Innopharma education

Introduction to Quality Control for Bio-Pharmaceutical Manufacturing

Bio-pharmaceuticals are complex products and to ensure batch-to-batch consistency and product quality, analytical testing is required in advance of releasing the product to market. These tests ensure the products identity, integrity, purity and activity.

This programme provides participants with an overview of the Quality Control function (QC), the test methods and the regulatory requirements in relation to QC in a bio-pharmaceutical manufacturing environment.

Aims and Objectives

The aim of this course is to provide learners with an essential understanding of the function of quality control within bio-pharmaceutical manufacturing, and how this relates to the manufacture of bio-pharmaceutical products.

On completion of the programme learners will be able to demonstrate knowledge of quality control regulatory requirements, cGMP, QC test methods, laboratory information systems and typical QC standard operating procedure documentation.

Learning Outcomes

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

- Identify the regulatory bodies which oversee bio-pharmaceutical manufacturing
- Describe the relationship between Quality Control (QC) and Quality Assurance (QA)

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 education in a bio-pharmaceutical environment.

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 Mí Louth and Meath Education and Training Board

Rialtas na hÉireann Government of Ireland

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CHANGE DIRECTION, ADVANCE YOUR CAREER

- Demonstrate an understanding of an organisation's regulatory requirements related to QC
- Identify the key components of SOPs in relation to QC documentation
- Describe the principles of validation
- Demonstrate an understanding of the principles of QC test method and understand the importance of the QC chain of custody
- Describe the standard QC test methods
- Understand the concepts of accuracy, precision and reliability in QC testing

Course Content

- Introduction to QA and QC in an bio-pharmaceutical context
- QC and validation
- QC Chain of Custody
- QC test methods and procedures
- Accuracy, precision and reliability
- cGMP compliance for healthcare products and bio-pharmaceuticals

Other courses options include

On completion of this programme learners will be able to:

- 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 cGMP for the Bio-Pharmaceutical Manufacturing
- Introduction to Validation for the Bio-Pharmaceutical Sector
- 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:
T: +353 (0)42 941 9040 Email: amtceskillstoadvance@lmetb.ie