen & CDA SS pipework and valves were installed throughout the cleanroom.

A house vacuum system was designed and installed within the E-Beam room to provide localised house vacuum for cleanroom cleaning practices.

HVAC: The system was designed to provide very close control temperature and humidity. Chilled water was used for cooling and hot water was used for heating. Sensible cooling coils were installed within the plenum areas connected to a chilled water and controls system providing control to +/- 0.05 degree C – though it actually performed at +/-0.03 degree C.

Laminar flow: The ISO4 E-Beam room was designed to provide full laminar flow airflow via ceiling-mounted FFUs and passing through floor mounted grills and returning to the plenum via built-in room return air ducts. Fresh air was provided via a roof mounted Air Handling United (AHU) combining cooling coils, frost coils, reheat coils and full controls system. The fresh air was ducted into the independent plenum areas and incorporated inline electric trim heaters for close temperature and humidity control.

ISO 6&7 areas: Designed using conventional airflow with air provided into the areas using FFUs and low-level grills located within room built-in return air ducts returning to the localised plenums mixing with close controlled fresh air.

THE RESULT

Cleanroom Solutions Projects Director Sean Gaylard said: "This was another cleanroom build that required us to ensure an E-Beam could function effectively – a similar build to the Cambridge Graphene Centre controlled environment we produced.

"The team at Glasgow actually asked us to install a sophisticated noise cancellation system within the cleanroom – and that was really interesting to be a part of.

"The facility had the Glasgow underground to contend with, too – so that equipment was vital to ensure the E-Beam functioned correctly in writing nano lines on wafers. It's so sensitive to any noise or vibrations that any tiny change can make a big difference. To be responsible for ensuring the control in such extraordinary circumstances was really special for us."

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CLIENT CASE STUDY

PHARMA DEVELOPMENT SUITE

ISO Class C

THE CLIENT

Vectura – experts in formulation science, device technology and inhaled medicines. Since launch, they have generated $11 billion in sales and in 2020 these products were used by 10 million patients worldwide.

THE STORY

This new facility was built in an existing building. The whole structure was totally self-supporting by using a specially designed steel mezzanine. The room fabric consisted of a cleanroom partition system, walk-on type ceiling with wall/ceiling and wall/wall coving, vinyl flooring, with a fully equipped changing room. The facility was designed as class C GMP turbulent flow with localised class A GMP powder control booths. The powder control booths were stainless steel.

Continued on page 28

Pharmaceuticals

400m²

From About on vectura.com...

Our partners have succeeded in bringing DPI, pMDI and nebuliser medicines to market with the help of our specialist capabilities. Our combination of formulation science, device technology and inhaled development expertise has contributed to the success of 13 inhaled medicines, launched by our partners and licensees. Since launch, they have generated $11 billion in sales and in 2020 these products were used by 10 million patients worldwide.

VECTURA

Cleanroom solutions

CASE STUDIES

The pressure regime was designed so that process rooms were kept at a negative pressure to the main corridor to help prevent cross contamination.

The whole facility was designed to save on running costs and therefore used re-circulated air. This air passes through a bank of safe change HEPA filters before it passed back to the AHU for re-use. Services included a compressed air system c/w pipework, nitrogen pipework and DI water pipework.

Air conditioning consisted of an air handling unit, chiller, chilled water pipework, humidifiers and controls (to meet industry standard 21 CFR part 11) to achieve the design criteria. This was mounted on the mezzanine.

THE RESULT

From the customer's various user requirement documents, a detailed validation procedure was produced and agreed, including DQ, IQ, OQ. The room was approved by the MHRA. Cleanroom Solutions Director Jan Pyrgies said: "It was a pleasure to deliver such a complex build that was also economical – a huge well done to all the team for their efforts on this excellent project."

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Guardtech group