SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

Regulations and Requirements for Combination Products

LS042

Regulations and Requirements for Combination Products

The distinction between Pharmaceuticals and Medical Devices, once clear-cut, has become increasingly blurred leading to the emergence of regulations, governing Combination Products that are part Medical Device and part Pharmaceutical or Bio-pharmaceutical. Regulatory requirements for Combination Products, and the expectations of regulatory agencies, differ in subtle ways between the US and Europe. This one-day course gives a clear oversight of the regulations and expectations from both sides of the Atlantic. The course is aimed personnel at all levels within an organization, who have responsibilities relating to the development, production and placing on the market of Combination Products in the US and Europe.

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?

Introduction to Combination Products Regulation

- Regulations and Guidance Documents that apply
- 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
- Parties Involved and their responsibilities
- Practical Exercises and Discussions

Who should participate?

- R&D Product Development Engineers and Management
- QA Personnel
- Supply Chain Personnel.
- Regulatory Affairs Personnel
- Sales Staff
- Any personnel in the Medical Device or Pharmaceutical Industries involved in the development, validation or registration of Combination Products

What will I learn?

On successful completion of this training course, delegates should be able to:

- State the EU and US Definitions of a Combination Product
- State the main Regulations governing Combination Products
- Identify and source the Harmonised Standards and Guidance documents related to Combination Products.
- Understand the Medical Devices Regulation 2017/745 and the process for CE Marking
- Understand the process for registering Medical Devices in the US
- Understand the process for registration of Pharmaceutical products in the EU
- Understand the process for registering Pharmaceutical products in the US
- Describe salient elements of the FDA Quality System Regulation 21 CFR Part 820 and ISO 13485 and how they differ from Part 210/211 and EU GMP Vol 4.
- State the main requirements for Design Controls form FDA Quality System Regulation 21 CFR Part 820 and ISO 13485
- State the main requirements of 21 CFR Part 4
- State the main requirements of the EU Medical Regulation 2017/745 and ISO 13485 in relation to Combination Products
- State the main requirements of the EU Medical Regulation Directive 2001/83/EC and EU GMPs Vol 4 in relation to combination products.
- Identify the main differences between
- State the requirements for Medical Device vigilance and Pharmaceutical post market surveillance
- State what each party is responsible for a given product scenario.
- State what each party is responsible for a given outsourced product scenario.

How do we train and support you?

In-House Courses

Course tutor will contact your organisation in advance to discuss the programme in detail.
In-house courses can be customised to meet your organisation’s specific requirements.

Course Manual

Delegates will receive a hardcopy course manual with relevant course materials.

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

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

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- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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