

## 2010 Training Courses

### Honeyman Provides On-Site GMP Training for World Famous Brand

First formulated in 1865 by Pharmacist, James Lofthouse in the Lancashire fishing town of Fleetwood, Fisherman's Friends provided relief from the coughs, colds and bronchial problems suffered by the fishermen braving the Atlantic and Arctic oceans. Today, nearly 150 years on, Fisherman's Friends continue to be manufactured by Lofthouse of Fleetwood and are sold in more than 100 countries. Having engaged the Honeyman Group in the past to provide consultancy support, Lofthouse of Fleetwood appointed Honeyman to carry out the training because of the group's reputation for practical, experience based training.



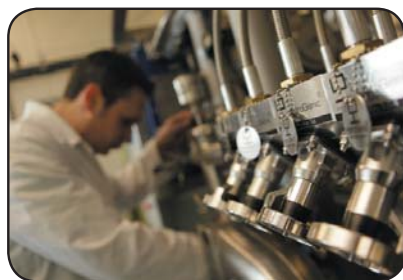
In order to tailor the presentations and course materials, Honeyman conducted a site visit to obtain data and photographs of the solid dose manufacturing facility, equipment and processes and devised workshops that would focus on the GMP issues relating to Lofthouse of Fleetwood. Five one day courses were delivered to delegates from a variety of functions including Production, QA, Engineering and Management, which examined:

- Why GMP exists, what it achieves and how it is managed
- The impact of GMP upon the organisation
- The importance of maintaining and using systems e.g. change control
- The need for qualification and validation
- GMP - the 5 P's
- Communication to staff and an overview of quality risk management



Beverley Cliff of Lofthouse of Fleetwood said; "Honeyman devised an engaging and relevant, value for money course that was applicable to everyone involved regardless of their function. Those who attended the course enjoyed the lecturer's anecdotal experience and knowledge and found the tailored guidance useful. Lofthouse of Fleetwood would thoroughly recommend the Honeyman Group and will look to working with them again as and when future training requirements arise."

### World's First HydroGienic® System Installed at Dales Pharmaceuticals



HydroGienic® the world's first parallel distribution system for pure water has been installed at UK contract manufacturing and packaging company, Dales Pharmaceuticals.

Set to revolutionise the industry, HydroGienic® distributes pure water around a manufacturing facility via a parallel delivery system rather than connecting user points in a conventional re-circulating loop. Featuring small bore PTFE hoses and a unique reverse flow principle for hydraulic balancing HydroGienic® overcomes all of the problems associated with stainless steel welded loops and enables the system user to:

- Use each user point simultaneously without any compromise to flow rates
- Easily expand or modify the system with minimal impact on production and downtime
- Isolate individual user points for sanitisation and maintenance quickly, effortlessly and without impact on any other user point
- Eliminate 'hot working' in production areas during the installation and thus avoiding disruption to the facility

Said Mike Annice, Managing Director of Dales Pharmaceuticals "The nature of our contract manufacturing business is such that we need to be able to alter production schedules quickly and efficiently to meet changing client requirements, fundamental to this are facilities that can be easily adapted and with its ease of modification HydroGienic® allows us to do exactly that".



# 2010 HOTEL BASED COURSES

[P] Denotes a course with practical sessions in the Honeyman MHRA approved laboratories

## Critical Factors for Sterile Product Manufacture

April 20th to 23rd 2010 (Barnard Castle, U.K.) November 2nd to 5th 2010 (Cork, Ireland)

Course Fee: £2150/€3010

The manufacture of sterile products is subject to special controls and relies heavily on the competency and knowledge of everyone involved in the process. This course covers all key aspects of sterile product manufacture, for both aseptically prepared and terminally sterilised products. Whether involved in production, QA, QC, Engineering or Regulatory Affairs, this course will be relevant to you.



