honeyman TRAINING

Critical Factors

For Sterile Product Manufacture

Critical Factors for Sterile Product Manufacture

Click for full details

4 Days Virtual Training

TBC - TBC

Who Should Attend?

All staff, supervisors and managers involved in production including;

- QA
- QC
- Engineering, Validation
- Regulatory Affairs

This course covers all key aspects of sterile product manufacture, for both aseptically prepared and terminally sterilised products.

Open discussion sessions on current best practices and regulatory trends in sterile product manufacture will be coupled with case studies to illustrate key points. All of the course lecturers are actively involved in the industry today and base their lectures on their current knowledge, feedback from recent inspections and today's technology, allowing for the inclusion of practical examples and real life case studies in the course.

Course Objectives & Learning Outcomes

- Review the key activities and processes which are critical to the success of sterile manufacturing operations.
- Have been refreshed on the special nature of sterile products and understand the challenges involved in aseptic processing and the consequences of failure.
- Be able to develop risk assessment methods and quantify risk
- Be able to apply risk management techniques to control contamination in cleanrooms
- Understand how the key aspects of the facility design, personnel, material flows and aseptic control within the cleanroom behaviours determine the success of aseptic processing
- Know how to implement and perform a successful aseptic validation program including practical trail design.
- Understand the current sterilisation and sanitisation processes and controls.
- Recognise the importance of critical utilities in sterile product manufacture including steam, high purity water and compressed gases.
- Appreciate the role of QC laboratories in sterile processes and the role of the QP in sterile manufacture.
- Be able to review the current regulatory requirements and trends in sterile manufacture
- Understand common GMP deficiencies and what inspectors are looking for.

Course Programme

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

DAY ONE

Day One Risks in Sterile Product Manufacturing, Bioburden Microbiology, Bioburden Control Sterilisation Steps, Principles of Viable Particle Monitoring (EM), Bioburden Control - Irradiation, Sterile Product Manufacturing Facility Overview.

Day Two

Filtration of Liquid and Air, Critical Utilities - Water & Steam, CAPA/OOS, Root Cause Analysis & The Role of the QP, Cold chain transport, Pharmaceutical QC and Micro Laboratories, Sterile Product Inspection Techniques.

Day Three

Introduction to Cleanrooms, HVAC Systems, Cleanroom Design, RABS & Isolator Technology, Non-Viable Particle Monitoring, Cleanroom Classification & Monitoring, People as a Source of Contamination, Cleanroom Garments for Effective Contamination Control.

Day Four

Aseptic Validation, PST Workshop, HEPA Filters, HEPA Filter Failure Workshop, Product & Equipment Preparations EU/ China and US Aseptic Processing Guidelines.

Honeyman Training & Consultancy Limited

1A Meal Market, First Floor,
Hexham, Northumberland,
NE46 1NF

enquiries@honeymantraining.com

www.honeymantraining.com

Pharmaceutical Water Systems: Principles in Practice®

3 Days Virtual Training

TBC - TBC

Who Should Attend?

Personnel involved in the design, management and operation of pharmaceutical, healthcare or biotech water systems from the following disciples:

- Engineering
- Quality Assurance
- Microbiology
- QC
- Production
- Operations
- High purity water SME's

The Pharmaceutical Water Systems: Principles in Practice® course provides a holistic view of the design, operation and management of compendial water generation and distribution systems.

This industry leading course has been held all over the world and has recieved unrivalled feedback. Developed and delivered by recognised experts in water system design, validation and support.

Course Objectives & Learning Outcomes

- Understand the different types of compendial water grades, their applications and how they can be achieved.
- Understand regulatory requirements, standards and expectations for pharmaceutical water systems.
- Be able to write a valuable URS that not only eliminates ambiguity but also provides a solid foundation for the IQ/OQ and PQ validations.
- Be able to compare different strategies for generation, pre-treatment, storage and distribution of pharmaceutical grade water and select the most appropriate for your application.
- Understand how GMP can be implemented at the start, your water system.
- Obtain a basic knowledge of microbiology and biofilm formation, and the impact on water system.
- Understand the phenomena of Rouge and how this can be managed.
- Be able to develop a strategy to monitor the quality of your water system.
- Understand how to design and build water systems cost effectively.

Pharmaceutical Water Systems: Practical Applications

2 Days Virtual Training

04th May 2022 - 05th May 2022
04th Oct 2022 - 05th Oct 2022

Who Should Attend?

This course has been created for personnel involved in the design management and operation of pharmaceutical and biopharmaceutical water systems folfollowing disciples:

- Engineering
- Quality Assurnace
- Microbiology
- QC
- Production
- Operations

This extremely poor Honeyman Pharmaceutical Water Systems training course is to be held online for the first time.

