IPI Academy

MANAGEMENT forum

Presented by
Management Forum

The Medical Device School - From Concept to CE Marking

10-14 June 2024
+ 2-6 December 2024

This comprehensive course has been designed to map the processes from device concept to marketing and show how regulatory, quality, clinical and other aspects of device development are joined into a continuous process.

Format:
Live online

CPD:
30 hours for your records

Certificate of completion

Course overview

Bringing a medical device to the marketplace is a complex and lengthy procedure which requires experience, knowledge and specialist skills. The contribution to successful market placement comes from many different skilled individuals and organisations who should be aware of all the stages involved and be able to relate their responsibilities to the needs of other professionals, scientists, clinicians and regulatory and quality experts.

This comprehensive course has been designed to map the processes from device concept to marketing and show how regulatory, quality, clinical and other aspects of device development are joined into a continuous process. The programme will commence with a general introduction as to what devices are and how they are developed, and continue with lectures, practical workshops and case studies covering each process applicable to device development, marketing and, eventually, postmarket procedures. There will be ample time throughout the five days for informal discussions with our expert faculty and fellow professionals.

Benefits of attending:

Understand the procedures for taking a medical device to the marketplace

- **Learn** what regulations control the manufacture and marketing of devices in the EU
- **Ensure** compliance with the MDR
- Gain an insight into different aspects of the process for obtaining the CE mark for a device
- **Discover** a holistic approach to device development and marketing
- **Participate** in workshops and learn from other people's experiences
- **Understand** how other professionals affect the process for bringing a device to market
- **Network** with participants from organisations similar to your own

Who should attend

This event has been designed primarily for those who wish to understand the processes involved in bringing a medical device to market. General medical devices as well as active implantable, in-vitro diagnostic and drug device products will be covered in the programme.

The course will be of particular interest to those seeking to introduce new medical devices to the market. Previous delegates who have benefited include regulatory, quality, clinical and marketing managers.

Programme

Day 1

Day One

What is a Medical Device?

- Definitions and examples

Device Design and Development

- Overview
- Device innovation
- How is a device developed from concept?
- From idea to market, the overall steps

What Regulations Control the Manufacture and Marketing of Devices in the EU?

- A brief history of the Medical Device Directives explained (AIMDD, MDD and IVDD)
- An overview of the Medical Device Regulations 2017/745

How Does a Device obtain a CE Mark?

- What does the CE Mark mean?
- Overview of the CE Mark process for a device
- Device classification

UKCA

Economic Operators, Competent Authorities and Notified Bodies

- Who are economic operators and what are their responsibilities?
- What is a competent authority?
- The role and responsibility of a competent authority
- What is a Notified Body?
- The role and responsibility of a Notified Body
- Relationships with manufacturers

Classification of Medical Devices

- How do you classify a medical device?

Classification workshop with case studies

Day 2

Day Two

Risk Analysis and Risk Management

- Review of ISO EN 14971:2007, 'Medical Devices Application of Risk Management to Medical Devices'
- What procedures must a manufacturer follow?

How Should a Risk Analysis be Conducted? – Risk Analysis Workshop

Biological Evaluation of Medical Devices

- ISO 10993 and the biological safety assessment process
- Where product safety assessment fits in New Product Development

Technical Files and Design Dossiers

- What are these documents?
- What should they contain and how should they be presented?

Quality Systems for Medical Devices

- What is a Quality System?
- What do manufacturers need to do to implement a Quality System?
- What are the regulations and guidelines for Quality Systems?

Labelling and Packaging of Devices

- What information needs to be provided and how should it be set out?
- What regulations and guidelines should be followed?

