Guardtech group

CLEANCUBE VALIDATION

BSL 2

THE CLIENT

Their vital research and knowledge exchange activities support the expansion and maintenance of the UK's forests and landscapes.

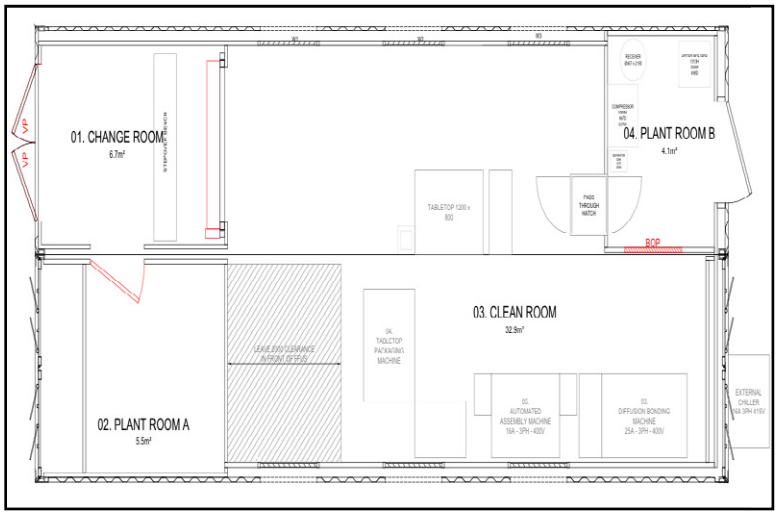
Biotech/ R&D

20+/-2C – 50+/-10% RH

60m²

THE BRIEF

The Guardtech Group Service Department were tasked with conducting a full Validation on a Cleancube Maxi portable cleanroom, including testing of: Air Change Rates, Pressure Differential, Installed Filter Integrity Leaks, Airflow Visualisation and Cleanliness Recovery, as well as measurements of Particulate Count, Lighting, Temperature, Humidity and Sound levels, plus Door Interlock and Disaster Recovery testing.



"A routine Validation to our usual high standards"

Guardtech Group Compliance Manager Chris McGinn said: "This was a fairly routine Guardtech Group Validation as part of an overall Operational Qualification for a bespoke Cleancube Mobile Cleanroom 'double 40ft container' for Research & Development work.

"Our team of Service Engineers and supporting staff work to the highest standards and therefore treated this Validation with the same diligence and attention to detail that set us out as the go-to source for high-quality post-cleanroom construction services."

