CLEANROOM SERVICE PLAN

Guardtech
service department

Guardtech
decontamination team

www.guardtech.com

Guardtech group

Guardtech cleanrooms
Cleanroom solutions
Isoblok pre-fab cleanrooms
Isopod rapid cleanrooms
CleanCube mobile cleanrooms

the Guard charter

- GUIDE — Knowledgeable & Collaborative
- UNDERSTAND — **Analytical & Reflective**
- ADAPT — Flexible & Innovative
- RESPOND — **Reactive & Thorough**
- DELIVER — Dependable & Committed

Guardtech service department

- **CLEANROOM COMMISSIONING**
- **FACILITY MAINTENANCE**
- **DETAILED REPORTING**

All work conducted is followed by reporting in line with ISO14644-1:2015 standards and cGMP guidelines, ensuring facilities are audit-ready and compliant with regulatory bodies.

ELITE CLEANROOM SERVICE PLANS FOR ELITE APPLICATIONS

From commissioning new-build cleanrooms to service, maintenance, testing & validation of existing controlled environments, the newly expanded Guardtech Group Service Department support ongoing compliance in all cGMP & ISO14644 classified cleanrooms.

We offer one, three or five-year Cleanroom Service Plans with two visits per year from Guardtech engineers as standard, but the team is happy to discuss the particular needs of your business to ensure you receive the appropriate level of support – the Guardtech Group are here to relieve the burden of managing your controlled environment.

PLANNED PREVENTATIVE MAINTENANCE (PPM)

Whatever your cleanroom Service & Maintenance needs are, we are here to help

CLEANROOM SERVICE PLAN OPTIONS:

LITE | PLUS | PRO | MAX

ONE-OFF | 1-YEAR | 3-YEAR | 5-YEAR

Plus, Pro and Max include a minimum of two visits per annum

HVAC Repairs & Upgrades

Regular service & maintenance for controlled environment air conditioning followed by comprehensive reporting. Engineers equipped with routine maintenance parts and can diagnose faults onsite, undertake repairs and optimise set-up for energy efficiency.

Compressors & Generators

Service, maintenance & repair of air compressors and gas generators, including full testing & reporting. Also available for local air and fume extraction and ventilation systems.

