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# 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.

**Course Benefits**

- 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**

Upon completion of this training, delegates 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, development professionals
- Quality managers
- Clinical affairs specialists
- Production managers

**Course Duration**

1 Day

**Prerequisites**

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