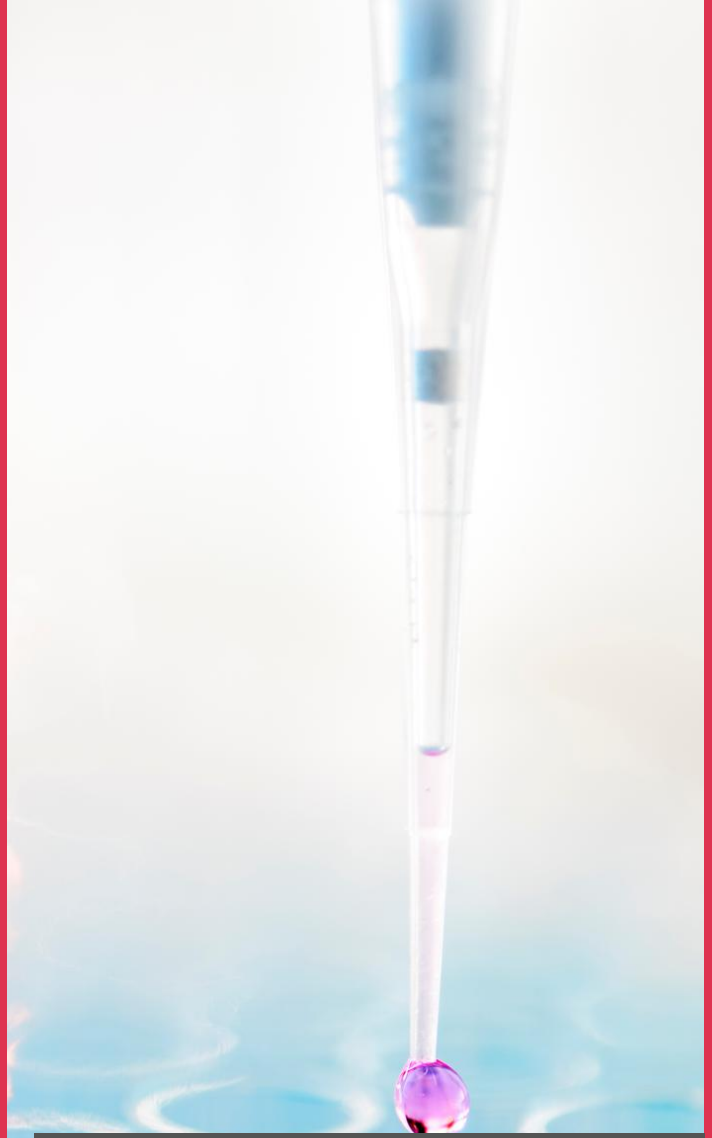
Brought to you by informa connect

Medical Device Regulatory Project Management

23 - 24 February 2021

LIVE Online Academy



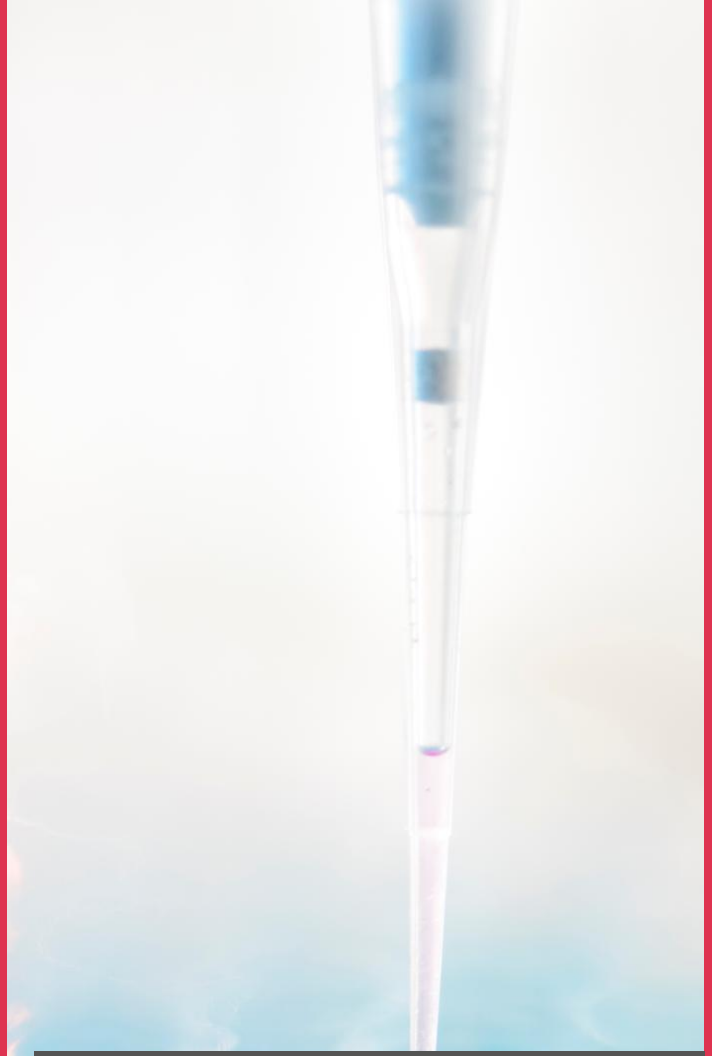
COURSE OVERVIEW

How can regulatory affairs professionals add value and efficiency into regulatory compliance practices in medical device development projects?

2020 marks an important date for the Medical Devices industry, as the European Union's Medical Device Regulation (MDR) will take effect. Two years after, the In Vitro Diagnostic Medical Devices (IVDD) will follow. These regulations are set to constitute major changes for the industry, and these changes bring a high degree of uncertainty with them. Among these changes and the ever-increasing intelligence of health tech solutions, it is more important than before to adopt modern business thinking into regulatory affairs.

This essential course will provide you with an effective and informative outlook on the regulatory essentials and project management methodologies used in regulatory affairs for medical devices. During the course, delegates will gain a solid understanding of the core ingredients needed for successful projects, and learn how to coordinate key regulatory requirements for medical devices throughout project management. In addition, this course provides an insight into the future challenges for medical devices and offers solutions to tackle them.

Delegates will be able to cement this knowledge through case studies and practical exercises, with additional time on the course provided to discuss the implications of Brexit.



MEET THE TRAINER

HEIKKI PITKÄNEN

Heikki is the CEO /founder of the consultancy company Lean Entries Ltd, advising on medical device regulatory compliance for both start-up and experienced teams across the globe by utilising both traditional and lean digital methods.

Heikki previously worked as a team leader at SGS, providing medical device manufacturers with NB, CBTL and training services, among others, for worldwide market access. He is a member of the CEN-CENELEC Advisory Board for Healthcare Standards.

Agenda: Session 1 - Introduction to Project Management

- **Early development stages in a project:**