Filter Replacements

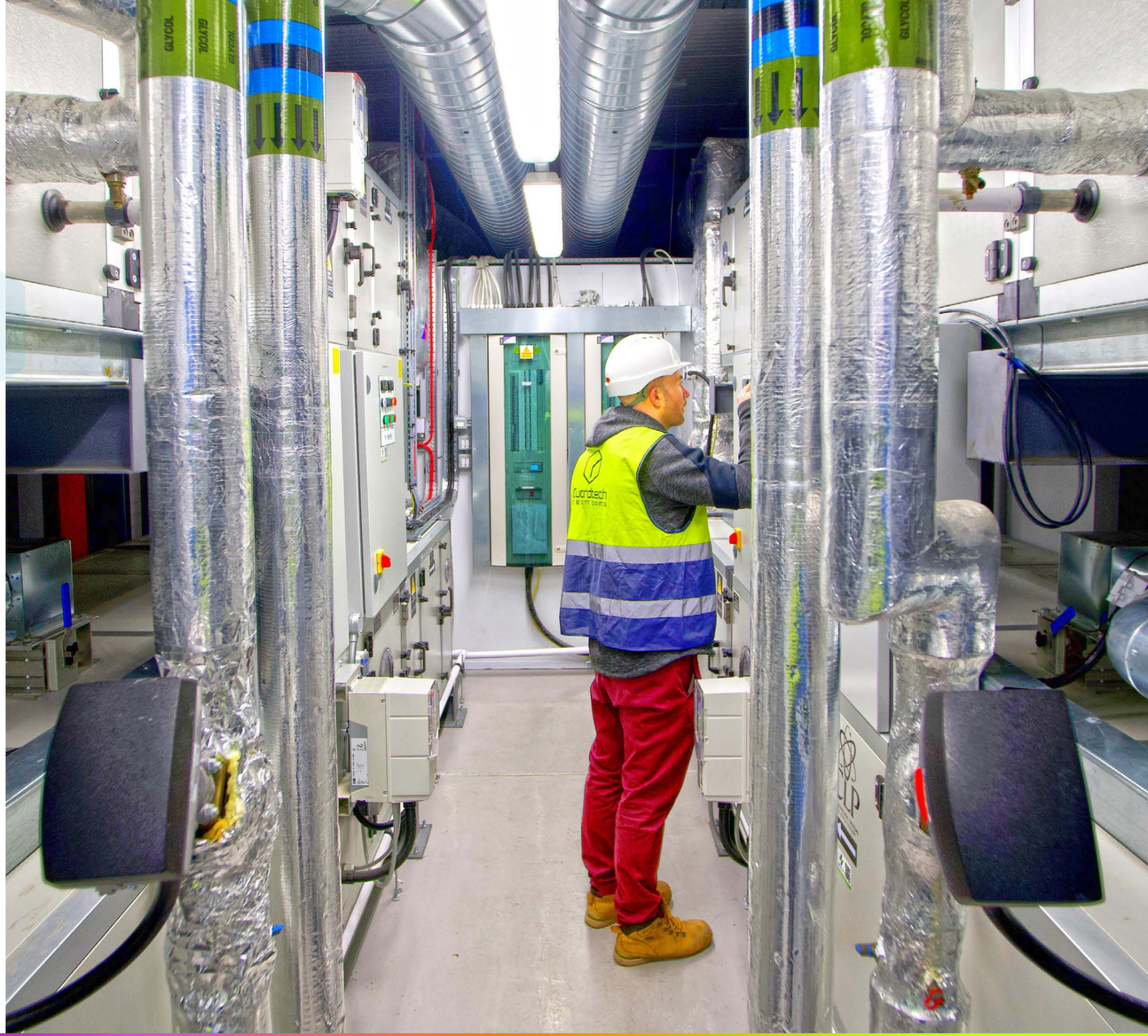
HEPA Filter replacement for terminal connections and fan filter units. All major HEPA filter brands supplied, pre-filter changes, airflow balancing conducted post-HEPA replacement.

Gauge calibration

As part of ISO 14644-3 cleanroom risk assessment, we recommend that all gauges used to monitor the environment are calibrated annually – we offer a full gauge calibration service.

EMS/BMS Servicing

The Guardtech Group Service team are experienced at installing and servicing a range of different Environmental Monitoring and Building Management Systems – from more modest solutions right through to large-scale facility management software and hardware packages.



VALIDATION

Press play for video content

TESTING

Guardtech
service department

● *Guardtech conduct cleanroom Validation which includes:*

Air Velocity Measurement

Guardtech utilise a range of industry-leading instruments to measure velocity and uniformity in the clean space, taking room size, AHU capacity, length of duct run and other factors into consideration.

Methods used to check airflow within a cleanroom vary depending on the ventilation set-up – the two most common being laminar flow and turbulent airflow.

Volumetric Flow Rate Measurement

Airflow volume readings shall be taken in accordance with ISO 14644-3 at each supply grille using a calibrated Ballometer set to read cubic metres per hour. Supply volumes from each filter are recorded and used to calculate the volumetric flow rates.

