

Bio
Pharma
Chem

Skillnet,

Data Integrity Training



Delivered by:



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Data Integrity Training

This course has been developed based upon current technologies and industry trends. The presenters are actively involved in projects around the world dealing with today's technology and current regulatory expectations.

Course duration is 1 day.

Who should attend?

The course is suitable for people with no prior experience in Data Integrity and provides a broad introduction to Data Integrity including Data Integrity Auditing.

The Programme

- Background and introduction to Data Integrity
- Industry Regulations and Guidance
- Data integrity in both paper-based and computer-based systems
- Introduction to the Data Life cycle - Collection/Processing/Review/Reporting /Archiving;
- Risk identification - what to look for, when, where, why and how;
- Audit challenge and threat management;
- Active listening skills and technical communications;

About the presenter

Stan O'Neill, The Compliance Group

After qualifying as a Pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (QP) and then joined the Irish Medicines Board (now the HPRA) for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, represented Ireland at European level for the negotiation of standards of inspection for medicinal products (including Annex 1) and trained Inspectors at Irish, European and International levels.

This training is delivered on behalf of BioPharmaChem Skillnet by GxP Training.

For further information please contact training@bpcskillnet.ie or phone 087 997 0848

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