  - Timelines and considerations on the device life cycle
  - Capturing the value proposition
  - Early validation through feasibility studies

- **Planning and initiating the project**
  - Regulatory strategy
  - Assigning roles and responsibilities in-house and across boundaries
  - Team communication, collaboration and leadership
  - Document and records management, logs and traceability

Agenda: Session 2

Applying Regulatory Requirements to Project Management

- The role of global regulations and standards in medical device project management
- Key regulatory considerations throughout the medical device lifecycle:
  - General Safety and Performance Requirements

    - Clinical Evaluation
    - Risk Management
- Design Control requirements in project management
- Other regulatory considerations for project management:
    - Quality system requirements (ISO 13485, FDA QSR)
    - Vendor control
    - Labelling and instructions for use

Managing Regulatory Changes and Communicating with Authorities

- Navigating the transitional periods of the changing global legislations through strategic regulatory planning, including:
    - MDD to MDR
    - IVDD to IVDR
- Communication and timelines with authorities, laboratories and certification bodies
    - Product testing and certification against international standards
    - Audits and technical file reviews
- Case Study for dealing with a variety of requirements and changing legislative timelines in a project

Agenda: Session 3

A Closer Look at Clinical Evaluation in a Project

- The importance of conducting a literature review
- Clinical investigations, sufficient clinical evidence and post-market activities
- Transitioning from the current to new clinical evaluation requirements (MDR)
- Case Study on how to conduct a clinical evaluation plan in accordance with regulations

Applying Risk Management in a Project

- Risk management practicalities
  - ISO 14971 and Design FMEA (Failure Modes & Effects Analysis)
  - Biocompatibility (ISO 10993 series)
  - Electrical safety (IEC 60601 series)
  - Software life cycle (IEC 62304)
  - Usability (IEC 62366)
- Benefit-risk analysis as the final outcome
- Case study on how to conduct a risk management plan and risk assessment in accordance with regulations