During the course there will be an opportunity for delegates to review pure water installations and to speak to peers and specialists about owning and managing these systems within the pharmaceutical regulatory environment. This shared experience will be invaluable to other pure water system owners and users, and for those planning to build new systems in the future. This two day course and is an abridged version of the three day 'Principles in Practice'® course.

Course Objectives & Learning Outcomes

- The current pharmacopeial specifications and requirements for pharmaceutical water.
- The uses and applications for water in the pharmaceutical and biotech manufacturing facilities.
- The methods of purification for Purified Water and Water for Injections.
- The building blocks of water systems, and how to configure them to maximise reliability and performance.
- Microbiological challenges including Biofilm and how to control them.
- The design principles and standard industry practices in storage and distribution systems.
- Approaches to quality, management and control of systems.
- Workshops designed for delegates to put the principles into practice.

Pharmaceutical Microbiology for Non-Microbiologists

2 Days Virtual Training

24th May 2022 - 25th May 2022
08th Nov 2022 - 09th Nov 2022

Who Should Attend?

Anyone who works in a sterile manufacturing operation who is not directly involved in microbiology or is new to this area.

This includes persons who review data but are not qualified microbiologists.

Controlling microbiology throughout the manufacturing process is a key success factor for production.

Microbiology is unseen and data is history, effective control requires all disciplines to be involved in the control measures and any out of specification investigations. Therefore, all key personnel should have a thorough understanding of microbiology. This course is designed to give non- microbiologists a comprehensive introduction to microbiology so that they can engage in the required control measures, investigations and corrective actions.

Course Objectives & Learning Outcomes

- Understand the basic principles of pharmaceutical microbiology.
- Be able to understand how microbiology is of a concern to your manufacturing processes.
- Understand the main sources of microbiological contamination.
- Be able to constructively participate in microbiological risk assessments.
- Understand how to effectively reduce microbiological hazards and contamination within your facility.
- Review microbiological data and understand the methods of analysis control within the cleanroom.
- Micro requirements for sterile and non-sterile product manufacture.
- Appreciate the importance of microbiological data and control in pharmaceutical and medical device manufacture.
- Reading micro-organisms on Agar plates.
- Monitoring methods: sampling methods, isolation and counting.
- Interpretation of microbiological data.
- Gram positive and gram negative bacteria, and gram staining.
- Bacterial identification (bacteriologyand mycology).
- Spores and spore forming microorganisms.
- Be able to participate in out-of-specification investigations & Implement control measures.

Aseptic Processing Principles in Practice®

3 Days Virtual Training

29th Mar 2022 - 31st Mar 2022
18th Oct 2022 - 20th Oct 2022

Who Should Attend?

This course is suitable for all members of staff working with aseptic processes, including:

- QP's & Quality
- Operational Managers
- Operations Personnel
- Technical
- Engineering
- Validation

We guarantee on completion of this course that you will look at aseptic processing from a new perspective.

Sterility of an aseptic product cannot be determined by direct assessment of the finished product. Microbiological safety of the product can only be achieved by careful assessment of the hazards and control measures in place to provide the confidence that items are safe for the patient and fit for use.

Historically aseptic processes have relied heavily on monitoring of the environment, air, surfaces and personnel to verify the success of the process. However modern aseptic processes require a more holistic assessment of all the protective measures in place within the process and the complex interactions between these control measures, this approach is fully covered within this course.

Course Objectives & Learning Outcomes

- To understand the fundamental mechanisms of contamination transfer from source to product and the protective measures in place to prevent product contamination.
- To have the opportunity to work with risk management techniques like HACCP and RMC through practical workshops.
- To introduce new thinking for validation and risk assessment of the process.
- To understand the technology associated with cleanrooms and aseptic processes and understand the key control measures and they impact the sterility assurance of the product.
- To understand the cGMP regulations and guidelines for aseptic processing and to engage in discussions regarding industry changes and best practice.

Current Requirements for Cleaning Validation

2 Days Virtual Training

TBC - TBC

Who Should Attend?

This course will be beneficial to new corners and experienced personnel from:

- QA
- QC
- Engineering, Validation
- Production

This course covers topics such as the development of regulatory expectations, effective cleaning procedures and the validation and control of these procedures.

It will cover all areas of Cleaning Validation from the inception of a cleaning strategy and policy through the development and performing of the exercise to the maintenance of the validated cleaning regimes. Uniquely developed and delivered, to make it relevant to both novice to experts.

