PHSS & USW
Quality Assurance

GMP & GDP
Principles

Venue
University of South Wales
Nr Cardiff

Date
16th - 18th September
3 Day Residential Course

Book this course online at phss.co.uk
This three day residential course, delivered by academics and pharma industry experts (QP/QA), will provide learners with an up to date and clear understanding of the underpinning principles, practice and philosophy of Quality Assurance (QA), GMP and GDP through a range of organisational and practical considerations over the product life cycle which has the potential to impact on companies’ manufacturing processes.

Content Summary
The module will examine the underlying principles of Quality Assurance as a key element of quality management systems which underpin the pharmaceutical, manufacturing and distribution industries. Indicative content covered in this module includes:

- Industry overview and product lifecycle
- Introduction to QMS/QA
- The Laboratory – (Basic skills required GLP vs. GMP)
- Introduction to GMP – understanding manufacturing systems, packaging, IPC’s, labelling, line clearance and changeover.
- Introduction to GDP – warehouse management, distribution and delivery, stock control, supply chain management
- Effective communication
- Customer Complaints

This module is delivered and accredited by the University of South Wales (10 HE credits) assessed on-line two weeks after completion of the course.

Delivery
The course is delivered by academics and industry expert QPs through the University of South Wales Faculty of Computing Engineering and Science at the Glyntaff Campus, Trefforest outside Cardiff. In 2010 the School of Applied Sciences received a £15million investment to provide new teaching and research facilities, high tech science laboratories, a state of the art Clinical Simulation Centre for nursing and social study and exciting new work based learning courses. The Pharmaceutical Suite of modules has been developed by USW and UHOVI in collaboration with the pharmaceutical sector and is accredited by USW on successful completion of assessments.
Course Details

- History of the pharmaceutical industry
- Breadth of the industry by identifying the therapeutic categories, modes of administration and types of product produced in the industry
- Overview of the regulatory framework the industry operates in and understanding of the terms used
- Stages of pharmaceutical development and life-cycle
- Overview of the elements of technology transfer
- Commercial manufacturing and product discontinuation
- Quality System terminology
- The relationship between the quality management system and quality assurance
- Introduction: Good Manufacturing Practice (GMP) ICH Q10 PQS
- Good Clinical Practice (GCP) Good Laboratory Practice (GLP)
- Good Distribution Practice (GDP)
- Corrective and Preventive action in continual improvement
- Role and function of policy within a management system
- The importance of clear responsibility
- Identify processes, sub-processes, and process interactions
- Effective communication
- GMP
- Understanding ‘Good’ Practice and GMP through case studies
- The Devonport Incident and the Clothier Report
- The scope of Good Manufacturing Practice (GMP) and the activities covered by it
- The key components and main elements of GMP
- Applying GMP and GMP Requirements
- GMP Quality Control
- The principles of stability testing
- The need for validation of analytical procedures
- The sources and categorisation of impurities in drugs
- The purpose and function of pharmacopoeias
- GDP in relation to medicinal products for human use
- How handling, storage etc can affect quality
- General arrangements for traceability under GDP requirements
- The concept of FIFO and FEFO in stock management
- The nature and source of complaints and importance within a QMS
- To understand the role of the DMRC
- Process and importance of Product Recall
- The communication and notification system related to complaints and recalls
Course Feedback Quotes from last year

“Aiding understanding of the pharmaceutical industries legislates, and how this filters down to staff through MA and SOPs.”

“This course has established a greater awareness and understanding of the role of the GMP and GDP which is essential for my role as a QA manager.”

“The course has helped me to think of all the departments working together and how it makes successful manufacture and quality of the production.”

“Invaluable background overview of the Pharma industry – sets me up for future and more in depth training.”

“QP interaction - Profession aspect as opposed to pure academia. Good to hear their experiences and knowledge. The exercise challenged and stretched to gain understanding of subject. Was also a chance to interact with other students and learn from their areas of expertise.”

Accommodation
If you would like help with accommodation, please contact PHSS office.

Cancellation and Refunds
Confirmed registrations cancelled 20 working days in advance of the course date will receive a full refund, 15 days, 50% refund and cancellation within 10 working days or less of the course date will be subject to the full attendance fee. Substitution may be made at any time.

Registration Fee
Member: £850.00 + 20% VAT = £1020.00
Non-Member: £975.00 + 20% VAT = £1170.00

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