Device – Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process

Course Description

This one day course has been designed to provide manufacturers with the knowledge and skills to interpret the requirements of the drug consultation process for devices containing ancillary medicinal substances.

Attendance on this course will provide guidance on how to reduce risks and uncertainty in the EU regulatory process. Participants will gain an appreciation of the realistic timescales involved for the consultation process and an awareness of common mistakes to avoid, ensuring delays are minimized.

This course focuses on determination of the applicable European legislation for borderline products, and provides insight into further information and guidance related to the distinction between medical devices and medicinal products. This course also examines devices incorporating derivatives of human blood or plasma.

Learning Objectives

On completion of this training, participants will be able to:

- Differentiate between a medical device and medicinal product in terms of classification
- Introduce and explain the key stages involved in the consultation process
- Guide a product development team through the planning process identifying realistic timescales
- Explain the consultation documentation requirements
- Identify common pitfalls and potential competent authority questions in relation to the drug consultation
- Appreciate notified body expectations in relation to submission documentation
- Evaluate changes made post CE marking.

Intended Audience

Medical Device and Pharmaceutical:

- Professionals working in Regulatory Affairs, Research and Development
- Consultants
- Project managers and any staff involved in the product to market process.

Course Duration

One day in-company training only.

Prerequisites

Participants should have experience and/or a basic knowledge of either pharmaceutical or medical device product development. Together with an awareness of the Medical Device Directive 93/42/EEC or pharmaceutical legislation Directive 2001/83/EC.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on +1 800 862 6752 or book online at bsigroup.ca/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.

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