

ICEB Accredited Basic Cleanroom Technology Course - Contamination Control Practices within the Cleanroom

One day Course



BACKGROUND

Contamination control and GMP are an essential and integral element of working within Clean room Environments and has never before been so vitally important to so many industries. Personnel working within these environments are generally aware that there are strict controls in place to minimise contamination before entering these environments. However very often personnel do not understand why these strict controls are in place and the impacts if these contamination controls are not adhered to.

A better understanding of the impact of contamination within the cleanroom and knowledge of how to minimise it, may encourage personnel to take greater care when performing activities within these environments and become mindful of what behaviours and practices are acceptable within their own cleanroom. Personnel performing tasks within these environments should be equipped with the relevant training, skills, awareness and knowledge to effectively address and prevent issues which may arise within these environments. Clients have seen a marked improvement in employee attitudes to their work environments and housekeeping as a result of this course.

COURSE OBJECTIVES

The key objective of this course is to create a core and thorough understanding of the impacts of contamination within the cleanroom and create a fundamental awareness in personnel as to how they and their processes, behaviours, methods and practices, can contribute to contamination within the cleanroom and how these contamination levels can be prevented or minimised.

To achieve this, the course objectives are as follows:

- Understand why Cleanrooms are used for manufacturing.
- Knowledge of what is 'contamination' of the Cleanroom.
- Identify different types of contamination within the Cleanroom.
- Identify sources and routes of contamination within the Cleanroom.
- Recognise the impact and effects of contamination within the Cleanroom.
- Appreciate how the Cleanroom functions to minimise contamination.
- Understand how personnel contribute to contamination.
- Consider the controls put in place in the Cleanroom to minimise contamination from personnel such as:
 - Acceptable Personal Behaviour within the Cleanroom
 - Gowning and De-Gowning
 - Transfer of Materials into and out of the Cleanroom
 - Effective Cleaning Practices
- Asses how a Cleanroom is tested and monitored
- Measuring the performance of a Cleanroom

WHO SHOULD ATTEND

Any person in the organisation/service sector who is involved in working with cleanroom environments eg: Management, Operations, Quality, Engineering, Purchasing, Warehouse, Maintenance, Cleaning, Security Staff and Construction workers.

COURSE PROGRAMME

The programme offers the participants, from different backgrounds, an opportunity to work together in exploring challenges, solving problems and finding solutions to issues that are relevant to all businesses working with cleanroom environments.

- Introduction into Cleanrooms & Contamination
- Controls put in place to minimise contamination during the Cleanroom set-up
- Cleanroom Clothing & Gowning Practices
- Personal Behaviour & Hygiene
- Transfer of Materials into the Cleanroom
- Effective Cleaning of surfaces and equipment
- Monitoring and Measuring the Performance of the Cleanroom
- Assessment
- Feedback

The training programme is very interactive, constantly encourages feedback from the participants and applies different training methods and styles to deliver the key messages e.g. discussions, group activities, demonstrations and practical exercises. There is an assessment on completion of the programme in which a pass mark of 50% must be achieved in order to receive certification. The certification lasts up to 3 years.

TRAINING SUPPORT for In-house Programmes

Prior to organising an in-house training programme, a cleanroom audit can be performed in order to examine specific problems / issues within the Cleanroom Environment, e.g. environmental monitoring trends, current cleanroom processes, methods and behaviours. This allows the tutor to further tailor the training programme to suit the specific client's requirements.

A cleanroom audit looks at:

- Current relevant procedures,
- The current level of GMP within the cleanroom and supporting areas,
- The Cleanliness and Housekeeping of the cleanroom environment,
- Effective Contamination Control Practices and Methods and
- Personal Behaviour.

A detailed report featuring observations, suggestions and recommendations will be submitted to the client as to how the standard of GMP can be improved. Any suggestions or changes taken on board by the client can then be rolled out as part of the training programme.

A follow up audit can be performed after the training has been completed in order to review improvements in Contamination Control practices that have been put in place by the client and to offer further guidance and support as required.

COURSE MANUAL

This course manual comprises a full set of powerpoint slides and accompanying notes, which proves to be an excellent source of reference after the course.

COURSE ACCREDITATION

This course is accredited by the ICEB and approved by the Irish Cleanroom Society. Certificates are issued by the ICEB with the approval of the Irish Cleanroom Society.

COURSE PRESENTER **Dr. Kevina O'Donoghue, Specialised Sterile Environments (SSE)**

This training programme has been developed and is presented by Dr. Kevina O'Donoghue, Microbiologist. Kevina O'Donoghue is a PhD graduate from the National University of Ireland, Galway and has worked with cleanroom environments for nearly 10 years. Beginning in the diagnostics sector, working for Cambridge Diagnostics, and then moving to the medical device sector, working for Abbott Vascular Galway, she worked as a Microbiologist and was closely involved in the setting up of new cleanroom environments, validation of cleanroom environments, management of the environmental monitoring programme, auditing of cleanrooms and their processes, sterilisation validations and training in contamination control and GMP. She accomplished a certificate in Training and Continuing Education, National University of Ireland, Maynooth and completed the Certified Auditor / Lead Auditor ISO 9001:2000 Quality Management System training in 2007. She is currently working as a microbiologist with Specialised Sterile Environments where she developed and delivers a training programme on 'Contamination Control Practices within the Cleanroom Environment' and is one of the founders and facilitator of the Cleanroom Technology Network Group.

Course Dates &
Venues
See attached Calendar

Course Times
9.00am - 5.00pm

Public Course Cost €395
(includes course documentation, lunch and refreshments as well as ICEB Certification)