Course Objectives & Learning Outcomes

- Understand the key GMP requirements for cleaning validation and verification.
- Understand the methods of cleaning including manual, automated of COP.
- Be able to develop effective cleaning procedures.
- Undertsand the significance of product development data in cleaning validation.
- Develop approaches to cleaning validation based on scientific rationale.
- Develop cleaning validation protocols, define worst case locations, set limits and define acceptance criteria.
- Apply best practice techniques for direct surface sampling and recovery.
- Understand the suitability and technology associated with specific and non specific analytical techniques.
- Apply risk assessment techniques of maintaining the cleaning validation state: cleaning stability studies and change control.
- Understand the importance of maintaining the cleaning validation state: cleaning stabililty studies and change control.
- Gain awareness through industry Case Studies: From API to Finished Products / Regulatory Requirements. Including Annex 15 (2015).

Pharmacuetical Sterilisation Principles in Practice®

3 Days Virtual Training

05th Apr 2022 - 07th Apr 2022
20th Sep 2022 - 22nd Sep 2022

Who Should Attend?

The course is regularly attended by:

- Engineers
- Microbiologists
- QA & QC Personnel
- Production
- Operational
- Technical Personnel

This course provides delegates with a comprehensive understanding of moist heat and dry heat sterilisation processes from theoretical foundation through to the practical aspects of validation and biological indicators.

The course highlights the GMP requirements and current industry expectations for the routine operation, monitoring and control of sterilisation processes and gives practical examples of how these techniques are applied through appropriate engineering to ensure reliability in full compliance with all European and US regulatory requirements.

Course Objectives & Learning Outcomes

- To facilitate delegates to make risk based decisions based on science through increased understanding of sterilisation technology.
- To improve regulatory compliance and increase awareness of industry best practice.
- Quality Systems Associated with Sterilisation Processes.
- To reduce re-qualification effort and ongoing costs.
- Understanding of current Sterilisation standards.
- Be able to understand and explain the principles of Moist Heat Sterilisation.
- Understand the different challenges of sterilising porous, liquid and heat sensitive products.
- Steam Quality Generation Distribution and use.
- Understand Dry Heat Sterilisation and Depyrogenation.
- Instrumentation and Control of Sterilisation Processes.
- Steam in Place.
- To Increase process capacity.
- Understand the Auditing Sterilisation Processes and Preparing for a Regulatory Inspection.
- Understand the reasoning behind the use of Biological Indicators.
- Understand the reasoning behind the use of Biological Indicators.
- Understanding of Routine Operation of Sterilisers.

Microbial Risk Management During Cleanroom Operations

2 Days Virtual Training

22nd Nov 2022 - 23rd Nov 2022

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.

Biotechnology Principles in Practice®

2 Days Virtual Training

10th Nov 2022 - 11th Nov 2022

Who Should Attend?

Ideal for anyone new to the industry or processes, as well as being a good refresher for those more experienced individuals.

The course would be suitable for different functional groups within the organisation including:

- Operations
- Quality Assurance
- Engineering
- Validation

This course provides a comprehensive overview of biotechnology ideology and practice, historically, as we are now, and expected developments in the future.

The course is spread over two days to allow interaction between the lecturer and attendees.

The presentations will be supplemented with workshops that will be used to verify understanding and look at the biotechnology industry and its future. This course itself will encourage discussion and participation which will lead to greater understanding of the current status of biotechnology and the future of the industry.

Course Objectives & Learning Outcomes

- To gain an understanding of the different types of biotechnology processes.
- Current and future GMP requirements for biotechnology.
- Typical product lifecycle phases and regulatory requirements.
- Steps involved in the manufacture of clinical batches including scale up, product characterisation, and control of process inputs and outputs.
- How the product can influence facility design and the use of disposable technologies.
- Differences between the production of a variety of cell substrates e.g. mammalian, bacterial, viral and plant cell products.
- Upstream processing including cell culture, fermentation, harvest.
- Downstream processing including typical purification techniques.
- Analytical techniques employed to verify final product purity.
- Fill Finish activities, storage and distribution of product.
- Principles of process and equipment validation.

Testimonials

Don’t take our word for it, here is what some of our clients have to say about Honeyman Training courses:

“Perfectly tailored to suit the training needs of the PPD Quality function considering current business needs and expectations.”

Qualified Persion, PPD

“Dynamic and interactive, relevant to our operations, made a technical subject accessible.”

Product Manager, Benchmark Vaccines

“Perfectly tailored to suit the training needs of the PPD Quality function considering current business needs and expectations.”

Qualified Persion, PPD

“Tailored to the business, pitched at the right level. Excellent, ‘spot on’ content delivery.”

QA Manager, Victoria Pharmaceuticals

“Informative, educational, enthusiastically delivered on-site. This will be a regular event for our department.”

“Excellent reputation, excellent service, dedicated staff.”

GE Healthcare