Innopharma education

Essential Skills for Medical Device Manufacturing

This programme provides participants with an overview of essential skills for medical device manufacturing.

Focusing on key areas of the medical device landscape in Ireland, an overview of ISO13485, Regulations, QMS, Risk Management, Lean Six Sigma, Operational Excellence, Sustainability in Manufacturing and future trends of the industry.

Aims and Objectives

The aim of this course is to provide leamers with an understanding of Medical Device Manufacturing, covering key industry aspects, market dynamics, and career opportunities.Participants will learn about emerging technologies, market trends, and sustainable practices, as well as Quality Management Systems and regulatory compliance. The programme includes principles of Lean, Six Sigma, and Operational Excellence (OpEx) for improving efficiency and quality, and fundamentals of risk management and Corrective and Preventive Actions (CAPA) systems, induding ISO standards compliance.

Learning Outcomes

On completion of this programme the learner should be able to

- Identify key players, market dynamics, global impact, career opportunities, and skills required in the medical device industry (Lectures 1 and 2).
- Describe emerging technologies, market trends, and sustainability practices shaping the future of medical device manufacturing (Lecture 3).

PROGRAMME DELIVERY

10 x 2.5 hour lectures (online)

PROGRAMME CERTIRCATION

Innopharma Education Certificate of Completion

WHO ISTHIS PROGRAMME FOR?

This programme is suitable for anyone interested in medical device manufacturing, including those currently employed in the sector and those seeking to begin a career in the industry.

COST

€299

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CHANGE DIRECTION, ADVANCE YOUR CAREER

- List components and functions of Quality Management Systems and regulatory compliance requirements in the medical device industry (Lecture 4).
- Define principles and methodologies of Lean, Six Sigma, and Operational Excellence {OpEx) (Lecture 5).
- State essential elements of risk management and Corrective and Preventive Actions (CAPA) systems, including handling complaints, audits, and compliance with ISO standards and regulations (Lectures 6 and 7).
- Describe key steps and methods in process validation, testing, assembly, packaging, and traceability of medical devices, including Unique Device Identification (UDI) requirements {Lectures 8, 9, and 10).

Course Content

- Key players, market dynamics, global impact, career opportunities, and required skills in the medical device industry.
- Career paths, qualifications in medical device manufacturing.
- Emerging technologies, market trends, and sustainability in medical device manufacturing.
- Quality Management Systems and regulatory compliance requirements.
- Lean, Six Sigma, and Operational Excellence (OpEx) principles and methodologies.
- Risk management and Corrective and Preventive Actions (CAPA), including complaints, audits, and ISO compliance.
- ISO standards, regulatory compliance requirements.
- Overview of medical device manufacturing validation
- Assembly and packaging methods ensuring product integrity and compliance.
- Traceability & Unique Device Identification (UDI)

A PROFILE OF IRELAND'S ADVANCED MANUFACTURING SECTOR

Advanced Manufacturing accounts for

36.7%

of GDP in Ireland

The sector employs

231,000

direct employees

9

out of the worlds top 10 STEM companies have a presence in Ireland

Ireland is the world's

3rd

largest exporter of pharmaceuticals

Ireland's life sciences sector has a global reputation for operational and innovation excellence

For more information on this course contact Pauline Flusk (Programme Lead) on: T: +353 (0) 1264 5570
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