SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

Navigating Combination Product Regulations

LS042

Navigating Combination Product Regulations

The distinction between pharmaceuticals and medical devices has become increasingly blurred, giving rise to Combination Products that merge aspects of both. This one-day training programme is designed for professionals with responsibilities in developing, producing or registering Combination Products and it provides a clear overview of the regulatory landscape and agency expectations in both the US and Europe. Delivered by expert tutors, the course ensures learners gain a practical skills and excellent understanding of the specific regulatory requirements they must address in their roles.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 1 day
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 programme offers a comparative and practical exploration of EU and US requirements for Combination Products. Learners gain clear insights into the regulatory pathways and the quality system obligations of each sector.

Key topics include:

- Introduction to Combination Products regulation
- Applicable regulations and guidance documents
- CE marking and medical device classification
- Registering a medical device in the US
- Registering a pharmaceutical product in the EU
- Registering a pharmaceutical product in the US
- Differences between medical device and pharmaceutical quality systems
- Medical device design controls
- Pharmaceutical and medical device vigilance
- Roles and responsibilities of involved parties
- Practical exercises and discussions

The training involves practical exercises covering all relevant topics, with learners encouraged to work on examples from their own workplace as part of these practical exercises. If required, content may be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This training programme is designed for professionals in both pharmaceutical and medical device sectors who are engaged in the development, production, validation or registration of Combination Products.

The training is particularly beneficial for:

- R&D Product Development Engineers and Managers
- Quality Assurance personnel
- Regulatory Affairs professionals
- Supply Chain Specialists
- Sales staff supporting regulated products

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:

- Define Combination Products under EU and US regulations
- Identify and interpret key regulations, harmonised standards and guidance documents
- Explain the process for CE marking in Europe
- Describe US medical device registration requirements
- Outline EU pharmaceutical registration processes
- Outline US pharmaceutical registration processes
- Compare medical device and pharmaceutical quality system requirements (FDA 21 CFR Part 820, ISO 13485, Part 210/211, EU GMP Vol 4)
- Summarise requirements for design controls and 21 CFR Part 4
- Explain vigilance and post-market surveillance obligations
- Clarify responsibilities of involved parties in different product scenarios
- Apply practical knowledge to manage outsourced Combination Product responsibilities

These outcomes ensure that learners return with the practical skills and knowledge necessary to navigate regulatory pathways and support compliance for Combination Products.

How do we train and support you?

Our training approach is practical, highly interactive and discussion-based, with flexibility to meet organisational needs

- Pre-training consultation for in-company courses to tailor content to organisational needs
- 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:

- Pharmaceutical Quality Risk Management and ICH Q9
- Software Validation
- 21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity
- ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)
- Technical Writing Skills

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

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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

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