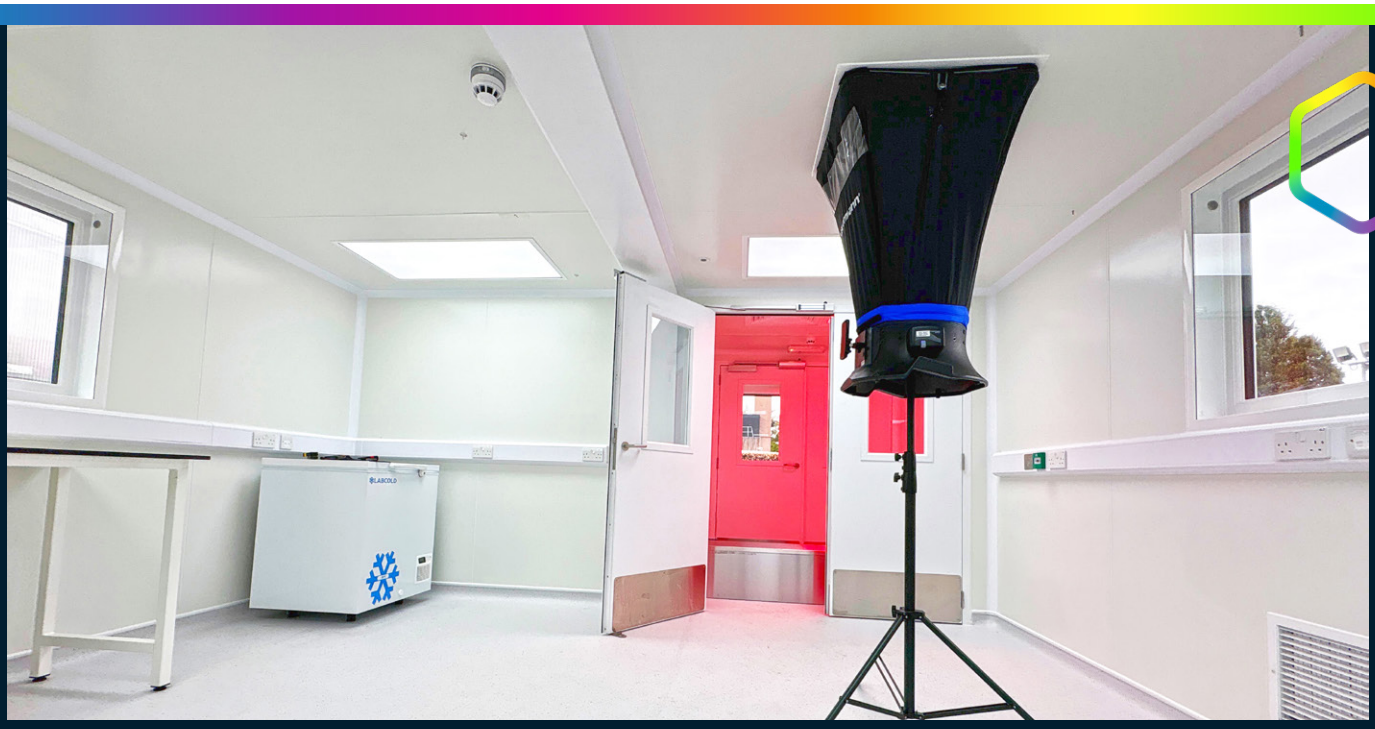
Chris McGinn
Guardtech Group
Compliance Manager

Cleancube
mobile cleanrooms

Guardtech
service team

CLIENT CASE STUDY

CLEANCUBE VALIDATION



THE PROCESS

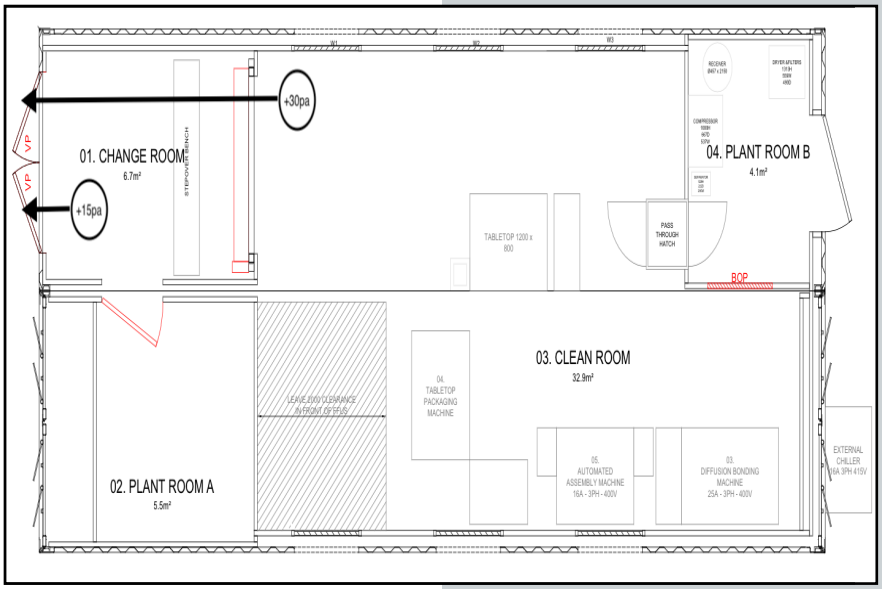
All testing was conducted in accordance with ISO 14644-3:2019

Air Change Rate Testing: Guardtech Validation Engineers took Airflow Volume readings at supply inlets using a Vane Anemometer set to read meters per second. The readings were taken approximately 150mm from the filter face. The Anemometer was held for at least 30 seconds or until a steady reading was displayed in five locations on the filter faces. The average of the five locations was then taken and used to calculate the Air Change Rate Per Hour (ACPH). The calculated ACPH was greater than the minimum required ACPH and therefore the Air Change Rate testing was passed.

