SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

# Pharma and Medical Device Industry - Introduction

LS006

# Pharma and Medical Device Industry – Introduction

Fifteen of the world's top 25 healthcare companies are located in Ireland with the sector sustaining over 40,000 jobs. This course is intended to give those aiming to move from general industry to the Pharmaceutical and Medical Device manufacturing sectors, a good grounding in the principles that govern the manufacture of both Pharmaceuticals and Medical Devices and to equip them for a smooth transition to working in a highly regulated environment. The course aims to highlight the differences between the healthcare manufacturing sectors and the rest of industry, whilst exploring with attendees the benefits that they can bring to employers within the healthcare sector.

## Duration & Price

Duration: 2 days
Delivery mode: This programme is available In-Company

## Dates & Locations

*In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.*

## In-Company Training

Please contact us for more information on our In-Company training options

## What's covered?

**Laws, Regulations and Guidelines Governing the Pharmaceutical and Medical Device Industries:**

- Regulations, Guidance, Standards and Harmonised Standards
- Europe: The Pharmaceutical and Medical Device Directives, CE Marking and EU GMPs
- US: The FDA, USA CFRs, cGMPs
- Japan, Australia, Canada and Global Harmonization and ICH Q7
- Ireland: The Role of the IMB and Notified Bodies
- ISO 13485 and its relationship with ISO 9000 and the FDA QSR (Part 820)
- CAPA and Continuous Improvement in the Pharmaceutical Industry and ICH Q10

**Hygiene and Sterilization:**

- The definition of Sterile and Sterilization Techniques
- Cleanroom manufacturing and cleanroom technologies. Equipment Design and Techniques for Clean Manufacture. Personnel Hygiene requirements
- Cleaning Validation
- The role of the Qualified Person

**Process Validation:**

- Principles of Validation in the Pharmaceutical and Medical Device manufacturing

- Regulations and guidance covering validation; FDA, ISPE etc
- Process design and characterization
- Process Validation; VMP, IQ, OQ, PQ

**Computer Systems and Software Validation:**

- The life cycle approach to computer systems and software validation
- Regulations and Guidance and GAMP 5 and ICH Q11
- Validation Documentation: URS, FDS, Traceability Matrices, IQ, OQ, PQ
- Electronic Signatures and Records regulations 21 CFR Part 11
- Laboratory Systems Validation and Method Validation

**Risk Management:**

- The application of Risk Management in the Pharmaceutical and Medical Devices industries
- Risk Management Regulations and Guidance and ISO 14971 and ICH Q9

**Good Documentation Practice:**

- Controlled documents. How to complete records correctly. The 2-3-4 date format. Corrections and amendments. Audits and dealing with auditors

**Who's who in the Healthcare Sector:**

- The major players in Pharmaceutical and Medical Device Manufacturing in Ireland and on the Global Scene

**A guide to Jargon and Abbreviations:**

- Common terminology and abbreviations used in the Pharmaceutical and Medical Devices world and how these differ from other industries e.g. URS, ICH, P&ID, GXP etc

**The Healthcare Sector and You:**

- What you can bring to the healthcare sector
- Your future role in Medical Devices or Pharmaceuticals

## Who should participate?

Managers, Engineers, Technical Specialists and Quality Assurance Personnel who wish to seek employment in the Pharmaceutical or Medical Device Industries would benefit greatly from completing this course. This course will be a great source of information for those about to apply for positions within the Pharmaceutical and Medical Device industries. By equipping attendees with the relevant information and helping them to maximise their own experience, this course will allow attendees to compete on a more equal footing with other candidates who already have experience within these industries.

## What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the principles that govern healthcare manufacturing.
- Understand the regulatory framework and identify the regulatory bodies and regulations that apply in various world markets such as the US, Europe, Canada and Asia.
- Understand the hygiene and sterility aspects of healthcare manufacturing.
- Understand the validation approach as applied in Medical Devices and Pharmaceuticals to:
    - Processes
    - Computer Systems
    - Laboratory Systems
    - Cleaning
- Understand how Risk Management techniques are applied in the healthcare sector.
- Identify the key documents used in the industry such as URS, FDS, VMP, IQ, OQ and PQ.
- Identify possible future career roles within the Pharmaceutical or Medical Device Industries

## Tutors

**Gerry Burke**
View Profile

**John Lafferty**
View Profile

## What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.


Click Here

# SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

## LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

## COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

## LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

QQI AWARD | IEMA APPROVED | CompEx Part of the JTL Group | FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE | CQI IRCA APPROVED TRAINING PARTNER | Chartered Institute of Environmental Health

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