SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY









Introduction to Life Sciences Manufacturing

LS006

Introduction to Life Sciences Manufacturing

Ireland is home to fifteen of the world's top twenty-five healthcare companies, employing over 40,000 people. This highly interactive two-day training course introduces learners to the Pharmaceutical and Medical Device sectors, equipping them with the knowledge and awareness required to move from general industry into these highly regulated environments. The course is delivered by expert tutors who guide learners through the principles that govern pharmaceutical and medical device manufacturing, highlighting both differences and opportunities compared with other industries. It also explores the valuable perspectives, transferable skills and problem-solving approaches that individual and companies from general industry can bring to the healthcare industry.

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?

This course provides an overview of the principles, regulations and practices shaping pharmaceutical and medical device manufacturing. Key areas covered include:

- Laws, regulations and guidelines across Europe, the US, Japan, Australia, Canada and globally (ICH Q7, CE Marking, EU GMPs, FDA cGMPs)
- ISO 13485, ISO 9000, FDA QMSR (Part 820) and their interrelationships
- CAPA and continuous improvement in line with ICH Q10
- Hygiene, sterilisation, cleanroom operations, cleaning validation and the role of the Qualified Person
- Validation principles and lifecycle: VMP, IQ, OQ, PQ, process design and characterisation
- Computer systems and software validation (GAMP 5, EU GMP Annex 11, 21 CFR Part 11)
- Laboratory systems validation and method validation
- Risk management principles (ISO 14971, ICH Q9)
- Good documentation practice and audit readiness
- Industry players and sector-specific jargon and abbreviations (URS, ICH, P&ID, GXP)
- Opportunities within the healthcare sector

Who should participate?

This programme is designed for organisations or individuals seeking to enter the pharmaceutical and medical device industries. It is particularly beneficial for:

- Managers
- Engineers
- Technical Specialists
- Quality Assurance personnel

The training is particularly beneficial for companies intending to supply into the healthcare industry or individuals applying for positions within regulated healthcare manufacturing. It equips learners with relevant knowledge and helps them leverage their existing skills to compete and succeed with the sector.

A good standard of written and spoken English is important to engage effectively with this programme.

What will I learn?

On successful completion of this course, learners will be able to:

- Explain the principles that govern pharmaceutical and medical device manufacturing.
- Identify the key regulatory bodies and frameworks in Europe, the US, Canada, Asia and globally.
- Apply knowledge of hygiene, sterility and cleanroom practices to healthcare manufacturing.
- Describe the validation lifecycle for processes, computer systems, laboratory systems and cleaning.
- Analyse the role of risk management and apply core techniques aligned with ISO 14971 and ICH Q9.
- Recognise the importance of documentation, records and audit readiness.
- Identify potential pathways within the pharmaceutical and medical device sectors.

These outcomes ensure that learners return with the practical skills and knowledge necessary to transition confidently into regulated healthcare industries.

How do we train and support you?

Our methodology emphasises interactive and practical learning.

- Emphasis on industry specific application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation.
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Live training is available virtually or delivered onsite to suit the needs of the team
- Real-time support from expert tutors

Class sizes are generally limited to 12-15 participants to support personalised learning and individual support.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- Process Validation & Equipment Validation
- 21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity
- Medical Device Risk Management and ISO 14971:2019
- ISO 134853
- Technical Writing Skills

This progression ensures ongoing professional development within the healthcare manufacturing sector.

Tutors



Gerry Burke
View Profile



John Lafferty
View Profile



Kevina O’Donoghue
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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