Course Content Includes:

- International Guidelines Related to Steriles Manufacturing
- An Introduction to Microbiology
- Media Simulations (e.g. of filling processes and other aseptic handlings)
- Hygiene Zone Concept
- Design Criteria for Clean Rooms
- Environmental Monitoring
- Cleaning and Disinfection
- Consideration for Microbial Testing (e.g. Bioburden, LAL and sterility)
- Qualification of Clean Room Personnel
- Rules for Working in Clean Rooms
- Sterile Product Release - Batch Documentation
- Auditing a Sterile Manufacturer or Microbial Laboratory
- Regulatory Framework and Guidance for System Design and Technology
- Process Simulation: Technical Considerations
- Introduction to Quality Critical Utilities
- Quality and Control Requirements
- Compressed Air and Process Gases
- Water Types and their Application in Manufacturing
- Steam Quality and Use
- Technology of the Manufacturing Environment
- HVAC Design, Control and Monitoring
- Sterilisation Methods and Controls

**"A well presented course with experienced subject matter experts."**

*Plant Engineering Manager, GlaxoSmithKline, Ulverston, UK*

## Sterilisation: Principles in Practice

February 9th to 11th 2010 (Cork, Ireland) September 7th to 9th 2010 (York, U.K.)

Course Fee: £1575/€2205

Providing both a theoretical foundation and a practical application of sterilisation equipment, this course gives detailed guidance on current requirements for qualifying steriliser equipment and validating sterilisation processes. The GMP expectations for the routine operation, monitoring and control of sterilisation processes will also be discussed together with practical examples of how these techniques are applied through appropriate engineering to ensure reliability in full compliance with all European and US regulatory requirements. Finally the ongoing operational, maintenance, thermal and biological validation requirements will be examined in detail.



Course Content Includes:

- Introduction to Sterilisation
- Principles of Moist Heat Sterilisation
- Steam Quality
- Dry Heat Sterilisation and Depyrogenation
- Instrumentation and Control of Sterilisation Processes
- Quality Systems Associated with Sterilisation Processes
- Auditing Sterilisation Processes and Preparing for a Regulatory Inspection
- Biological Indicators
- Validation Strategies for Sterilisation Processes
- Routine Operation of Sterilisers

**"The lecturer's knowledge of the topics discussed was boundless, his expertise is unrivalled."**

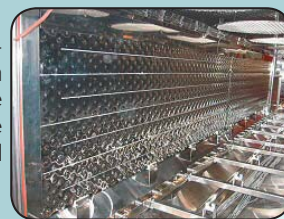
*RBC Serum Processing Technician, Immucor Inc, Atlanta, USA*

# Advanced Sterilisation Validation and the Application of Biological Indicators

June 9th to 11th 2010 (Cork, Ireland) December 15th to 17th 2010 (York, U.K.)

Course Fee: £1295/€1815

The validation of sterilisation processes is becoming an increasingly expensive and time-consuming exercise. Developing the correct strategy for validation and planning the approach up front will significantly reduce problems and expense in the execution stage. Building upon the Sterilisation: Principles in Practice course, this two and a half day course delivers a comprehensive review of the performance qualification (PQ) of sterilisation processes, including both thermal and biological validation.



Course Content Includes:

- Validation Strategies and Protocol Preparation
- Planning the Validation Workload for Efficient Delivery
- Data Logging and Thermal Measurement Calibration and Validation Requirements: Validating the Validator
- Biological Indicator (BI) Application Examples
- BI Population and D Value Verification Requirements
- BI's for Porous Loads, Fluids Loads and Stopper Cycles
- Understanding the Product Effect on the D Value of Biological Indicators
- Top 10 Issues with Sterilisation Validation
- Strategies for Reporting and Handling Deviations

**"Exceedingly useful! I thought I knew quite a lot about validation before the course but I am definitely taking lots of new information back to site with me - thanks!"**

*Lab Technician - BD, Plymouth, UK*

## Good Engineering Practice

May 19th & 20th 2010 (Barnard Castle, U.K.) November 24th & 25th 2010 (Barnard Castle, U.K.)

Course Fee: £1175/€1645

The purpose of this course is to highlight how current GMP's are applied to pharmaceutical engineering and technical services to ensure facilities, equipment and processes are maintained to the highest possible standards expected by the Regulatory Authorities. This course is suitable for both introductory training and as a refresher course for engineers already working in the pharmaceutical and related healthcare environments.



