Bio Pharma Chem Skillnet

GXP:
Fundamentals for working in a Regulatory Environment

Level 6 Minor Awa
5 ECTS Points
Accredited by UCC
School of Pharmac

Delivered by:

the compliance group

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bpcskillnet.ie

The fundamentals for working in a Regulatory Environment

This programme was developed in conjunction with The Compliance Group in response to a need in the sector to provide an orientation to the pharmaceutical industry for new employees and those returning to work.

The course is designed in two phases; first giving an overview of non-GMP aspects of the life cycle of a pharmaceutical product, and the second phase focusing on GMP aspects.

Who should attend?

The course is suitable for anyone looking to up-skill in the sector, those recently recruited into or promoted within the industry, recent graduates or people returning to the sector from a career break.

Week 1 – Regulatory Affairs

Day 1

Regulatory Introduction

- **Ireland and the EU – Regulatory Structure**
- **Irish and EU Medicines Legislation**
- **Irish and EU Guidance**
- **Medicinal Products Regulation – Definitions and Terminology**
- **Regulatory documentation - Dos and Don'ts**

Getting Started - Clinical Trials

- **Clinical Trials and GCP**
- **Getting your Clinical Trial Approved - Introduction**
- **Clinical Trial Pharmacovigilance**

Day 2

Getting Licensed and Staying Licensed

- **The Common Technical Document**
- **Making a Medicinal Product Application - Application Types and Regulatory Procedures**
- **Renewals**
- **Variations**

Post-Marketing Pharmacovigilance

- **Introduction to Post-marketing Pharmacovigilance**
- **PV Systems, Audits and Inspections**
- **PV Regulatory Requirements**

Week 2 – Good Manufacturing Practice

Day 3

Good Distribution Practice

Ireland and the EU – Regulatory Structure

Practical aspects of GDP

Roles and responsibilities of the Responsible Person

Good Manufacturing Practice

Introduction

- Global Environment – EU, FDA, WHO, PIC/S, GMPs
- GMP Structure, including role of APIs
- Legislative background in Ireland
- Process of GMPs

Quality Management

- Chapter requirements
- ICH processes

Personnel

- Chapter requirements
- Specific requirements

Premises & Equipment

- Chapter requirements
- Qualification of equipment
- Dedicated facilities

Day 4

Good Manufacturing Practice

Documentation

- Chapter requirements
- Specific requirements

Production

- Chapter requirements
- Validation

Quality Control

- Chapter requirements
- Specific requirements

Contrast Manufacture and Analysis

- Chapter requirements
- Technical agreements

Complaints and Product Recall

- Chapter requirements
- Recall guidance

Self Inspection

- Chapter requirements

Day 5

Special GMP Topics

Common GMP deficiencies

Cleaning Validation

Annex 1 – Manufacture of sterile products

Autoclave validation

Regulatory Inspections

The Inspection process

Guidelines for efficient inspections

- For enquiries, please contact training@bpcskillnet.ie or telephone: 087 9970848
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Skillnet IRELAND