SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

Cleanroom Microbiology

LS011

Cleanroom Microbiology

Many companies do not have their own dedicated microbiologist on site and in this case, various departments acquire responsibility for looking after the establishment and maintenance of the environmental monitoring and product testing. Personnel often are unsure of the exact regulatory requirements with regard to the testing required, how best to perform the testing so as to gain the most relevant and appropriate data, how to interpret the results, and understand the severity of the impacts the result may have on the safety and quality of the final product.

Very often environmental controls such as the microbiological and particle testing are viewed as something that has to be addressed, however the real understanding of why and how this monitoring should be performed and the interpretation of the results and data is often not thought out effectively. What is best practice? How does the information gained compare to the cost of all this monitoring?

Duration & Price

Duration: 1 day
Public Virtual Training: £375
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
23 Feb 2026	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

The programme offers the participants, an opportunity to work together in establishing an effective environmental monitoring plan in compliance with the ISO standards and exploring challenges, solving problems and finding solutions to microbial issues that could potentially have an impact on the final product and in turn on the business and people working within it.

- Environmental Monitoring Program
    - Choice of Microbiological Sampling
    - Sampling Locations based on risk assessment
    - Sampling Map
    - Sampling Frequency
    - Alert & Action Limits
    - Interpretation of Results
    - Out of Spec Results
    - Investigations
    - Reporting Trending & Documentation Systems
- Particulate Monitoring
- Cleanroom audit awareness
- Bioburden Sampling
- LAL Sampling
- Feedback

This training programme is very interactive, constantly encourages feedback from the participants and applies various, different training methods and styles to deliver the key messages effectively e.g. discussions, group activities and practical exercises. Participants are given the opportunity to learn how to perform a cleanroom audit on their own cleanroom facility and become aware of what areas and behaviours are of potential concern with regard to contributing to contamination levels. On finishing the course, participants must complete in detail, an out of spec investigation.

Who should participate?

Any person in the organisation who has responsibility for :

- Looking after the cleanroom testing i.e. microbial, particulate or product testing, establishing limits and/or completing out of spec investigations
- Personnel working within the cleanroom on a regular basis, as they are the eyes on the ground to help identify the root cause of out of spec results.

In order for personnel to participate in the completion of investigations they must understand why this monitoring is performed and have an awareness of how significant levels of contamination can enter the cleanroom in order to cause these out of spec results.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the requirements and purpose of microbial testing.
- Understand the regulatory requirements as detailed in ISO14698 and ISO 14644
- Set up and maintain an effective Environmental Monitoring Plan
- Trend results appropriately
- Establish alert and action limits
- Interpret the results and define the impacts correctly.
- Manage out of spec results
- Investigate current issues/out of spec results where required
- Document investigations clearly
- Prescribe appropriate corrective action

Tutors

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What Our Learners Say

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