Creating and Maintaining Technical Files and Design Dossiers

Course Description

BSI's Creating and Maintaining Technical Files and Design Dossiers one day course is designed to support manufactures by confirming current regulatory requirements of technical documentation. The aim of the course is to speed the Notified Body certification process and enable manufacturers to sell compliant devices within the European Union.

On completion of training you will be able to identify and locate all regulatory requirements and guidance documentation necessary to write procedures enabling the creation and maintenance of compliant technical files and design dossiers.

Benefits to Your Business

- Generate technical documentation that support safe products that perform as intended meeting regulatory requirements – first time
- Place products on the market in line with your critical launch dates
- Reduce costs by streamlining the certification process.

Learning Objectives

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

- Confirm the technical documentation requirements as specified in the Directive
- Interpret the general requirements of the Directive using relevant and harmonized standards together with various European & GHTF guidance documents for specific products
- Define the process enabling the creation and maintenance of compliant technical files and design dossiers
- Explain the Notified Body certification process and level of response required to questions and nonconformities raised.

Intended Audience

- Regulatory, Design and Development Professionals
- Quality Managers
- Clinical Affairs Specialists
- Production Managers.

Course Duration

One day.

Prerequisites

Participants should have experience with or basic knowledge of European Device Directives – 93/42 EEC and 90/385 EEC.

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 +44 845 086 9000 or book online at bsigroup.co.uk/training

In-company Training

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