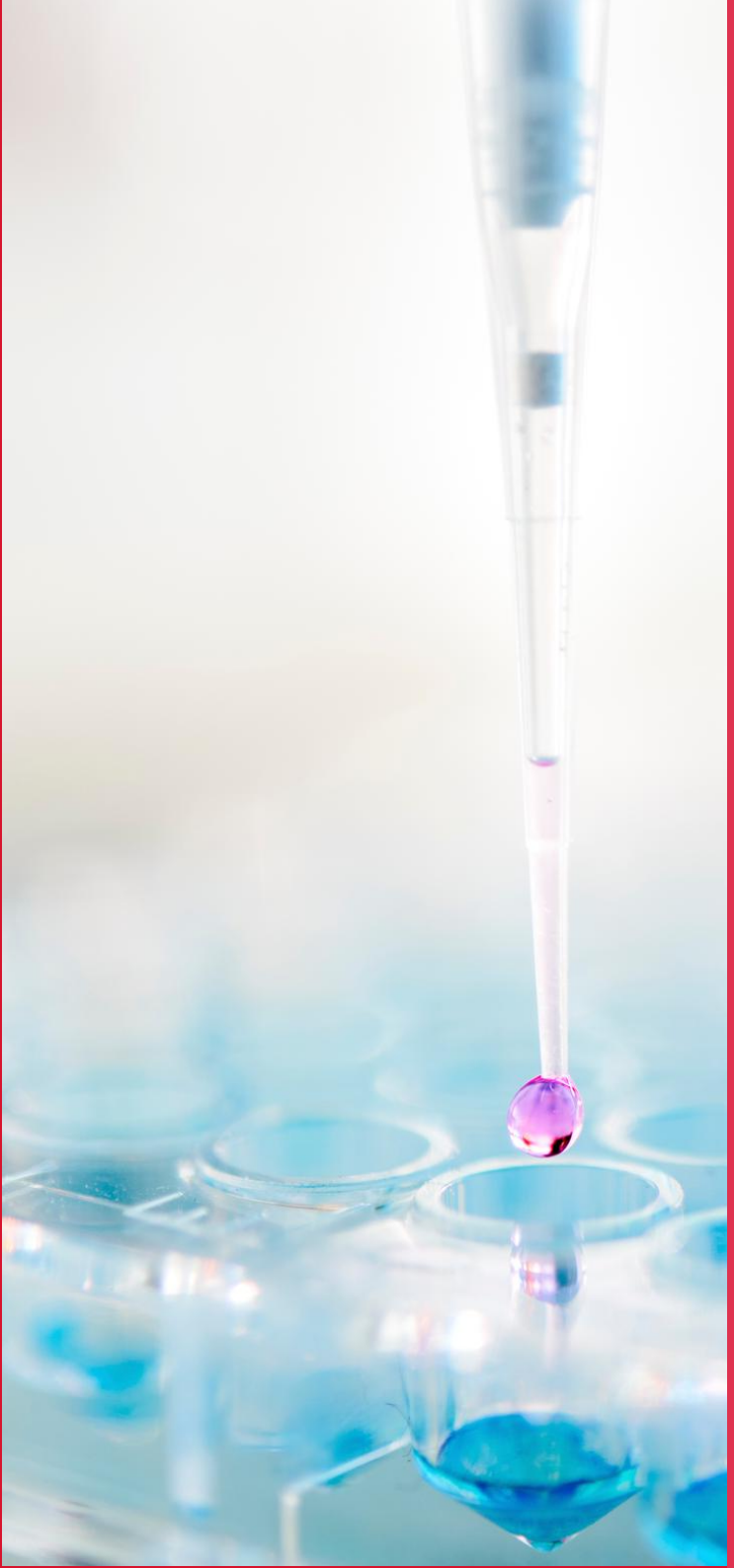
Agenda: Session 4

Managing Medical Device Project Cycles

- Product life cycle thinking: Does the project have an end?
- Design Control as the middle cycle: The typical project cycle
  - Design Inputs, Outputs, Verification, Validation, Process Validation, Transfer,
- Changes and Reviews
- The micro cycles of project management: The daily work
  - Plan-Do-Check-Act / Build-Validate-Learn / Agile methodologies
- Maintaining alignment and adapting to change
  - Post market activities – surveillance and clinical follow-up
  - Corrective and preventive actions and methods
  - Project metrics

Course Feedback Session

- Delegates will get the opportunity to finish the course by asking any remaining questions and queries regarding the course content and the simulation exercises.



Brought to you by informa connect

For information or to book a course please contact our Training Consultant

Jessica Purnell
jessica.purnell@informa.com
+44 (0)20 7551 9521

Register Now >>