Day 3

Day Three

Regulations and Guidelines Applicable to Medical Device Studies

- Review of ISO 14155 and other available guidelines

Clinical Evaluations

- How to conduct clinical evaluations
- Controls of the clinical evaluation plan and clinical evaluation report
- Literature search

Conducting Medical Device Clinical Investigations

- How to conduct medical device clinical investigations
- Study design
- Study content

Documents Necessary for Medical Device Clinical Investigations

- Clinical investigation plan
- Clinical investigation report

Clinical Investigation/Evaluation Workshop

Approvals for Conducting Clinical Studies

- Documents required
- Ethics committees
- Competent authorities

Day 4

Day Four

Software and Medical Devices

- Understanding the requirements for medical device software
- Software qualification and classification
- Clinical evidence for medical device software
- Additional considerations for Artificial Intelligence

In-Vitro Diagnostic Products

- The IVD Directive
- New IVD Regulation (2017/746)
- Transition period preparation
- Impact on compliance and risk analysis

Making Sense of the European Reimbursement Environment

- Making sense of reimbursement, regulation and market access
- Understanding different approaches adopted to the reimbursement of medical devices
- Implications for manufacturers of medical devices

Drug/Device Products

- Regulations for demarcation of medicinal products and devices
- Exploration of borderline issues
- Quality considerations

Devices Incorporating Materials of Animal Origin

- What's the risk?
- Specific standards on animal materials
- Conformity assessment for devices containing animal-derived materials

Programme

Day 5

Day Five

Post-market surveillance (PMS)

- What constitutes PMS? The basic principles
- The regulatory requirements for PMS
- The increasing importance of PMS
- A review of available guidelines for PMS

EC Medical Device Vigilance

- Basic principles
- Reporting arrangements
- Role of manufacturer, competent authority and Notified Body
- Review of the available guidelines for device vigilance

Workshop with case studies

Presenters

Paula Wittels

Key positions held in career
Programme Director Translucency Ltd
Director of Operations Quintiles Consulting, specialising in medical device reimbursement
Marketing Director Howmedica International (at the time a Pfizer company) manufacturing orthopaedic implants
Group Product Manager Amersham International (now part of GE healthcare). Launch of novel IVD platform

Major areas of expertise
Experience across a wide range of medical technologies
Business planning
Market assessment
Product management

Services offered through Translucency
Early commercialisation
Market access
Product reimbursement
Management of multi-country projects

Educational and professional achievements
PhD in Public Health
MA in Natural Sciences (specialist subject biochemistry)
MSc in Information Science
Member of the Chartered Institute of Marketing
Speaker on medical device reimbursement at conferences

Janette Benaddi

Janette Benaddi is a business mentor, international speaker/trainer and consultant to the medical device industry. Janette has over 25 years' experience of managing pre and post market clinical studies in both devices and pharmaceuticals. Janette has worked with several multinational organizations in various clinical, regulatory and marketing roles.

She has extensive experience of conducting clinical studies with medical device products as well as regulatory expertise for CE marking of devices. Specifically she has been involved in writing and reviewing hundreds of Clinical evaluation reports for the medical device industry, she has also provided training to Notified bodies in this subject.

Janette qualified as a registered nurse in 1984, she has a BSc in Management studies, a Diploma in Company Direction, and a Diploma in Management studies, holds a teaching certificate and is a Chartered Scientist and Chartered Director. Janette sits on several committees in the device community and industry and has been an instrumental advocate of improving and advancing medical device research in the UK. Janette has published several articles relating to medical device regulation and clinical studies.

Theresa Jeary

Theresa works for SFL as Head of Combination Products. Theresa has over 25 years' experience working in both the Pharmaceutical and Medical Device industries and has worked in a variety of roles across the full development cycle from product concept and early stage development, process transfer, validation and regulatory departments, and has been a part of the team for many commercially available medicinal and medical device products.

Zuzanna Kwade

Zuzanna Kwade is Software Clinical Evaluation Lead at Dedalus Healthcare. Zuzanna holds a PhD in Biochemistry and has 15 years of experience in clinical and medical research. She is the co-author of several white papers on regulatory aspects of clinical research and clinical evaluation.

Since 2016, she has been actively involved in Clinical Evaluations according to MEDDEV 2.7.1 (Rev.4) for multiple devices, including high risk hardware devices and medical software. She also represented COCIR in the European Union Task Force on clinical evaluation of software and co-authored MDCG2020-1 guidance on clinical evaluation of MDSW.

