

The evolution of cleanroom contamination control



Cleanroom contamination control has evolved significantly over the last decade

BASED AT THE WEST OF SCOTLAND SCIENCE PARK IN GLASGOW, CLEANROOM ZONE AND ASSURED MICRO PROVIDE A NATIONWIDE CLEANROOM CONTAMINATION CONTROL, CLEANING AND MICROBIOLOGY TESTING SERVICE. THE PARTNERED COMPANIES HAVE ENJOYED A PERIOD OF RAPID EXPANSION OVER THE PAST FEW YEARS AND BUSINESS IS EXPECTED TO DOUBLE AGAIN IN THE NEXT TWO YEARS. *INNOVATION INTO SUCCESS* SPOKE TO MANAGING DIRECTOR OF BOTH COMPANIES, KENNY GORDON.

Cleanroom Zone was formed back in 2002 when Kenny Gordon spotted a gap in the market for a specialised, professional cleanroom cleaning service within the growing pharmaceutical, medical and semiconductor cleanroom sector.

At this time there were no unique cleanroom contamination control

specialists and the only service available was via contract cleaning services, but this did not cover measurement of contamination before or after the service.

During Cleanroom Zone's early development it became increasingly evident that customers also needed Environmental Monitoring (EM) in place



Cleanroom Zone and Assured Micro are based at the West of Scotland Science Park in Glasgow

Case study

Cleanroom Zone and Assured Micro recently worked on a pharmaceutical company's new manufacturing facility near Glasgow.

The construction company had handed over the cleanroom areas to the client but they had left high levels of particulates and gross contamination.

Before the firm could start the manufacturing process, it required cytotoxic, non-cytotoxic and component preparatory areas to be qualified and a team of operators to be trained



Cleanroom Zone's Managing Director, Kenny Gordon

and gown qualified before an MHRA inspection to approve the cleanrooms.

The company also needed a quick turnaround

to be ready for the MHRA inspection – MHRA requires stringent monitoring prior to a license being granted – so the race was on.

Kenny Gordon takes up the story: "We paid our client a site visit to establish an account of material and people flow and we followed this up with a number of risk assessments and determined key locations for sampling. This would demonstrate effectiveness of cleaning along with the functionality of the room itself. We set up cleaning procedures for our client to allow for the most efficient and quickest cleaning turnaround possible. We also implemented a sampling plan for gown monitoring based on key areas where there is a risk of contamination.

"A base line builders clean was performed removing gross contamination, dust and builders waste. This was followed up by three commissioning cleans with at rest monitoring sessions performed in between cleans. The actions were completed within a 100-day time frame and this enabled the client to get into the areas to begin business with minimum delay.

"Further gown monitoring sessions were performed as the client expanded their staff resource and required them to enter cleanroom areas as soon as possible. Following on from initial monitoring the sampling was ramped up to provide meticulous detail of all areas.

"From the first commission clean the levels of bacteria were in spec for the grade of areas required. The further cleans ensured the areas were free of bacteria and contamination. Monitoring results were reported back to the client as soon as the incubation period had been completed. This kept the client up to date and let them plan their schedule to accommodate manufactures with minimum delay.

"Following the MHRA inspection the client was awarded its manufacturing license."



"We measure contamination levels beforehand, then deploy our best-practice cleaning methods using only industry standard cleaning materials and equipment."

after the cleaning service, and some required it be done by a third party company. This led to the creation of

Assured Micro in 2009 – now they could deliver the full package of EM, under a different company name and new staff but managed by Kenny.

The specialised cleanroom cleaning service offered by Cleanroom Zone includes routine daily, weekly, monthly, commissioning, post-build and emergency cleans. While specialising in cleanrooms and critical areas the company also cover the pharma, medical devices, semiconductor, engineering and NHS sectors – services include initial consultation of cleanroom conditions and requirements for particulate and microbiological levels.

Kenny said: "We measure contamination levels beforehand, then deploy our best-practice cleaning methods using only industry standard cleaning materials and equipment, and finally record the post-clean contamination levels using our own calibrated equipment.

"We are niche in this area in that we are the only company we know of offering this complete service in the UK. Our customers have reported increases in their product yield performance due to reduced particulate levels from the cleaning methods we have used.

"We cover all classifications of cleanrooms whether it be Grades A, B, C,

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Cleanrooms

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D in the pharma/medical industry or the class 1000, 100, 10 in the semiconductor rooms."

The GMP MHRA-certified microbiology services offered by Assured Micro include incubation, on-site sampling, water testing, growth promotion, bioburden, biological indicators, particle counts, airflow measurement, detergent efficacy and endotoxin.

This is carried out in the controlled environment of Assured Micro's 1,500 sq ft laboratory – equipment used at the facility includes a range of temperature-controlled incubators, class 2 LAF cabinet, standard LAF cabinet, fridges and freezers, air samplers and particle counters.



Identifying bacteria

In 2013, Assured Micro underwent a MHRA inspection and successfully attained GMP accreditation. This was a major boost for the company as it opened channels to larger clients who require an approved company to perform their work.

As Kenny explained: "We predominantly support companies who do not have in-house microbiology facilities, but also work with larger pharma clients as an independent service for regulatory purposes."

Where Cleanroom Zone and Assured Micro stand out from its competitors, continued Kenny, is its rapid turnaround time with results.

"We offer same day results delivered to client (after incubation period) and this is often the limiting factor for client batch release. This often differentiates us from other companies and gives us a leading edge in this sector.

"We are unique in our EM in that all our staff have worked in cleanrooms and



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Cleanroom Zone support companies without in-house microbiology facilities

therefore understand cleanroom function and the strict requirements. They can also offer specific advice if results are out of specification. An immediate re-test is available as part of the service which is not always the case elsewhere."

Kenny said Cleanroom Zone and Assured Micro are now in a period of high

business growth and expansion, securing long-term contracts with new clients almost every month.

"The future focus is strengthening the current markets in pharma and extending further into semiconductor cleanrooms. For microbiological we aim to get into the food micro testing services.

"A business strategy was formulated early in 2014 to grow both businesses and this has progressed to plan. Beyond this year, the plan to double revenue is firmly within sight," he added.

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