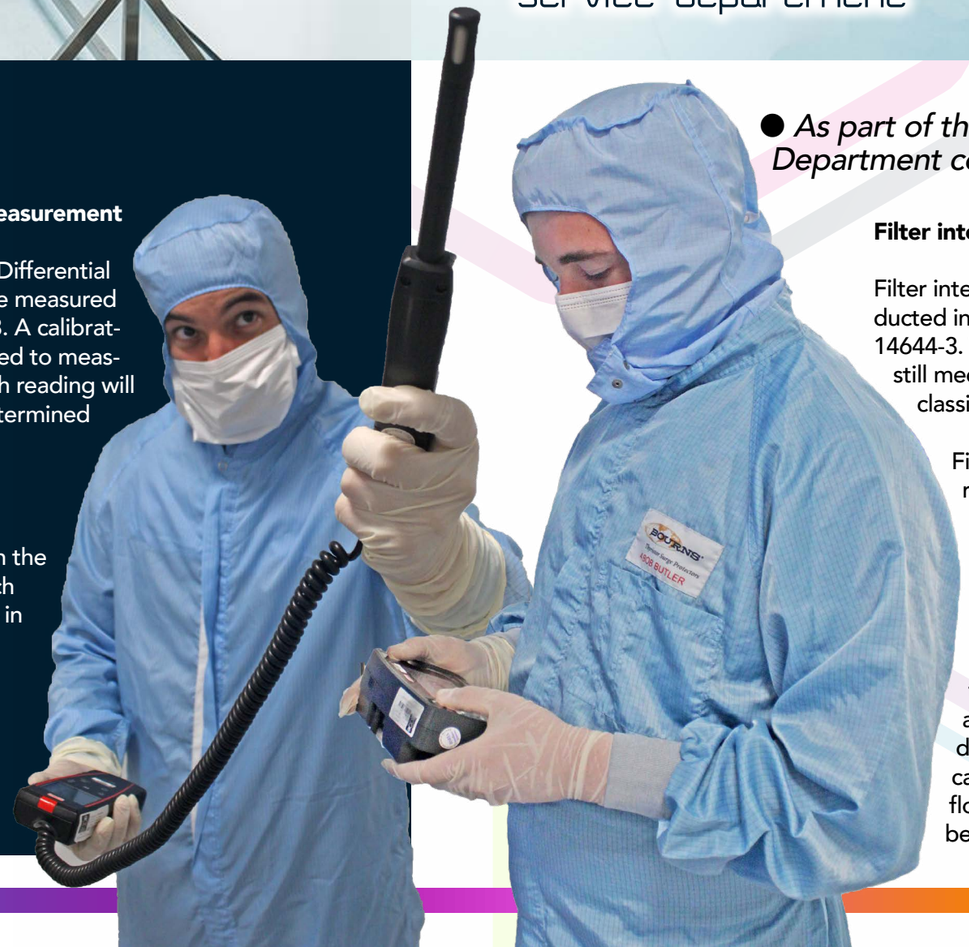
Room Differential Pressure Measurement

Measurements of the Pressure Differential between cascading areas will be measured in accordance with ISO 14644-3. A calibrated Micro Manometer will be used to measure each room to absolute. Each reading will be recorded, and a pass/fail determined for each reading.

Particle Counting

Particle counts are conducted in the cleanroom at bench height. Each sample will be for one minute – in accordance with ISO 14644-1.

All particulate counts shall be recorded, and a pass/fail determined for each reading based on the classification.



● *As part of their Validation schemes, the Guardtech Service Department conduct a series of critical testing programmes*

Filter integrity testing

Filter integrity testing is conducted in accordance with ISO 14644-3. This ensures filters are still meeting the stated HEPA classification.

Filter integrity tests are recorded and a pass/fail is determined for each reading.

Separative Devices

Service, maintenance, filter replacement, testing and repair of separative devices, including biological safety cabinets, laminar flow hoods, LAF workbenches & LAF cabinets, air showers, downflow booths, fume hoods & cupboards and garment stockers.

Performance Testing: Temperature, Humidity & Lux

Measurements of the temperature & humidity levels are conducted in accordance with ISO 14644-3 using a calibrated thermal hygrometer (lux levels are measured with a lux meter).

Tests are conducted in set positions in each room at bench (working) height where equipment or an operator will potentially be sited.