Course Content Includes:

- The Role of Engineering and the Engineer in the Pharmaceutical Industry
- Current International GMP Regulations and Regulatory Requirements
- Good Manufacturing Practices
- The Manufacturing Environment
- Services and Utilities
- Auditing and Self Inspection
- Instrumentation and Controls
- Cleaning and Cross Contamination
- Review of Current Regulatory Concerns

**"This was a fantastic course that provided a good grounding in the topics. It was delivered by people who are clearly passionate about the subject and have a wealth of experience."**

*Senior Project Manager, Boots UK Ltd, Nottingham, UK*

## Pharmaceutical Water Systems: Principles in Practice

March 9th to 11th 2010 (Barnard Castle, U.K.) October 5th to 7th 2010 (York, U.K.)

Course Fee: £1575/€2205

Water systems are always a major area of interest during regulatory inspections and continue to represent a significant cause of many non-compliance issues. This course presents an independent view of the design, qualification, validation, operation, management and maintenance of high purity pharmaceutical water systems and provides an interactive mix of lectures and workshops.



Course Content Includes:

- Pharmacopoeial Water Qualities (USP, Pharm. Eur) and their Applications
- Basic Microbiological Aspects of High Purity Water Systems
- Pre-treatment and Purification Methods for High Purity Water
- Sanitisation of Pharmaceutical Water Systems
- Approaches to Water System Validation
- Maintenance of Water Systems
- Quality Systems Associated with High Purity Pharmaceutical Water Systems
- Routine QC of High Purity Water Installations
- Biofilms - Properties and Significance
- Rouge in High Purity Water Systems
- Future Concepts - HydroGienic® a New Solution for Cost Effective Water Distribution Systems
- GMP Aspects of Sanitary Equipment, e.g. Piping and Valves
- Instrumentation and Controls

**"An excellent course which was well presented. The interaction and examples given by other delegates attending the course was also excellent."**

*Production Manager, Cardiff & Vale NHS Trust, Cardiff, UK*

## Current Requirements for Cleaning Validation and Disinfectant Efficacy [P]

June 29th & 30th 2010 (Barnard Castle, U.K.)

Course Fee: £1175/€1645

This course covers topics such as the development of regulatory expectations, effective cleaning procedures and disinfectant regimes, development of effective cleaning and disinfectant agents, and the validation and control of these procedures. For those new to this area, this course provides a detailed and structured introduction to cleaning validation and disinfectant efficacy testing. Whilst for those who have been working in these areas for some time, this up to the minute course will provide details of current best practice, cGMP expectations, industry trends and regulatory issues for both the EU and US markets.



Course Content Includes:

- Methods of Cleaning: Manual, Automated or COP
- Disinfection Efficacy: Disinfectants and the Selection Approach
- Cleaning Procedures: Cleaning Validation Master Plans, Establishing Methods of Cleaning, Protocol Development, Development of Cleaning Acceptance Criteria, Cleaning Reports
- Analytical Cleaning Methods and Sampling Techniques
- Maintaining the Cleaning Validation State: Cleaning Stability Studies and Change Control

**"A very enjoyable and valuable course which I would definitely recommend. As someone who is new to the field of validation I found it to be very informative."**  
*Chromatography/Validation Technician, Protherics UK Ltd, Ceredigion, UK*

## Environmental Monitoring [P]

January 28th 2010 (Barnard Castle, U.K.)

Course Fee: £499/€700

This course is ideal for anyone wishing to gain or increase their knowledge of environmental monitoring within the pharmaceutical industry. This one day course focuses on the technical aspects of the subject including; viable and non-viable monitoring, sampling methods and techniques, selection of monitoring locations and frequencies and the interpretation of results and includes practical workshops held in our MHRA approved contract testing laboratories.



