Pharmaceutical Auditing

Across the many diverse business functions within the pharmaceutical industry, the requirement to perform audits of key service and material suppliers has become a significant driver for regulatory compliance and corporate governance. A successful audit relies on both the technical ability and the soft skills of the auditor(s).

about the course

This 6 day course covers many of the technical and nontechnical aspects of pharmaceutical auditing and incorporates the skills needed for audits of GMP, GCP, GVP, GDP and API. The final two days give attendees a chance to experience practical elements of on-site auditing. The course is divided into one block of 4 days of lectures and 2 days of practical auditing experience. Delegates can choose to attend all six days or just particular days that are specific to their requirements. However to attend the site visits on the final two days, it is necessary that delegates first complete days 1-4.

who should attend

Company personnel associated with internal and/or external audits. The programme is designed to be practical, covering the core material described below, but with the depth of detail being adjusted to in accordance with the experience and needs of the delegates.

about the compliance group

The Compliance Group is a specialised consultancy group consisting of ex-regulators. Consultancy Services are provided to Regulatory Agencies, NGOs, State Bodies and companies.

what else should i know

Course Fee: €3000 for 6 days or €650 for individual days from days 1 to 4. (Note: to participate in the site audits on days 5 & 6 it is necessary to complete days 1-4)

how to apply

Applications can be made online at
www.compliancegroup.eu

location and date

For dates see **www.compliancegroup.eu**

course content

day one Behavioural Training	day two General Pharmaceutical Quality Aspects including GDP	day three APIs, Non-sterile pharmaceuticals, Quality Control and specialised items
Basic Auditor Skills Intermediate Skills Guidelines for efficient Audits Conflict Resolution Regulatory Affairs – Marketing Authorisation obligations Self Inspection	Temperature mapping, monitoring, and cold chain, Pest control and General GDP Deficiencies Training, Documentation QP release concept Contract Manufacture and Analysis Recalls, Anti-counterfeit measures, Computerised Systems Data Integrity Detection	Active Pharmaceutical Ingredients Solid and semi-solid dosage forms Qualification - IQ, OQ, PQ , Computerised Systems Quality Control, Analytical validation, Chromatography Risk Management Process Validation Cleaning Validation Technical transfer

about the presenters

Stan O'Neill is the Managing Director of The Compliance Group, having previously worked as a Qualified Person, and then as a Senior Inspector with the Irish Medicines Board, (IMB) now the Health Products Regulatory Agency (HPRA).

Dairine Dempsey is the Owner of Dairine Dempsey Consulting, having previously worked as a Senior Regulator in the area of pharmacovigilance, herbal medicines and pharmaceutical assessment with the Irish Medicines Board, (IMB) now the Health Products Regulatory Agency (HPRA).

Paula Dillon An ex-Inspector with the Irish Medicines Board, (IMB) now the Health Products Regulatory Agency (HPRA) and over 9 years of experience in the regulation of controlled drugs and GDP, Paula has represented Ireland at European and International level, including as a member of the GDP Drafting Group which was responsible for establishing the new GDP Guidelines.

Ita Walsh is a Senior Regulatory Consultant with The Compliance Group, having previously worked in Regulatory Affairs, Technical Services and Quality Assurance as a Qualified Person and as a Pharmaceutical Assessor with the HPRA.

Richard Bierney is a Senior Regulatory Consultant with The Compliance Group, having previously worked in senior management levels in the pharmaceutical industry (Manufacturing Director, Quality Control, Site Head etc) and as a GMP Inspector and Pharmaceutical Assessor with the Irish Medicines Board, (IMB) now the Health Products Regulatory Agency (HPRA).

Kevin Sweeney is a Senior Regulatory Consultant with The Compliance Group, having previously served in the Irish Army and as a Detective and Sergeant in An Garda Síochána. Kevin holds a PhD in Interview Techniques and specialises in fraud detection.

course accreditation:

School of Pharmacy
University College Cork

The course has also been accredited by the School of Pharmacy UCC. Candidates undertaking this 5-credit accredited module, will be registered for the module online with UCC Adult Continuing Education (ACE).

Candidates will then be able to access all lecture notes and course material provided on the course online via UCC website. In addition, candidates will have access to UCC library resources.

To pass the module, candidates must complete an MCQ exam and submit a 1,500 word essay on Pharmaceutical auditing (based on experience during the Mock GMP audits).

The course fee includes the UCC ACE registration fee.

course content

day four Sterile pharmaceuticals and Biotechnology	day five GMP Audit of a Biologics Facility, Covering	day six GMP Audit Covering
Microbiological principles Methods of sterilisation Aseptic processing Media fills, HVACs, environmental monitoring. Autoclaves Fo, Steam in place Parametric release, Upstream and downstream processing Audit preparation.	Dispensing Inoculation Fermentation Downstream Processing Quality Control Laboratory Clean Utilities (Air handling/WFI)	Warehousing Primary Packaging of solid dose products Validation documentation QMS fundamentals