Mode of Payment

You can make payment through Cheque, NEFT transfer or e-payment.

Below are the details

BSI Group India Private Limited
Current Account No.: 166045294001
HSBC Bank, 25, Barakhamba Road, New Delhi-110 001
IFSC/RTGS Code: HSBC0110002
Swift Code: HSBCINBB

Please note: *Service Tax will be charged extra as per prevailing Government Rates.*

BSI's Personal Certification Programmes

CPQP
CERTIFIED PHARMA QUALITY PROFESSIONAL

CPQP+
CERTIFIED PHARMA QUALITY PROFESSIONAL

CHIP
CERTIFIED HEALTHCARE INDUSTRY PROFESSIONAL

Prerequisites for this training

Participants should have experience with or basic knowledge of quality management systems for the medical device industry or experience of the manufacture, design, marketing or use of medical devices.

About BSI

BSI is the business standards company that helps organizations all over the world make excellence a habit. For more than a century we have been showing businesses how to improve performance, reduce risk and achieve sustainable growth. We lead the world in advocating, defining and implementing best practice across every field of human endeavour.

We have more than 100 years' experience of shaping standards. Originating as the world's first national standards body, the Group has over 2,250 staff operating in over 100 countries through more than 50 global offices.

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 webinar.

bsi. | CERTIFIED MEDICAL DEVICE PROFESSIONAL
CE Marking • Medical Devices • IVDs

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T: +91 11 2692 9000, E: info.in@bsigroup.com

Steps to Becoming a CMDP

Certified Medical Device Professional

CMDP
CERTIFIED MEDICAL DEVICE PROFESSIONAL
CE Marking • Medical Devices • IVDs

bsi. | CERTIFIED MEDICAL DEVICE PROFESSIONAL

...making excellence a habit.™

What is CMDP?

CMDP (Certified Medical Device Professional) is an integrated personal certification programme for Medical Device Professionals focusing on providing in-depth implementation knowledge on product certification for CE marking. In this program we will facilitate you develop your skills and understanding of the practicalities involved while preparing the Technical File that conforms to the requirements of Medical Device Directives. This includes introduction on Clinical Evaluation, Risk Management, harmonised standards applicable for Medical Device Directive (93/42/EEC) & In-vitro Diagnostic Device Directive (98/79/EEC) and effective submission of Technical File for CE Marking the Medical Devices and IVDs.

At the end of the course, participants write an exam and successful clearance earns them CMDP certification.

1 Why CMDP Personal Certification?

- A modular step by step program to build your credentials in technical and regulatory areas of focus in the medical device industry
- Gain an edge over competition with this personal certification program and stand out in this fast growing sector
- Learn the latest developments that impact the regulatory environment for medical device registrations in key markets.

2 Who should become Certified Medical Device Professional?

- Regulatory, quality, design, development, manufacturing, marketing managers and personnel
- Organizations designing/manufacturing/distributing Medical Devices & IVDs
- Organizations preparing "own branding" or "private labeling" of Medical devices & IVDs
- Potential internal auditors and others who need an in-depth knowledge of the requirements of the medical devices & IVD directives

3 What will you learn?

Upon completion of this training, delegates will be able to:

- Explain the European CE marking approach
- Explain the structure and purpose of the medical devices directive and IVD directive
- Implement the EU risk classification criteria for medical devices & IVDs
- Identify the conformity assessment routes and quality assurance requirements for the various risk classes
- Identify the product specific harmonized standards applicable for Medical Devices and IVDs
- Identify the Safety Test requirements
- Describe the role of the essential requirements as the basis for CE Marking
- Identify the requirement of clinical data
- List the labeling requirements
- Identify the regulatory significance of risk management and process validation
- Identify the necessary steps required for post market surveillance for different risk classes
- Interpret the criteria for reporting adverse incidents under the vigilance system
- Define the manufacture's regulatory responsibilities, including reporting of changes to products and QMS system to the notified Body
- Identify the relevance of recent changes to the medical devices & IVD directives
- Conduct internal and external audits for compliance with the directives4

4 What each course module offers?

- The three-day medical device CE marking module provides in depth knowledge on the regulatory framework that governs CE marking of medical devices covered under the Medical Device Directive (93/42/EEC) {Includes details on device classification and selecting the appropriate conformity route}
- The one-day in-vitro diagnostic device CE marking module provides in depth knowledge on the regulatory framework that governs the CE marking of in vitro diagnostic devices covered under the in-vitro diagnostic device directive (98/79/EC) { Includes details on device classification and selecting the appropriate conformity route}
- The one-day module on risk management provides a thorough outline to develop and build the risk management process within an organization in line with the requirements of the EN ISO 14971
- The one-day module on clinical evaluation of medical devices provides in depth knowledge on how to prepare a clinical evaluation summary that meets the requirements of the EC directives for CE marking

5 How will your organization benefit?

- An understanding of Medical Device Certification for CE Marking
- Have the capability to Improve the effectiveness and efficiency of the Product Certification processes
- Be confident that you will be able to play pivotal
- Role in third party and customer audits
- Can be utilized as qualified internal auditor

An examination is held on the final day and successful delegates will be awarded with CMDP Professional certificate.

6 Program fee & duration

Instructor led classroom based training program

Course duration : 7 Days
Course fee: INR 42,000/- per delegate

(Service tax extra as applicable)

Next Steps

To book your seat in this program, call one of our dedicated BSI advisors on +91 11 2692 9000 or email at info.in@bsigroup.com