honeyman TRAINING

Training Prospectus

2021 Public Course Dates

Honeyman Group

honeyman GROUP
Assuring Compliance in Life Science

Operating extensively within the global pharmaceutical, biotech, medical device and related healthcare industries, the Honeyman Group has a well-earned and highly regarded reputation for technical problem solving, knowledge transfer and successful project delivery.

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

Honeyman's unique position in the market as a holistic service, product and knowledge provider, is built on decades of close alliances with clients, suppliers and industry experts.

Proud winners of

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.

honeyman VALIDATION

Validation Services: Thermal mapping, Cycle development, Control system upgrades, Service and maintenance, Environmental monitoring.

honeyman TRAINING

Training: Public Courses, Onsite Courses both generic and bespoke, e-Learning (generic or bespoke solutions), Consultation.

Honeyman Training 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.

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Virtual Training

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.

Why Honeyman?

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 demonstrations 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 training@honeymangroup.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

Call +44(0)1833 690101 and ask to speak to one of our training advisors to discuss your booking.

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 discuss the pricing options available to you. Please contact us by email or phone with the required course, dates and number of delegates and we'll be in touch with you.

CLEANROOMS PRINCIPLES IN PRACTICE®

Click for full details

VIRTUAL TRAINING

Overview

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.

Who Should Attend?

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

- Engineers
- QA Staff
- Validation and
- Operations Personnel

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

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 and high purity water SME's.

Overview

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 received 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
- Understand how to design and build water systems cost effectively
- Be able to validate and manage water systems cost effectively
- 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 systems
- 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

Pharmaceutical Water Systems PRACTICAL APPLICATIONS

Click for full details

VIRTUAL TRAINING

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*

Overview

This extremely popular 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

Click for full details

VIRTUAL TRAINING

Overview

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.

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.

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
- Appreciate the importance of microbiological data and control in pharmaceutical and medical device manufacture
- Micro requirements for sterile and non-sterile product manufacture
- Micro limit testing
- Monitoring methods: sampling methods, isolation and counting
- Interpretation of microbiological data
- Gram positive and gram negative bacteria, and gram staining
- Bacterial identification (bacteriology and mycology)
- Spores and spore forming microorganisms
- Reading micro-organisms on Agar plates
- Be able to participate in out-of-specification investigations and
- Implement control measures

CRITICAL FACTORS FOR STERILE PRODUCT MANUFACTURE

Click for full details

Overview

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.

Who Should Attend?

All staff, supervisors and managers involved in production including;

- QA, QC
- Engineering, Validation
- Regulatory Affairs

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

ASEPTIC PROCESSING PRINCIPLES IN PRACTICE®

Click for full details

VIRTUAL TRAINING

Who Should Attend?

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

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

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

Overview

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 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 introduce new thinking for validation and risk assessment of the process.
- 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

VIRTUAL TRAINING

Overview

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.

Who Should Attend?

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

- QC,
- Validation,
- Engineering,
- Production and
- QA

Course Objectives & Learning Outcomes

- Understand the key GMP requirements for cleaning validation and verification
- Understand the methods of cleaning including manual, automated or COP
- Be able to develop effective cleaning procedures
- Understand 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 to cleaning validation
- Understand the importance of maintaining the cleaning validation state: cleaning stability 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

VIRTUAL TRAINING

Who Should Attend?

The course is regularly attended by:

- Engineers, Microbiologists
- QA and QC Personnel
- Production, Operational and Technical Personnel.

Overview

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.
- To Increase process capacity
- 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
- Quality Systems Associated with Sterilisation Processes
- Understand the Auditing Sterilisation Processes and Preparing for a Regulatory Inspection
- Understand the reasoning behind the use of Biological Indicators
- Be able to develop Validation Strategies for Sterilisation Processes
- Understanding of Routine Operation of Sterilisers

MICROBIAL RISK MANAGEMENT DURING CLEANROOM OPERATIONS

Click for full details

VIRTUAL TRAINING

Overview

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.

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.

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 identified risks, or their methods of control can be monitored 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

Overview

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.

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, and
- Validation.

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

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

“What stood out was your vast experience and the practical examples that bring the training to life.”

Management and Organisation Lead, GSK

"Dynamic and interactive, relevant to our operations, made a technical subject accessible"

Product Manager, Benchmark Vaccines

Benchmark Vaccines Ltd

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

Qualified Person, PPD

"Tailored to the business, pitched at the right level. Excellent, 'spot on' content delivery."

- QA Manager, Victoria Pharmaceuticals

Belfast Health and Social Care Trust

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

“Excellent reputation, excellent service, dedicated staff.”

- GE Healthcare

GE Healthcare

Accredited Specialist

In line with the growing trend for subject matter experts, the Honeyman Group has introduced a new professional status, Accredited Specialist, which demonstrates technical expertise and competency through a formal qualification. With the increasing focus on ASTM E2500 and the regulatory pressures being placed on sites to foster and cultivate knowledge and skills, it is expected that as with the Qualified Person (QP) status this will become an industry standard qualification.

What is an Accredited Specialist (AS)?

An Accredited Specialist is an individual that has successfully completed a formally assessed and accredited training course, demonstrated a high level of knowledge and thorough understanding of a particular subject, and is competent in identifying, managing and evaluating system and process improvements.

What is driving the need for Accredited Specialists?

A number of factors including current regulatory inspection trends, new standards such as ASTM E2500 and the focus to contract work back in are all resulting in a significant need for subject specialists. These factors will all contribute to increased ownership and control, improved compliance, reduced operating costs and an improved knowledge base but require up to date knowledge and expertise in the form of technical subject specialists.

What are the benefits of becoming an Accredited Specialist?

- Become a subject specialist
- Gain an internationally recognised University Certificate in Professional Development (UCPD)
- Accrue recognised degree level credits
- Access University library, resources and Virtual Learning Environment
- Identify and develop process improvement opportunities to increase your site's efficiency
- Obtain feedback on your process improvement ideas from our expert team of Lecturers and Consultants
- Be able to formulate, implement and evaluate improvements to satisfy regulatory requirements, new product innovations and evolving business objectives

How do I become an Accredited Specialist?

The Accredited Specialist status in a subject can be obtained by successfully completing one of our Principles in Practice training courses which have been University accredited. In addition to attending the course, you will be required to complete a series of formal assessments demonstrating your knowledge and understanding.

Currently, the Accredited Specialist status is available in:

- Pharmaceutical Water Systems
- Pharmaceutical Sterilisation
- Pharmaceutical Cleanrooms
- Microbial Risk Management During Cleanroom Operations

Further courses will be added to this range in the near future, to broaden the choice of Accredited Specialist (AS) subjects on offer. Please check www.honeymantraining.com for the latest information.

What will I be required to do?

If you'd like to be assessed for accreditation, please request further information regarding pre-course preparation and reading that you'll be required to complete, and e-mail you the link to enable you to enrol as a part-time University Student

Your pre-course preparation takes approximately 5 days to complete, and will include data collection and a written review and appraisal of applicable site systems and processes (500 – 1,000 words). You will then attend your chosen course.

At the end of the course you will be required to complete a written examination. Upon return to site, you'll have 12 weeks to complete a project to demonstrate and consolidate your learning. This typically requires a minimum of 10 days input and will be formally assessed by our partner University and Course Leader

Prerequisite for the Accredited Specialist option

Delegates must have previous knowledge and experience of working with the accreditation subject prior to enrolment on the chosen course.

Please contact the Honeyman Group for further details.

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