

INTRODUCTION TO cGMP FOR THE (BIO)PHARMACEUTICAL INDUSTRY

This programme aims to provide learners with the core knowledge required to work in a cGMP (Good Manufacturing Practice) (bio)pharmaceutical manufacturing environment.

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

Programme Learning Outcomes

- Understand the terminology associated with cGMP and the regulatory requirements when working in this environment
- Identify the essential facts related to relevant legal, quality and regulatory frameworks governing the manufacture of (bio)pharmaceutical products
- Describe the elements of quality management systems in the context of (bio)pharmaceutical manufacturing
- Describe the basic principles associated with validation within a (bio)pharmaceutical context
- Understand the technologies associated with the production of (bio)pharmaceutical and chemical synthesis products
- Describe the sources of contamination and the risks associated with product contamination

Indicative Programme Content

- What is a bio(pharmaceutical) product
- Origin and history of cGMP
- Quality Management System (QMS)
- GDP - Good Documentation Practices
- Validation
- Product contamination
- GLP - Good Laboratory Practices
- Micro-organisms
- Personnel hygiene & cleanliness
- Summary of cGMP rules

PROGRAMME DURATION

1 day blended learning delivery.

LEARNER CERTIFICATION

Innopharma Education Certificate of Completion (Digital badge).

For more information on our award winning range of courses contact us on:

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