

Introduction to Clinical Trials for the Pharmaceutical Sector

This introductory programme will provide learners with a comprehensive overview of the phases of clinical trials, and the quality, regulatory and organisational aspects of clinical trials for the pharmaceutical sector.

Aims and Objectives

The aim of this programme is to introduce learners to the broad field of clinical research and provide an understanding of the importance of clinical trials for the pharmaceutical industry. Learners will gain knowledge of the drug development life cycle, phases of clinical trials, good clinical practice and pharmacovigilance. Participants will also be advised of the current regulatory requirements when conducting clinical research.

Learning Outcomes

On completion of this programme the learner should be able to:

- Appreciate the importance of clinical research and understand the key concepts of clinical trials
- Outline the development lifecycle for a typical drug in the pharmaceutical industry

PROGRAMME DELIVERY

1 day online delivery.

PROGRAMME CERTIFICATION

Innopharma Education Certificate of Completion & AMTCE Digital Badge.

WHO IS THIS PROGRAMME FOR?

This programme is aimed at employees in the pharmaceutical sector wishing to up skill in the area of clinical trials.

ENTRY REQUIREMENT

To be eligible for this programme you must be in current employment.

CHANGE DIRECTION, ADVANCE YOUR CAREER

- Identify the four phases of clinical trials and understand the regulations governing the conduct of clinical trials, within the EU and the US
- Understand and appreciate the importance of Good Clinical Practice (GCP), ethics and pharmacovigilance

Course Content

- Introduction to clinical research
- Drug development life cycle
- Phases of clinical trials
- Pharmacovigilance
- Good clinical practice guidelines (GCP)
- Governing regulations related to clinical trials

Other courses options include

- Introduction to Technical Writing for the Manufacturing Sector
- Advanced Technical Writing for the Manufacturing Sector
- Introduction to cGMP for the Bio-Pharmaceutical Industry
- Introduction to Validation for the Pharmaceutical Sector
- Introduction to Quality Control for Bio-Pharmaceutical Manufacturing
- Certificate in Supply Chain (Special Purpose Award/QQI Level 6 20 credits)
- Certificate in Operational Excellence (Special Purpose Award/QQI Level 6 25 credits)

A PROFILE OF IRELAND'S ADVANCED MANUFACTURING SECTOR

85+

bio-pharmaceutical companies located in Ireland

12

of the top selling medicines are manufactured in Ireland

Bio-pharmaceuticals account for

67%

of the total goods exported from Ireland

The bio-pharmaceutical and chemical sector had an export value of

€106Bn

in 2020

80,000

employed directly and indirectly by the bio-pharmaceutical sector

For more information on this course contact Pauline Flusk (Programme Lead) on: T: +353 (0) 1 264 5570
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