Medical Devices Utilizing Materials of Animal Origin: Practical Guidance on the Legislative Approval Process

Course Description

This one day course has been designed to provide manufacturers with the knowledge and skills to interpret the regulatory requirements relating to materials of animal origin, including those for which a TSE risk is expected.

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 typical hazards associated with animal tissues & derivatives, the justifications needed to use these materials and awareness of common mistakes to avoid in sourcing, collection and handling ensuring delays are minimized.

This course focuses on determination of the applicable European legislation and guidance including 93/42/EEC, 90/385/EEC, 722/2012/EC, EN ISO 22442 and MedDev 2.11.1.

Learning Objectives

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

- Determine the current legislative approval process
- Explain the key stages involved in the consultation process under 722/2012/EC
- Identify the requirements for demonstrating control over suppliers of materials of animal origin
- Appreciate Notified Body expectations in relation to submission documentation
- Identify common pitfalls and potential Notified Body and / or Competent Authority questions
- Identify the requirements for gathering post-production information.

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 medical device product development, together with an awareness of the MDD or AIMD and Regulation 722/2012/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.

Toronto Office
6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office
515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007
TF: 1 800 862 6752
F: 613 271 9007

Montréal
1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115