Innopharma education

Introduction to cGMP for the Bio-Pharmaceutical Industry

Current Good Manufacturing Practice, also known as cGMP, is a set of regulations that ensure the quality of biotechnology products, pharmaceutical products, medical devices, food and beverage, and dietary supplements.

The programme will provide learners with essential knowledge of the key concepts of cGMP within a bio-pharmaceutical context. Key topics include the regulatory requirements, the importance of cGMP and quality management across different business functions.

Aims and Objectives

This programme aims to provide learners with the core knowledge of cGMP in a bio-pharmaceutical manufacturing environment.

On completion of the programme learners will be able to demonstrate knowledge of quality management systems, industry regulatory requirements, validation, documentation, contamination control and manufacturing technologies.

Learning Outcomes

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

- Understand the terminology associated with cGMP and the regulatory requirements for working in this environment
- Identify the essential knowledge related to relevant legal, quality and regulatory frameworks governing the manufacture of bio-pharmaceutical products

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 working in a manufacturing setting, or those wishing to upskill and gain essential knowledge of cGMP in a bio-pharmaceutical context.

ENTRY REQUIREMENT

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

AMTCE Ionad Oiliúna Barr Feabhais Ard-Déantúsaíochta Advanced Manufacturing Training Centre of Excellence

SOLAS learning works

Imetb Bord Oideachais agus Oiliúna Lú agus na Mí Louth and Meath Education and Training Board

Rialtas na hÉireann Government of Ireland

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CHANGE DIRECTION, ADVANCE YOUR CAREER

- Describe the elements of quality management systems in the context of bio-pharmaceutical manufacturing
- Describe the basic principles associated with validation
- Understand the technologies associated with the production of bio-pharmaceutical products
- Describe the sources of contamination and the risks associated with product contamination

Course Content

- What is a bio-pharmaceutical product
- Origin and history of cGMP regulations
- Quality Management System (QMS)
- GDP - Good Documentation Practices
- Introduction to validation
- Product contamination and the associated risks
- GLP - Good Laboratory Practices
- Micro-organisms and bio-pharmaceuticals
- Cleanroom etiquette and contamination control
- Summary of cGMP rules

Other courses options include

- Introduction to Technical Writing for the Manufacturing Sector
- Advanced Technical Writing for the Manufacturing Sector
- Introduction to Clinical Trials for the Pharmaceutical Sector
- 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
e-mail: fluskp@innopharmalabs.com Visit our website on www.innopharmaeducation.com

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For more information on this course, and funding available contact us at:
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