Pressure Differential Testing: Using a Calibrated Pressure Gauge, the Guardtech team measured the Pressure Differential in the specified zones shown on the diagram *(right)* by running a tube between the rooms. Each reading was then recorded once a steady result was obtained. All relevant equipment and plant associated with the cleanroom, such as the Air Handling Unit and extract systems, had to be operational, while all relevant doors were closed. The recorded Pressure Differentials satisfied the requirements set out in our results table and a pass was recorded.

Installed Filter Integrity Leak Testing: Using an Aerosol Generator capable of generating particulate in the range of 0.1µm-0.3µm, the Guardtech Group Validation team injected aerosol into the AHU system upstream from the filter to be tested. The generator was filled with an appropriate oil and an aerosol photometer was set to detect it, therefore presenting information on any potential leaks greater than 0.01% of the upstream concentration. All output alarms were set to be activated. Using the calibrated aerosol photometer, the Filter face, gasket and housing was scanned to determine if any leaks were present (scan speed of 5cm per second) at a distance of no greater than 3cm from the filter

Figure 4 – Pressure Measurement Locations (plan view)



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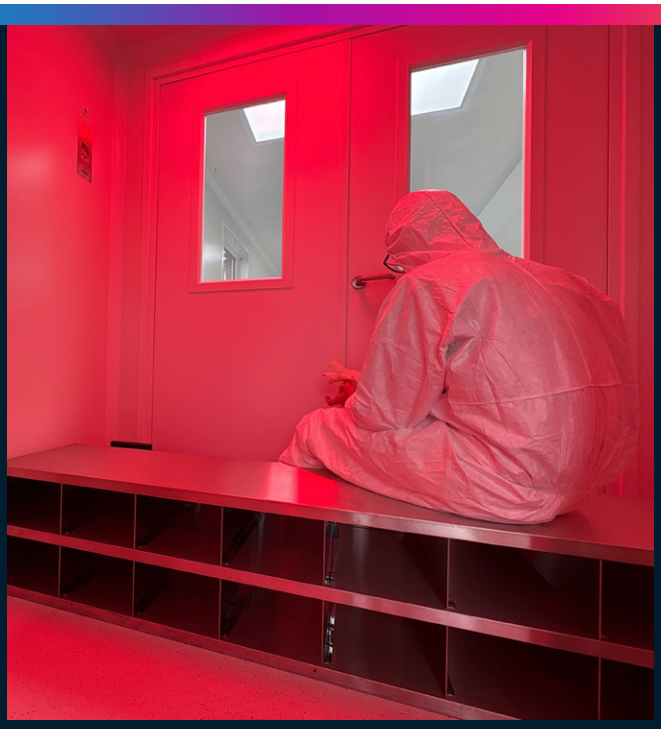


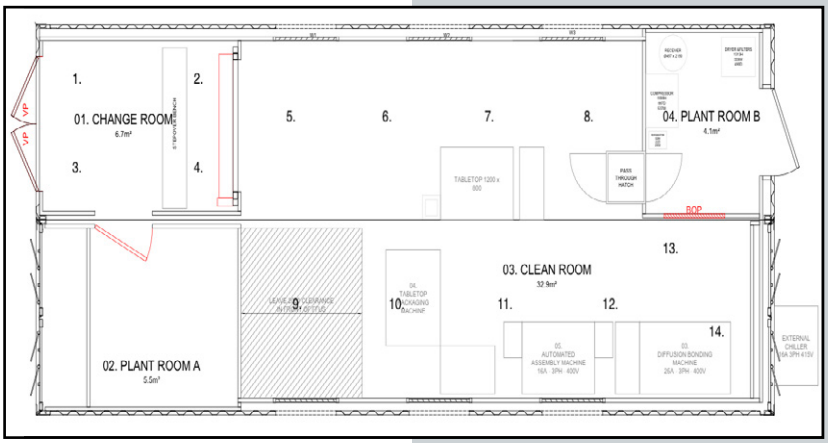
face, but not touching it. Any leaks found were marked on a drawing of the filter and documented. Any filters that required replacing were duly changed. All filters are factory tested in accordance with EN 1822:2109, but Guardtech always perform in situ filter integrity testing in accordance with ISO14644-3:2019 to ensure they have not been damaged in transport or install. A filter in this Cleancube failed for precisely this reason, due to it being damaged in transport, and so the team replaced and tested the new one in front of the client as a demonstration of our due diligence. Filters that were deemed to have passed the test had an upstream concentration between 1µg - 100µg, whilst the upstream concentration had to be confirmed at 100% ±15% before and after the downstream scan. The maximum recorded penetration percentage was not allowed to exceed 0.01%.