Adrian Keene

Adrian Keene is Director, Product Development Strategy at NAMSA, where he utilises his broad experience of changing EU medical device regulatory requirements to support clients worldwide. He was previously Head of Notified Body for the UK Notified Body SGS. Prior to that he was Global Clinical Affairs and Regulatory Manager for Medical Devices, with responsibility for conformity assessment activities of high risk (class III) devices under the Medical Devices Directive.

In this role he combines his experience from new product development with EU regulatory requirements to provide a balanced interpretation of the needs and expectations of both competent authorities and manufacturers. He works with a broad range of devices including drug-device combination products.

Adrian has 25 years experience in the medical device industry, and previously held the role of Technical Manager – Medical Devices at the Notified Body LRQA. Prior to that he worked in the medical device industry, latterly as Global Product Safety Manager at Smith and Nephew. Here he created a highly effective team delivering product safety and risk management to Smith and Nephew's global wound management portfolio. His team was responsible for providing toxicological and risk management strategies to expedite product launches, commercialisation, and post market activities, including Far Eastern markets (Japan and Korea).

He joined Smith & Nephew directly from The School of Pharmacy (University of London) following postgraduate research in retinoid-induced skeletal toxicity and an honours degree in Toxicology and Pharmacology. He also holds a Diploma in Managing Medical Product Innovation from the Scandinavian International Management Institute.

Adrian is a UK expert for ISO/TC 194 (Biological Evaluation of Medical Devices), and has been an active participant in NB-MED and NBRG.

Presenters

Will Burton

Will is currently the Director of Russell Square Quality Representatives (RSQR) Ltd. He is engaged in providing a range of consultancy and training services to the international medical device, pharmaceutical and biotechnology industry sectors. Prior to founding RSQA in 1995, Will was the Professional Services Manager of the Manufacturer Registration Scheme Business Unit of the UK Medical Devices Agency (now MHRA).

David Howlett

In 2003 David established PharmaDelivery Solutions Ltd as a specialised consultancy service in the field of drug delivery combination products (especially respiratory) device technology. This has led to involvement in projects with focus in pulmonary, nasal and other delivery routes, with an international client base. Much of the activity of PharmaDelivery Solutions Ltd is focused in the area of development programme support, regulatory GAP analysis and generation of documentation supporting development and test programmes, together with data review and contingency evaluation.

David has over 35 years experience in the development, industrialization and approval of inhalation drug delivery systems, combination products and medical devices.

Stuart Angell

Stuart Angell is a joint director in his own consultancy specialising in global regulatory affairs strategy and compliance for in vitro diagnostics and medical devices focusing on the transition to the new IVD/Medical Device Regulations, MDSAP and ISO13485:2016.

He has over 15 years in the IVD industry and in previous roles has been responsible for designing, reviewing and maintaining regulatory frameworks for self-declared and annex list II products including technical documentation for EU and global submissions (FDA, Health Canada, TGA, Russia, Latin America). He has an excellent understanding of risk management, Post Market Surveillance (PMS) and vigilance.

Course dates

10-14 June 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 13698*	GBP **1,999** ~~2,499~~ EUR **2,889** ~~3,589~~ USD **3,309** ~~4,089~~ **Until 06 May**
2-6 December 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 14078*	GBP **1,999** ~~2,499~~ EUR **2,889** ~~3,589~~ USD **3,309** ~~4,089~~ **Until 28 Oct**

How to book

Online:
ipi.academy/2131

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Really engaging and focused on the EU. Enjoyed the fact this was current and mentioned up to date legislation and regulation updates.

Chelsey Ludlow
Regulatory Affairs Coordinator
Vision RT Ltd
Jun 12 2023

★★★★☆

Speaker are very good and expert in their area

Lutfhi Zarkasyi
Plant Head
PT. Forsta Kalmedic Global
Jun 12 2023

★★★★☆

I really enjoyed the workshops as it gave the opportunity to interact with the other delegates on the course and discuss and develop learnings from the presentations.

Emma Hickson
Research Advisor
Convatec
Jun 12 2023

★★★★☆

excellent

Lutfhi Zarkasyi
Plant Head
PT. Forsta Kalmedic Global
Jun 12 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy