honeyman TRAINING

# Training Prospectus

## Public Courses 2024

# Contents

# Honeyman Training

Operating extensively within the global pharmaceutical, biotech, medical device and related healthcare industries, Honeyman Training has a well earned and highly regarded reputation for knowledge transfer and consultancy.

Whether it be manufacturing process issues, audit preparation and responses, or independent review of facility projects and operations, we have the technical expertise and knowledge to provide unbiased and regulatory compliant solutions and advice.

Honeyman Training's unique position in the market, as a knowledge provider and consultancy delivering pharmaceutical process troubleshooting, is built on decades of close alliance with clients, suppliers and industry experts.

Training solutions available: Public Courses, On-site Courses, generic or bespoke online or in-person and Consultation.

The Science of Pharmaceutical Manufacturing
For current Good Manufacturing Practice (cGMP) compliance

## Strategic Partnerships

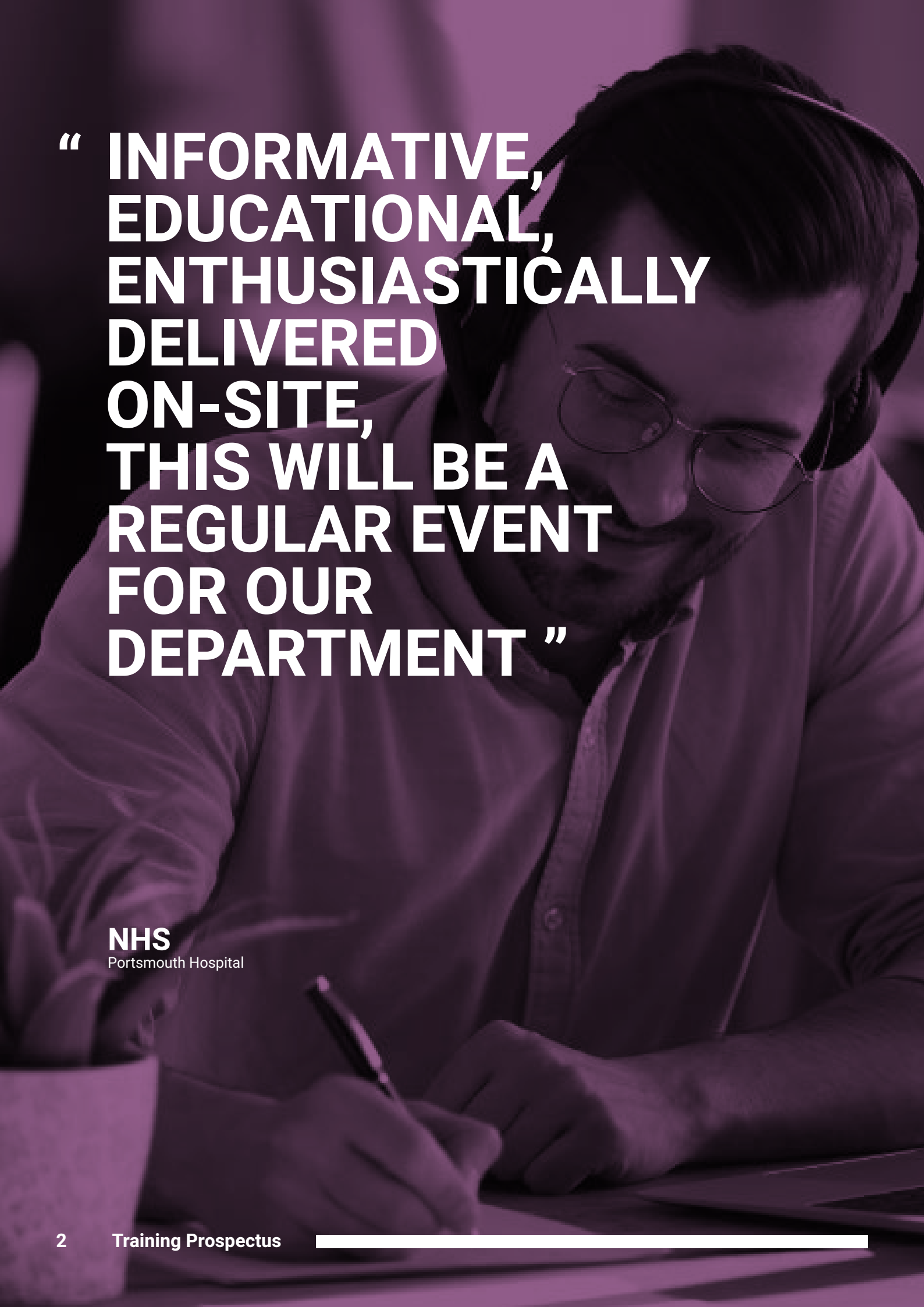
Honeyman Training works collaboratively with Honeyman Laboratories and Honeyman Water to extend their services to its clients and delegates.

honeyman LABORATORIES

Contract Laboratory: Water and clean steam testing, Finished Products QC release Microbiology, and Finished Product QC release Chemistry, Clean room validation support (e.g. DET, Environmental Monitoring).

honeyman WATER

Water and Steam: Purified Water & WFI generation and storage, URS consultancy, IQ/OQ and PQ validation, Maintenance and troubleshooting, Consultancy.



“ INFORMATIVE, EDUCATIONAL, ENTHUSIASTICALLY DELIVERED ON-SITE, THIS WILL BE A REGULAR EVENT FOR OUR DEPARTMENT ”

**NHS**
Portsmouth Hospital

# Honeyman Traning Courses

Over three decades, Honeyman has become a cornerstone in professional development by training thousands of people within the pharmaceutical, biotech and medical device industry.

Our engaging courses continue to remain popular because they provide delegates with a sound understanding of scientific principles in each technical area, complemented by interactive workshops, discussions, practical demonstrations and case studies to put these principles into practice.

All our courses are delivered by experts who actively work within the industry, therefore, we continue to share pragmatic, current best practice advice to enable you to meet current GMP and regulatory expectations.

## Virtual Training and In-Person Courses Available

> We are renowned for industry leading GMP knowledge-transfer, lectures, consultancy and courses usually delivered face-to-face.
>
> We now have an active Virtual Training schedule to help you 'keep your space' and stay at the top of your game.

## Group Booking?

Do you need training for a group or department? **Don't worry!**

At Honeyman we can train large groups and to ensure training is delivered cost effectively, we are happy to discuss the pricing options available to you. Please contact us by email or phone with the required course, dates and number of delegates then we'll be in touch with you.

# Why Honeyman Training?

Over the last 30 years, Honeyman has trained thousands of people within the pharmaceutical, biotech and medical device industry.

Our courses continue to remain popular because they provide delegates with a sound understanding of scientific principles in each technical area, complemented by interactive workshops, discussions, practical demonstations and case studies to put these principles into practice.

All of our courses are delivered by experts who actively work within the industry; therefore we will continue to share pragmatic, current best practice advice to enable you to meet current GMP and regulatory expectations.

## 3 easy ways to book the right course for you:

Simply email us at **enquiries@honeymantraining.com** with the required course name, dates and delegate name(s) and we'll email the available payment options to complete your booking.

Complete the course booking form and payment online at:
**www.honeymantraining.com**

Request a call back - Send us an email and we will arrange to call you back at a convenient time to discuss requirements.

“ EXPERIENCE I LEARNED FROM YOUR COURSES HAVE BEEN PASSED TO ENGINEERS FROM INDUSTRY ACROSS EUROPE ”

**ISO1 Cleanroom**
European Space Agency

# Cleanrooms Principles in Practice®

Click for full details

### 3 Days Virtual Training

### 5th -7th June 2024
### 19th -21st November 2024

### Who Should Attend?

All personnel involved in the operation and management of cleanrooms, Including:

- Engineers
- QA Staff
- Validation
- Operations Personnel

The Cleanrooms: Principles in Practice® course provides a holistic view of the design, operation and management of cleanrooms, and is suitable for all personnel who work in or manage a cleanroom environment.

The course has been developed by industry experts in cleanroom design, cleanroom validation, microbiology and quality assurance.

## Course Objectives & Learning Outcomes

- Develop fundamental principle knowledge of all personnel involved in the management and operations of cleanrooms.
- To be able to apply the knowledge gained to participate in risk assessments and investigations in their own facility.
- Have been provided the background on how GMP regulations and ISO standards define cleanroom design, operation and validation.
- Understand the main sources of microbiological contamination and how to control and minimise them within the cleanroom.
- Recognise current best practices for gowning, changing and operator qualification.
- Appreciate the features of cleanroom facility design and how the type of product and operations influence the design.
- To understand the qualification of HVAC systems and how to interpret data.
- To understand key tests involved in cleanroom qualification, smoke testing and particle counting.
- To understand how to use impact assessment to define system boundaries and identify critical components.
- Be able to present a cost-effective approach to validation of cleanrooms.
- Appreciate cleaning and maintaining control within the cleanroom.

# Pharmaceutical Water Systems: Principles in Practice®

Click for full details

**Barnard Castle, UK**
**3 Day Training Course**

**14th - 16th May 2024**
**22nd - 24nd October 2024**

## Who Should Attend?

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

- 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 application and how they can be achieved
- Understand regulatory requirements, standards and expectations for pharmaceutical water systems
- Understand how to design and build water systems cost effectively
- Be able to write a valuable URS that eliminates ambiguity and provides a solid foundation for IQ/OQ and PQ validation
- Be able to validate and manage water systems cost effectively
- Be able to develop a strategy to monitor the quality of your water system
- Understand the phenomena of Rouge and how this can be managed
- Obtain a basic knowledge of microbiology and biofilm formation, and the impact on water systems
- Understand how GMP can be implemented at the start, your water system
- 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
- Validation and Qualification including URS, DQ, IQ,OQ and PQ activities

# Pharmaceutical Water Systems

Click for full details

## 2 Days Virtual Training

## 23rd - 24th May 2024

## Who Should Attend?

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

- Engineering
- Quality Assurance
- Microbiology
- QC
- Production
- Operations

This extremely popular Honeyman Pharmaceutical Water Systems training course is now available online as a virtual training course.

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

- Understand the different types of compendial water grades, their application and how they can be achieved
- Understand regulatory requirements, standards and expectations for pharmaceutical water systems
- Understand how to design and build water systems cost effectively
- Be able to write a valuable URS that eliminates ambiguity amnd provides a solid foundation for IQ/OQ and PQ validation
- Be able to validate and manage water systems cost effectively
- Be able to develop a strategy to monitor the quality of your water system
- Understand the phenomena of Rouge and how this can be managed
- Obtain a basic knowledge of microbiology and biofilm formation, and the impact on water systems
- Understand how GMP can be implemented at the start, your water system
- 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.
- Validation and Qualification including URS, DQ, IQ, OQ and PQ activities

# Pharmaceutical Microbiology for Non-Microbiologists

Click for full details

## 2 Days Virtual Training

## 26th - 27th November 2024

## Who Should Attend?

Anyone who works in a sterile product manufacturing operation or non-sterile operation where microbiology is controlled but who is not directly involved in microbiology or is new to this area.

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.

# Pharmaceutical Microbiology for Non-Microbiologists

Click for full details

**Barnard Castle, UK**
**2 Day Training Course**

**30th April - 1st May 2024**

## Who Should Attend?

Anyone who works in a sterile product manufacturing operation or non-sterile operation where microbiology is controlled but who is not directly involved in microbiology or is new to this area. Includes practical demonstration of microbiological method of analyis.

