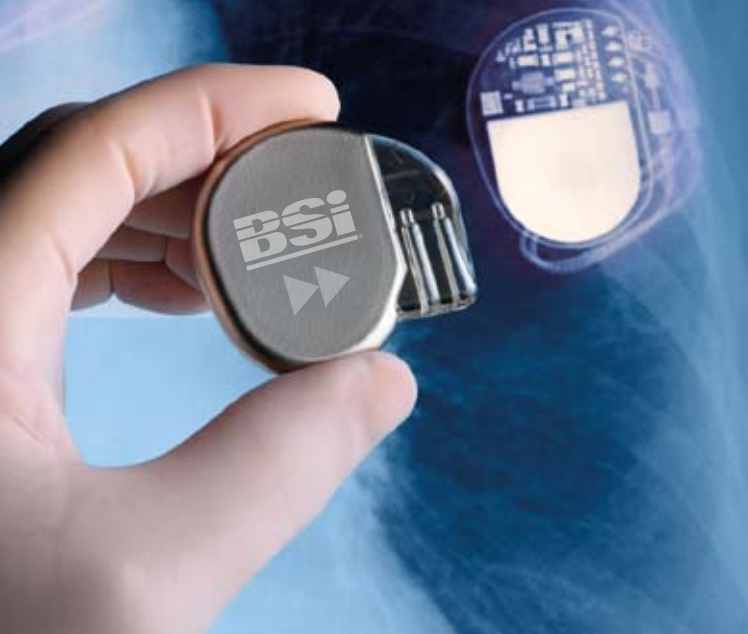


# Setting the pace



Medical Devices training in the Netherlands

▶▶ Fast forward  
training from BSI

*raising standards worldwide™*





## Setting the pace

### Introduction to CE Marking

A one-day introduction to the medical device directives (MDD, AIMDD, IVDD) covering their background and key features

**1 day**      15      September 2010      Amsterdam

### Medical Devices CE Marking

This course examines European medical devices regulatory and standards principles, focussing on sound implementation of the regulatory requirements.

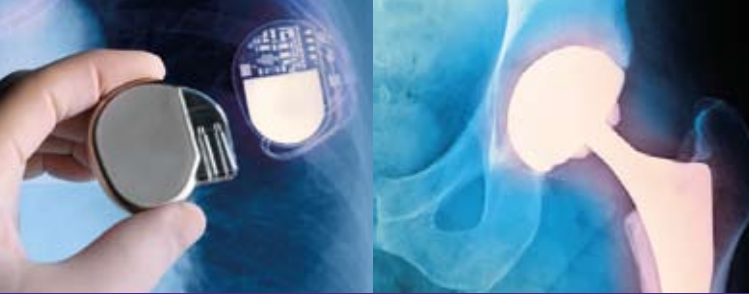
**3 days**    05-07      October 2010      Amsterdam

### Post Market Surveillance and Vigilance

This course is designed to help you identify the requirements of the European medical device directives (90/385/EEC, 93/42/EEC, 98/79/EC), standards and guidance documents to enable effective implementation of a post market surveillance system.

**1 day**      22      June 2010      Amsterdam  
              29      June 2010      Eindhoven  
              20      October 2010      Amsterdam

**Call: +31 (0)20 346 0780**



## Medical Devices training

### Medical Devices Risk Management: ISO 14971

The application of an all encompassing risk management system towards medical devices, including details of the horizontal ISO 14971 standard, as well as selected risk management tools including FMEA, FTA and HAZOP.

<b>1 day</b>	15	June 2010	Amsterdam
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### Introduction to: ISO 13485

This course covers an introduction to ISO 13485, its importance and link to the Medical Device Directives. It also compares its requirements to that of ISO 9001 and the FDA's QSR.

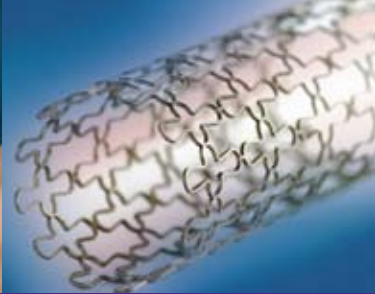
<b>1 day</b>	01	June 2010	Amsterdam
	08	June 2010	Eindhoven
	13	October 2010	Amsterdam

### Implementing to: ISO 13485

The course introduces the concepts needed to understand, develop, and implement a quality management system as outlined in ISO 13485 solid enough to achieve certification.

<b>2 days</b>	08-09	September 2010	Amsterdam
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**Email: [info.nl@bsigroup.com](mailto:info.nl@bsigroup.com)**



## 2010 course schedule

### Internal Auditor: ISO 13485

In addition to outlining details of ISO 13485 and compares its requirements with ISO 9001 this course also covers the planning, preparation, conducting, reporting and closure of internal audits.

**2 days**    22-23    September 2010    Amsterdam

### Lead Auditor: ISO 13485

The course begins with a review of ISO 13485 and continues to teach the principles of process auditing in accordance with quality management system standards addition, the concepts of risk management (ISO 14971) integrated into the audit approach are introduced.

**5 days**    01-05    November 2010    Amsterdam

### In-company Training

We also offer in-company training on all the courses shown here. Contact our team to discuss how we can train your staff at a time to suit you.

**Visit: [www.bsigroup.nl](http://www.bsigroup.nl)**



## About BSI

Medical devices for use in the European Healthcare market face a wide range of demanding regulatory approval requirements and standards. Compliance can seem like a daunting task for many organizations.

### **World class experience...**

BSI holds Notified Body status for 15 European Directives, including the Medical Devices Directive and In-Vitro Diagnostics Directive (IVDD), we can offer one of the most comprehensive certification services in the world and our a team of experts understand precisely what each Directive requires for each product – to make your life easier.

### **A partnership approach...**

With an in-depth understanding of all the latest regulatory changes, our training team here at BSI Netherlands works in partnership with organizations training staff members to rise to the challenge of meeting these standards.

### **Useful Links**

For further information regarding the European Directives affecting the healthcare market in Europe visit:

<http://ec.europa.eu/enterprise/sectors/medical-devices/>

<http://www.eucomed.be/>

To find out more information and reserve your place on one of our training courses contact our Netherlands Training Team:

**Call: +31 (0)20 346 0780**

**email: [info.nl@bsigroup.com](mailto:info.nl@bsigroup.com)**

**or visit our website at: [www.bsigroup.nl](http://www.bsigroup.nl)**

**BSI Netherlands**

Adam Smith Building  
T.R.Malthustraart 3c  
Amsterdam  
1066 JR  
The Netherlands

T: +31 (0)20 346 0780

F: +31 (0)20 346 0781

Email: [info.nl@bsigroup.com](mailto:info.nl@bsigroup.com)

[www.bsigroup.nl](http://www.bsigroup.nl)

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