Airflow Visualisation Testing: This test was conducted in accordance with ISO 14644-3:2019. Guardtech operatives filled the classified area with a visible mist using an aerosol generator and documented the movement of the air, recording video evidence of: airflow movement around and through return air grilles, airflow movement around and through doors, airflow movement around supply inlets, airflow movement through the room, airflow direction cascade between adjacent rooms, airflow around furniture & equipment. Satisfactory airflow movement was demonstrated and a pass was recorded for each room in the container.

Cleanliness Recovery Testing: Guardtech Engineers used a smoke instrument capable of producing the particulate size to be tested. The team had to ensure the test locations were not conducted directly beneath airflow outlets and the Air Handlers had to be running for the duration of the test. The team generated sufficient particulate within the room to achieve a 10-fold concentration of the target cleanliness level. Sample measurements were taken every minute and Engineers recorded the time that the target concentration threshold (t10n) was reached. All classified rooms returned to the target cleanliness limit within 20 minutes from achieving the target concentration level and the test was therefore deemed a pass.

Particulate Count Measurement: With the rooms At Rest, the Validation Engineers carried out particle counts in the cleanroom at bench height. The Occupancy State is determined in accordance with ISO 14644-1:2015 section 3.3. The number of locations tested was determined by ISO 14644-1:2015 and was situated as marked out in the diagram *(below)* in accordance with ISO14644-1:2015 Annex 4.3. Each

Figure 8 – Particulate count monitoring positions at bench height (plan view)



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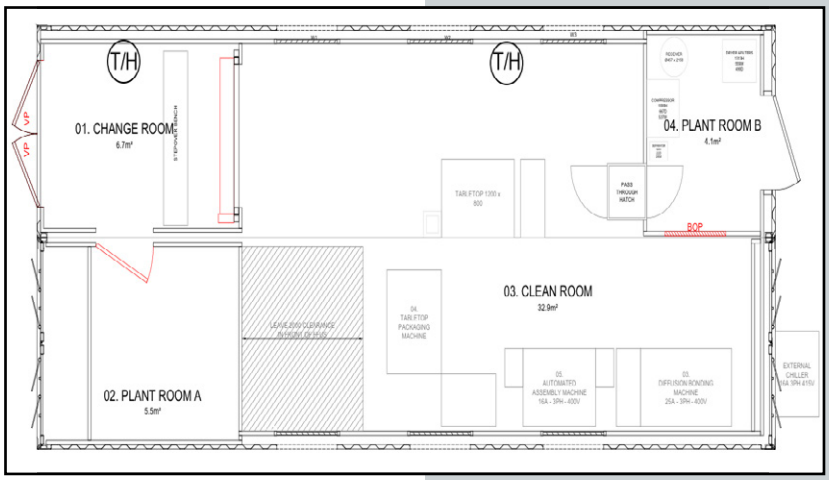
location was sampled for one minute in accordance with ISO 14644-1:2015 Annex 4.4. Engineers set the flow rate to 50 Lmin-1 and the units of measurement set to m3. The particle counter was set to measure for 0.5 and 5µm-sized particulate. The highest recorded particulate counts were recorded in the test results table, where a pass or fail would thus be determined against the Grade/Class determined in accordance with ISO14644-1:2015 section 4.3. Later, the Complete Raw Data was appended, detailing all test location results. Each reading from all locations was below the maximum permissible value for the Classification as stated in the results table and so the test was deemed to have been passed.

Lighting Levels: Measurements of the lighting level were carried out in each room at bench (working) height in several of the positions where equipment or an operator will potentially be sited using a calibrated Luxmeter. Each measurement was recorded and the average of each room was then calculated. All average readings satisfied the minimum lux level requirements and so the Cleancube's lighting level readings achieved a pass.