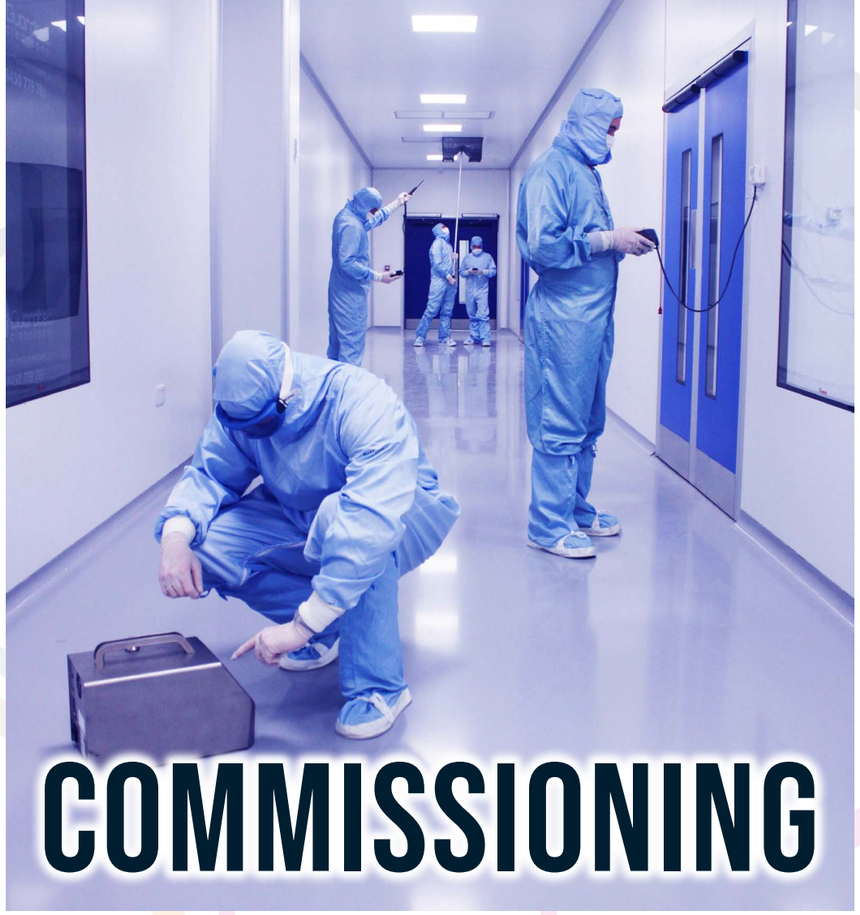
A reading for each of the tests shall be recorded and a pass/fail determined for each reading.

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
- System pressure testing



COMMISSIONING

- Fan speed, inverter and electrical checks

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

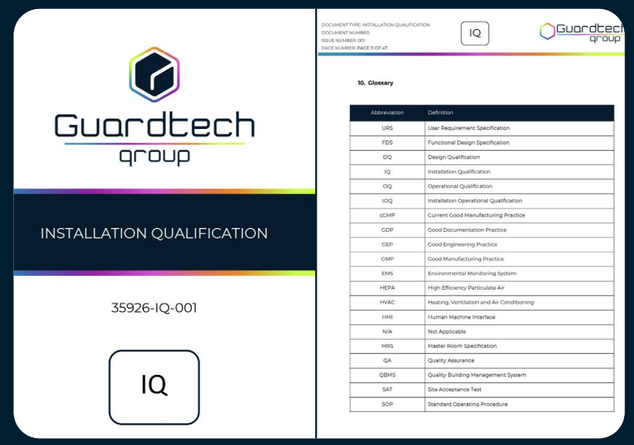
COMPRESSED AIR & GASSES
- Air purity & oil-free test ISO8573-1:2010
- Pressure, micro-organism, moisture testing

EXTRACTION
- Airflow & velocity measurements

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

FIRE ALARM
- BS5839-1 operational testing

To comply with ISO 14644-3, facility monitoring is recommended. As part of risk assessment, we recommend all gauges used to monitor the environment are calibrated annually.



COMPLIANCE

For all non-cGMP-rated projects, standard Commissioning documentation will apply.

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.

DECONTAMINATION

Guardtech
decontamination team

FULL FACILITY DECONTAMINATION
DECON-ONLY PACKAGES AVAILABLE
BESPOKE AND STANDARD CLEANS

The Decon Team are specialists in restoring control to critical environments – our programmes can be part of your Cleanroom Service Plan or arranged as a separate package.

- 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**

DECON-ONLY CONTRACT OPTIONS:

LITE ★ — QUARTERLY
PLUS ★★ — MONTHLY
PRO ★★★ — WEEKLY
MAX ★★★★ — DAILY

Also available: annual cleans, one-off post-build or pre-validation cleans. Alternatively, simply tell the Decontamination Team about your unique requirements and they will put together the perfect bespoke cleaning package to suit your application.

● *The Decontamination Team offer a comprehensive range of periodic deep clean contracts. 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.*

From builders' cleans to deep hand over cleans to regular deep cleans, detergent and alcohol cleans, alcohol and biocide/sporicide cleans or alcohol-only cleans, the Decon Team will work with you to determine the programme that best suits your business.

If it's the physical removal of marks and debris you require, our team know how to get the job done. The Decontamination Team use HEPA filtered vacuum cleaners prior to wet cleans – and there isn't a cleaning challenge they're not prepared to face.

Taking care of those awkward,

hard-to-reach surfaces, under benches and chairs, ledges and cleanroom equipment, as well as general work surfaces, walls, ceilings and floors, is all part of the process for our diligent, dedicated team, who also offer strip and reseals of floors, including ESD vinyl.

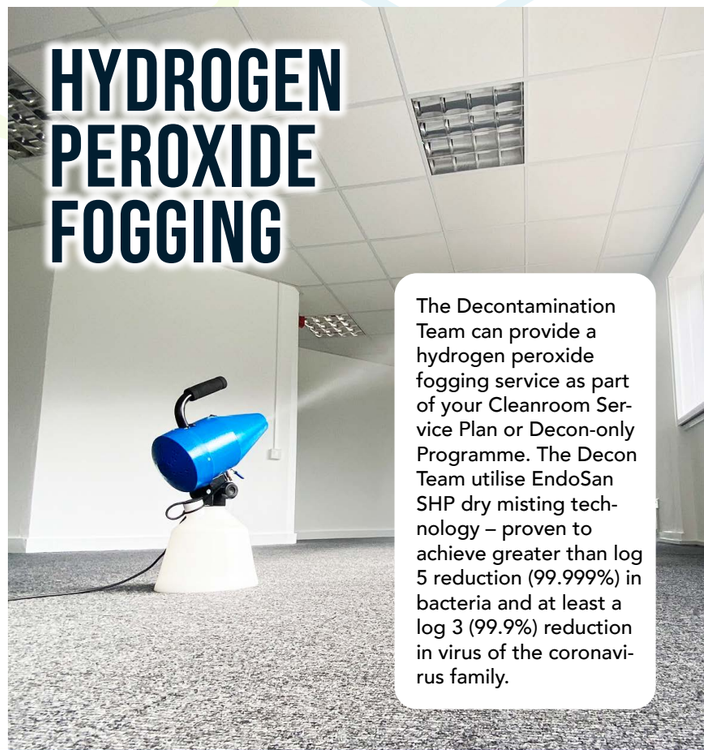
The Guardtech Decontamination Team work to GMP standards for pharma and medical device facilities, ensuring the removal of gross and micro particles to maintain ISO standards as per agreed SOPs and good practice.

Post-construction cleans

Builders' cleans are conducted post-construction and prior to validation to ensure the removal of visible dust, fibres and large particulate. This can include full coverage of the cleanrooms' structure, equipment, furniture and extend as far as ductwork or plenum cleaning.

Contamination cleans

Guardtech Deep Cleans utilise biocidal or sporicidal agents to drastically reduce the presence of bioburden, spores and bacteria within cleanrooms. 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. All cleans are followed by in-depth reporting & verification testing to prove efficacy.



The Decontamination Team can provide a hydrogen peroxide fogging service as part of your Cleanroom Service Plan or Decon-only Programme. The Decon Team utilise EndoSan SHP dry misting technology – proven to achieve greater than log 5 reduction (99.999%) in bacteria and at least a log 3 (99.9%) reduction in virus of the coronavirus family.

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