MARKTHOMPSON
LIFESCIENCES

Clean Room Technology, The Manufacturing Environment

Overview

One of our most popular courses, generally tailored to sites clean room design and requirements.

This Course covers Clean Room design from Fresh air intake to the highest grade clean room conditions, including where required containment of hazardous product.

Multi product facilities have several challenges in terms of clean room design, cross contamination control, pressure cascades as well as the detail regarding Material and People flows in the facility.

This course covers the design, AHU, Filtration, Environmental controls, and air flow controls. Also the routine testing and environmental monitoring of areas. From the high level regulatory expectation to the details in ISO 14644.

As with all MTL courses there are many case studies, regulatory feedback and current best practice ideas presented alongside the science and engineering of controlling the manufacturing environment.

Target audience

Clean Room Controls, as with many areas of Pharmaceutical technology, require a multidiscipline approach. Engineering design and maintenance, Operational Controls, EM (Viable and non viable), Qualification Technicians etc.

The best courses often have representatives from all areas ensuring a holistic view of clean room controls on the site can be discussed.

About the Lecturers

Dependent upon the final content of the training course agreed this course is delivered by 1 or 2 people. All of the Associates who work with Mark Thompson Lifesciences are actively engaged in the Pharmaceutical Industry ensuring information is current and reflects Industry best practice as well as regulatory trends and expectations.

"Mark has delivered our Clean Room Training on site for the last 3 years now and this has provided constant engagement in process improvement through better understanding of the subject" Training Manager, UK Site

Course Programme

DAY 1:

- Introduction to Clean Rooms
- How do we measure 'Clean'
- Regulatory Guidance and Structure
- Viable and Non Viable definitions
- The Spectrum of clean rooms and defining grade for operation.
- Measuring Viable and Non Viable Contamination
- Risk Assessment for Contamination
- Viable monitoring techniques
- Particle Counter operation and calibration
- Installation of Viable and Non Viable fixed monitoring
- EM Risk Assessment, Trending and Data Review.
- Handling deviations and adverse trends in EM Data

DAY 2:

- The air we start with.
- Design and components in an Air Handling Unit
- Air Filtration and Filter specifications
- Filter testing and Filter life
- AHU to Terminal HEPA's/ULPA's
- Designing System Pressures, Cascades, Balances, responses.
- Air flow requirements in different classification areas.
- Achieving Unidirectional air flow and velocity
- Grade A requirements
- RABS Technology and Operation
- Isolator Technology and Operation
- Aseptic Line set up, operation and interventions
- Cleaning and Disinfection
- VHP decontamination
- VHP Cycle design and development
- VHP qualification, monitoring, trending and requalification

DAY 3:

- Qualification of a HVAC system
- Variable definition, control and risk assessment understanding
- Qualification based upon risk assessment, CQA's and CPP's
- Maintaining the Qualified State
- Everything justified by Risk Assessment, making the link.
- Air flow visualisation studies Protocol development
- Best Practice for performing Smoke studies
- Review and documentation of Smoke studies
- Requalification Controls and requirements
- Industry and Regulatory Trends

| Consultancy & training in sterile product manufacture |
| T: +44 (0)7780 430383 |
| E: mark@markthompsonls.com |
| W: markthompsonls.com |