Course Content Includes:

- Regulatory Requirements and Recommendations
- Selecting Representative Sites
- Viable (Microbiological) and Non-Viable Monitoring
- Methods and Techniques
- Selection of Monitoring Locations and Frequencies
- Interpretation of Results
- Trend Analysis and Review of Data
- Defining 'Action' and 'Alert' Levels
- Handling Out of Specification Results: Investigation of Processes, Analyses and Controls
- Documentation
- Personnel Training
- Latest Industry Trends
- Good Manufacturing Practice (GMP) Compliance

**"Excellent, interactive and extremely useful - thank you!"**  
*Quality Director, Pharmapak (UK) Ltd, Wirral, UK*

## On-Site Courses

These courses and those on the planner overleaf can also be delivered on your site with tailored content illustrating your products, your processes and your procedures for an even more interactive and pertinent training programme that will engage team members of all levels and disciplines.

Why On-Site Training?

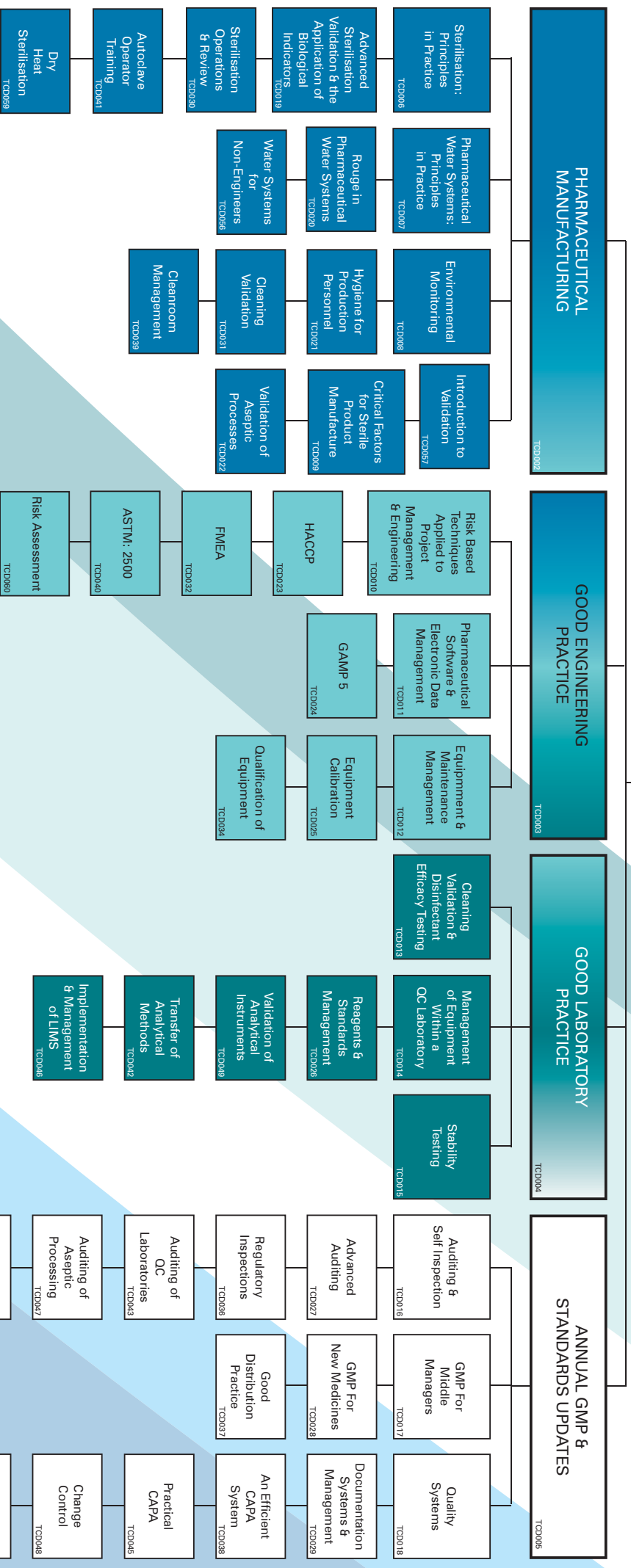
- Training is based upon current project experience rather than outdated theory.
- Content considers current technology, cost challenges and regulatory expectations – today's technology, today's industry pressures.
- Focused training, not a seminar – professional trainers not a collection of speakers.
- Reduce costs and ensure key team members are on site for longer – cut accommodation and travel expenses.
- Certification is for knowledge gained – not just attendance.



