PAYMENT

$2150.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

CANCELLATION POLICY

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1.

Go to http://www.cfpie.com

2.

Go to “REGISTER HERE” and select your course.

3.

Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 295
Malvern, Pennsylvania 19355

http://www.CfPIE.com

CfPIE® *The Center for Professional Innovation and Education, Inc.*

Medical Devices: The New MDRs, EU Directives, Guidance, CE Marking and ISO Standard Certifications

INSTRUCTOR: JONATHAN LEE

September 25 & 26, 2019 - Los Angeles, CA

COURSE DESCRIPTION

The European Union (EU) provides an attractive marketplace for medical device distribution. Development of requirements harmonized across the 27 member states should make it a straightforward process to get products approved in each country- but is it? This course works through the requirements for medical devices, the steps to obtain entry into the marketplace (including setting up a number of on-going procedures and relationships), and shares some lessons learned from the Course Director, who has over 20 years of experience with CE marking medical devices for distribution in the EU.

The course will introduce the Medical Device Directives (AIMD, MDD & IVDMDD), the meaning of the CE symbol and how & when to legitimately apply this mandatory mark of conformity, the significance of Notified Bodies, Competent Authorities, and Authorized Representatives. Additionally, the significance of the QMS, ISO 13485 and ISO 14971, and reference to ISO 14000 will be explained as necessary elements in addressing the essential requirements, technical dossiers, declarations of conformity and the six steps required for manufacturers to market medical devices in the European market.

Throughout the course, examples and case studies will help participants apply the concepts being covered.

INSTRUCTOR CREDENTIALS

Jonathan Lee has more than 25 years of broad-based medical device experience with extensive Quality System experience encompassing ISO, MDD & GMP standards and regulations, through consulting and senior management positions in QA/RA, R&D, Project Management, Product Management, and Product Introduction disciplines, in both the United States and Australia A multiple patent holder, Mr. Lee's prior roles include VP R&D at Cardiac Control Systems, Vice President Quality, Regulatory & Clinical affairs at Medtronic. In addition, his consulting roles supporting implantable bio stimulation telemetry systems, implantable heart sub-system, catheter defibrillation system, surgical tool, vertebral stiffness measuring system, respiratory interfaces, cardiac catheter development, medical device process V&V, quality system development & implementation, and product approvals, have provided for an extensive accumulated experience.

Today, as Principal Consultant and Managing Member of "MedDev Consulting Solutions International" he provides strategic direction and tactical solutions for unique medical device challenges. Including areas such as integration of quality systems with compliance, product performance and elevated stakeholder expectations.

Mr. Lee holds an Electrical Engineering (Biomedical) BE degree from the University of NSW in Australia with post graduate work in Computer Studies at the same University. He has participated in compliance symposia at Harvard University and served as an instructor on quality systems at University of Southern California School of Pharmacy Master's Degree Program.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance).

DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)

FIRST DAY

Introduction to the European Commission, the EU, and the CE Mark for Medical Devices:
- Differences in approach & philosophy
- MedDev

The AIMD, MDD, IVDMDD & CE Mark:
- Device types
- Refurbished product

European Commission's 6 Steps for Manufacturers

Introduction to the "Players:"
- The Medical Device Manufacturer
- The Competent Authority
- The Notified Body
- The Authorized Representative

Quality Management System (QMS & EMS):
- What is it?
- The role of ISO 13485
- The Notified Body
- The role – or not – of ISO 14001
- Comparisons with:
  - FDA 820
  - rPAL
  - CMDCAS
  - TGA

"Green" Europe, standards and requirements to be aware of:
- WEEE
- RoHS
- REACH
- ISO 14000

Product Classification:
- Sterilized product and the impact of TSEs
- Devices with a measuring function
- The flow charts
- ISO 14000

Overview of Important Documentation:
- The essential requirements
- The Technical Dossier/Design Dossier
- Declarations of Conformity

SECOND DAY

Conformity Assessment, Certification & Obtaining the CE Mark:
- The Six Steps (or is it 5?) to CE Marking

Key roles & Their Selection:
- The Authorized Representative
- The Notified Body

Product Classification & Conformity Requirements:
- Review of device types
- Declarations of conformity

The Essential Requirements:
- What to include
- Do's & don'ts
- Updating

The Technical Dossier/Design Dossier:
- Not all reviews are the same
- Outcome driven content and review

Marketing in Europe & Retaining the CE Mark:
- Site QMS auditing
- Managing & reporting change
- Post Market Surveillance
- Field actions & the Vigilance System

Lessons Learned & Related Topics:
- Labeling and language
- Harmonized standards
- The role of GHTF
- "One World" and communication
- Involvement of the CAs
- Politics and specialties
- Europe and GREEN policies
- Key websites

Course summary and Q&A