honeyman
TRAINING

Microbial Risk Management

During Cleanroom Operations

Microbial Risk Management During Cleanroom Operations

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2 Days Virtual Training

Who Should Attend?

The course is suitable for all personnel involved in the management and operation of cleanrooms including:

Production Managers and Supervisors, Quality Assurance, Microbiologists, Sterility Assurance Specialists and Sterility Assurance Engineers.

This course will provide an understanding of the Risk Management of Contamination (RMC) system that can be utilised for the control of contamination during manufacturing operations in cleanrooms.

All general sources of cleanroom contamination, their routes of transfer and the associated control methods will be discussed and a method of assessing their risks to product explained.

Course Objectives & Learning Outcomes

- Delegates will be able to identify the sources of contamination, routes of transfer to the product and contamination control measures and apply this in their facility.
- The course will provide a scientific assessment of the fundamental mechanism of contamination transfer, via surface contact or from airborne deposition, and how this mechanism is used to provide the most accurate methods of assessing risk of microbial contamination of product.
- Delegates will recognise how the indentified risks, or their methods of control can be monitord and limits set to ensure that contamination is adequately controlled are outlined.
- Delegates will recognise the advantages of using a quantitative system to assess and prioritise risk based on actual process data.
- Methods of periodic verification that the contamination system is under control will be presented.
- Delegates will participate in risk assessment workshops lead by industry experts to enhance learning and facilitate debate.
- Methodology will be presented to determine the microbial risk to patient from aseptically prepared products.

Honeyman is renowned for industry leading GMP knowledge-transfer, lectures, consultancy and courses, delivered online and in-person.

Course Programme

DAY ONE

- Risk Management of Contamination (RMC) During Cleanroom Manufacture

- Microbial Risk Assessment Method

- Mechanism of Contamination Transfer Sources and Routes

- Key Control Measures and Risk Diagrams

- Level 1 Risk Assessment for:
  - General Cleanroom Areas
  - Aseptic Filling Processes
  - Assessment of Manufacturing Stage Risks

- Areas for Aseptic Improvement.

DAY TWO

- Level 3 Risk Assessment for Critical Area Contamination for:
  - Airborne Deposition
  - Surface Contact
  - Critical Area Contamination
  - Surface Contact

- Establishing an Effective Monitoring Programme

- Regular Verification of the Risk System

- Documentation and Staff Training

- Assessing Microbial Risk to Patients from Aseptically Manufactured Products

- Calculation of Risk to Patients

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