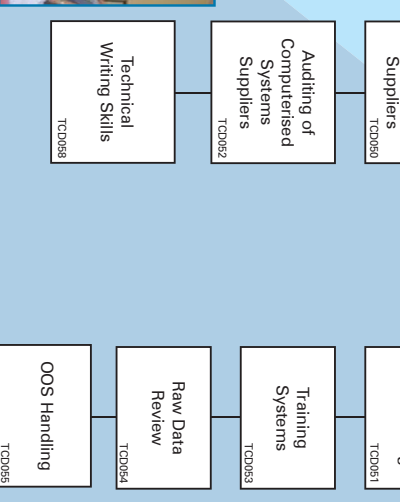
**TO RESERVE YOUR PLACE ONLINE OR FOR FULL COURSE DETAILS VISIT [WWW.HONEYMAN.CO.UK](http://WWW.HONEYMAN.CO.UK)**

# A COURSE FOR EVERY STAGE OF YOUR PROFESSIONAL DEVELOPMENT PLAN

## INTRODUCTION TO CGMP



FOR MORE INFORMATION  
ON ANY OF OUR COURSES:  
PHONE: +44 (0)1833 690101  
EMAIL: [enquiries@honeyman.co.uk](mailto:enquiries@honeyman.co.uk)  
VISIT: [www.honeyman.co.uk](http://www.honeyman.co.uk)



## Course Fees and Reservation Form

### Fees

Course fees are listed below, all of which exclude VAT at the standard rate, where applicable.

Course/Seminar	Course Fee (£)	Course Fee (€)
Critical Factors for Sterile Product Manufacture	£2150	€3010
Sterilisation: Principles in Practice	£1575	€2205
Advanced Sterilisation Validation and the Application of Biological Indicators	£1295	€1815
Good Engineering Practice	£1175	€1645
Pharmaceutical Water Systems: Principles in Practice	£1575	€2205
Current Requirements for Cleaning Validation and Disinfectant Efficacy Testing	£1175	€1645
Environmental Monitoring	£499	€700

The course fee includes tuition, comprehensive course notes, refreshments and lunch. Reservations not confirmed by payment by the course start date will be allocated to any persons on a waiting list. Payments should be made by cheque to Honeyman Group Ltd or by credit / debit card via our website. We don't enforce a dress code on our courses, however we do recommend that delegates dress smart/casual and comfortable.

To reserve your place, please complete the registration form below and forward to Honeyman Group Ltd by either by post, fax or email (details below). Upon receipt, Honeyman will forward written confirmation and an invoice for immediate payment.

### Course Reservation Form

Course Title/Date/Venue: .....

Reservation Made By: .....

Delegate Name (M/F): .....

Position/Department: .....

E-mail Address: .....

Company Name: .....

Company Address inc. Post Code: .....

Telephone: .....

Fax: .....

Purchase Order Reference: .....

Invoice Address: .....

Special Requirements: .....

### Discounts & Cancellations

Book early and receive a 10% discount if payment is received 6 weeks prior to the course start date. Further discounts are also available for multiple bookings and for government and regulatory agency employees - please contact us for details. Written cancellations (received and confirmed by Honeyman Group Ltd) will be accepted up to 31 working days before the start date of the course, after which a cancellation fee will be payable. Unfortunately, no refund can be made for cancellations within 10 working days of the course start date and the full course fee will be due for delegates who fail to attend. Substitutions may be made at any time up to the start of the course, free of charge. We reserve the right to charge an administration fee to those delegates who fail to attend a course but wish to have their place transferred to the next available course. We reserve the right to change the programme, speakers, date or venue without notice, or to cancel an event. If cancellation occurs delegates will be notified as soon as possible and will receive a full refund of fees paid. Honeyman Group Ltd will not be responsible for transportation, accommodation or other costs incurred due to cancellation.