Temperature Levels: The temperature was measured at a minimum of one location for each temperature-controlled zone *(see diagram below)*. Each sensor was placed at a designated location at work-level height using a calibrated Temperature Sensor. After sufficient time was allowed for the sensor to stabilise, the Guardtech Engineers recorded temperature readings at each location. Measurements were performed as appropriate for the purpose of the application and the measurement time was at least five minutes, with one value recorded at least every minute. The average temperature reading from each room was above the minimum permissible temperature value and so a pass was recorded.

Humidity Levels: The humidity was measured at a minimum of one location for each humidity-controlled zone. Each sensor was placed at the designated location at work-level height using a calibrated humidity sensor. After sufficient time was allowed for the sensor to stabilise, the humidity reading at each location was recorded. Measurements were performed as appropriate for the purpose of the application and the measurement time was at least five minutes, with one value recorded at least every minute. The average reading from each room was above the minimum permissible humidity value and so the Cleancube was deemed to have passed.

Figure 11 – Humidity Monitoring positions at bench height (plan view)



CLIENT CASE STUDY

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Sound Levels: Measurements of the Sound levels were carried out in the centre of each room at bench (working) height by Validation Engineers using a calibrated Sound Meter. Each reading, from the locations on the diagram below, had to be below the maximum permissible value as stated in our results table. Once this was achieved, a pass was awarded.

Door Interlock Testing: The Guardtech team were tasked with ensuring all interlocked room doors were fully operational. Using our Matrix result tables, Engineers were required to open each door, and check the other referenced interlocked door to ensure the interlock has engaged. The process was then repeated for all remaining interlocked doors. With the Door Under Test 'open', the Interlocked Door had to interlock/not open. All doors operated correctly and the test was deemed be a pass.

Disaster Recovery testing: With the room completely set up and commissioned, Validation Engineers were required to record the room pressure differentials as part of a Disaster Recovery Test. Engineers turned the power off in the cleanroom facility for a period of five minutes, then switched the power back on and allowed the cleanroom facility to become fully operational. They then recorded the pressure differentials at one minute, five minutes and at 10 minutes following the switch-on for each EMS gauge. The room pressure differentials returned to their commissioned set point following the reinstatement of the power and the test was deemed a pass.

THE RESULT

Guardtech Group Compliance Manager Chris McGinn said: "This was a fairly routine Guardtech Group Validation as part of an overall Operational Qualification for a bespoke Cleancube Mobile Cleanroom 'double 40ft container' for Research & Development work.

"Our diligent and thorough team of Service Engineers and supporting staff work to the highest standards and therefore treated this Validation with the same diligence and attention to detail that set us out as the go-to source for high-quality post-cleanroom construction services."
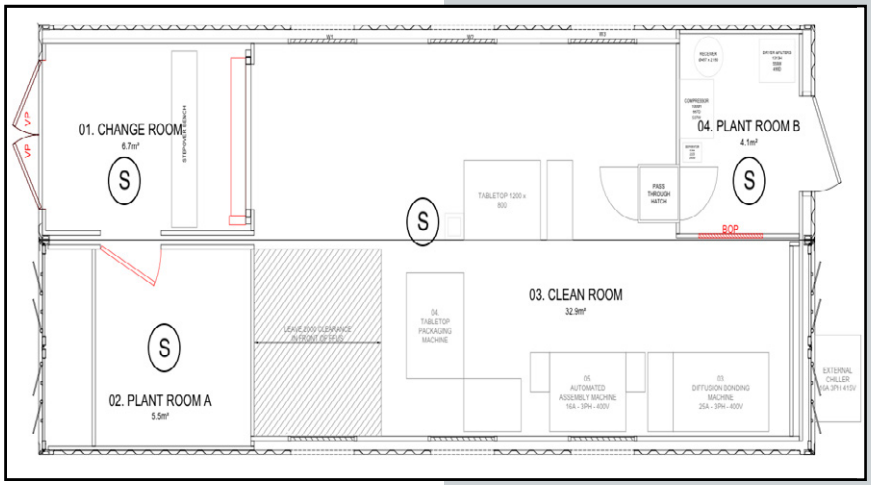
Figure 12 – Sound Level Monitoring positions at bench height (plan view)