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.

# Critical Factors for Sterile Product Manufacture

Click for full details

**Barnard Castle, UK**
**4 Day Training Course**

**18 - 21 June 2024**

## Who Should Attend?

This course is suitable for all levels of experience and often includes members of the following departments:

- New Graduates
- Operational / Production Supervisors & Managers
- Technical/ Process Team Members
- Engineering & Validation Team Members
- QP's and QA Professionals.

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

This face-to-face course has been designed to provide a comprehensive overview of the critical factors to consider for the preparation of aseptically filled and terminally sterilised products. The course considers the cGMP requirements defined in Annex 1 including the development of a contamination control strategy and introduces risk management tools which have been designed to control microbial contamination in the cleanroom environment, with special consideration to protection of the product. The course is presented using a blended learning approach consisting of interactive presentations, team-based workshops designed to allow our delegates to put the principles into practice as well as a physical review of a state-of-the-art sterile product manufacturing facility.

## Course Objectives & Learning Outcomes

•Understand the fundamental mechanisms of microbial contamination transfer within the facility and the control measures in place to protect the product.

•Have reviewed the development of the US and EU GMP regulations and ISO guidelines associated with cleanroom design and monitoring as well as review of current requirements.

•Understand the critical control points within a typical aseptic processing operation with focus on RABS and Isolator technology, Liquid & Air Filtration, Sterilisation & Decontamination steps.

•Understand how Cleanrooms are classified with practical examples on how to meet current ISO requirements and interpretation of the cGMP requirements as defined in Annex 1.

•Have participated in workshops to define practical Process Simulation Test for aseptically filled products.

•Understand the key differences between manufacturing operations designed for manufacture of aseptically filled and terminally sterilised products.

•Understand common cGMP deficiencies in sterile product manufacturing operations and what regulatory health inspectors are looking for.

# Aseptic Processing: Principles in Practice®

Click for full details

### 3 Days Virtual Training

### 19th - 21st March 2024
### 1st - 3rd October 2024

### 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

Click for full details

## 2 Days Virtual Training

## TBC

## Who Should Attend?

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

- QA
- QC
- Engineering, Validation
- Production, Operations

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®

Click for full details

### 3 Days Virtual Training

### 23rd - 25th April 2024
### 17th - 19th September 2024

### 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 have increased awareness of the development of the current regulatory requirements and standards for sterilisation processes and how this has shaped the way the industry approaches sterilisation.
- To be able to make risk-based decisions based on science during the qualification and routine operation of sterilisation processes.
- To be able to drive sterilisation process improvement initiatives in the workplace and improve compliance for sterilisation processes.
- Be able to implement value adding test plans for Equipment Qualification based on science, experience and compliance with GMP principles.
- To participate in the most up to date review of future international sterilisation standards and changes to the Pharmacopoeias.
- Understand the Auditing Sterilisation Processes and Preparing for a Regulatory Inspection.
- Understand the reasoning behind the use of Biological Indicators.
- Understanding of Routine Operation of Sterilisers.
- Understand the different challenges of sterilising porous, liquid and heat sensitive products.

“ This course includes a combination of Presentations, Workshops, Group Activities and Demonstrations to allow you to put the Principles into Practice®”

# Microbial Risk Management During Cleanroom Operations

Click for full details

## 2 Days Virtual Training

**13th - 14th February 2024**
**3rd - 4th December 2024**

## 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®

Click for full details

## 2 Days Virtual Training

## 2nd - 3rd May 2024

## 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.

“ EXCELLENTLY DELIVERED, STRONGLY RECOMMEND, THE TRAINING MATERIAL IS INVALUABLE ”

**Specialist QA/QP**
Amgen (Technology) Ireland

# 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

**Honeyman Training & Consultancy Limited**

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

**enquiries@honeymantraining.com**

**www.honeymantraining.com**