

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: €3250 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) . This course includes all course material, lunches and refreshments.

how to apply

Applications can be made online at <https://gxp.ie/training/pharmaceutical-auditing>

location and date

For classroom based training, the School of Pharmacy, UCC, for lectures. The audits will be Dublin based site visits. For dates see <https://gxp.ie/training>

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.

Denise Coakley is a Senior Regulatory Consultant with The Compliance Group, having previously worked in the Irish Medicines Board (IMB), now the Health Products Regulatory Agency (HPRA) as a GMP Inspector. She has worked in the pharmaceutical and biopharmaceutical industry, including, laboratories, quality, validation, clinical, project management and QP.

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.

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).

course accreditation:



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 online assessment, based on experience during the course.

The course fee includes the UCC ACE registration fee.

course content

| day one | day two | day three |
|--|---|---|
| Behavioural Training | General Pharmaceutical Quality Aspects including GDP | 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 |

course content

| day four |
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| Sterile pharmaceuticals and Biotechnology |
| 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. |

| day five | day six |
|--|---|
| GMP Audit of a Biologics Facility, Covering | GMP Audit Covering |
| Dispensing Inoculation Fermentation Downstream Processing Quality Control Laboratory Clean Utilities (Air handling/WFI) | Warehousing Primary Packaging of solid dose products Validation documentation QMS fundamentals |