IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Managing Competence within the Medical Device Industry

5 November 2024

This webinar has been designed to help you understand the 'big picture' of competence management, from selection of the right competencies for success to the maintenance of collective organisational knowledge.

Format:
Live online

CPD:
1.5 hours for your records

Certificate of completion

Course overview

Many medical device developers and manufacturers rely heavily on the competence of their staff to achieve their business goals. Like many companies, particularly in the start-up phase, it can be a daunting task to know where to start with documenting the necessary evidence to demonstrate that competence to third parties such as investors and notified or approved bodies.

Under the MDR / IVDR, the requirement to have a Person Responsible for Regulatory Compliance brings the need to demonstrate competence into even sharper focus.

This webinar has been developed to help you understand the 'big picture' of competence management from selection of the right competencies for success to maintenance of collective organisational knowledge.

Benefits of attending

- **Identify** the competencies required for the growth of the company
- **Plan** recruitment effectively to deliver competency
- **Utilise** performance reviews to manage competency
- **Document** the right information as evidence of competence
- **Learn** how to meet the competence-related requirements of ISO 9001:2015 clauses 7.1.6 and 7.2, ISO 13485:2016 clause 6.2 and regulatory requirements of Article 15 in MDR/IVDR Person Responsible for Regulatory Compliance (PRRC)

Who should attend?

- Quality assurance managers
- Regulatory affairs associates
- Human resource managers
- Senior management

Programme

What do we mean by "competence" in the context of the medical device industry?

Understanding an organisation's competence needs

- Determining types of competence needed from skills, experience, knowledge and qualifications
- Identifying potential sources, internal and external
- Identifying the touch points within the quality management system for competence management

Maintaining appropriate records of education, training, skills and experience

Capturing and sharing undocumented knowledge and experience

Utilising external competence resources effectively

Demonstrating competence to third parties

Presenter

Anne Jury

Anne Jury is a regulatory affairs consultant with over 25 years experience in the medical and diagnostic healthcare products industries. With a degree in Microbiology, she went to work as company microbiologist for Smith & Nephew Textiles on sterile wound dressing products. Later she went on to work for Notified Bodies, BSI and then TÜV Product Service as a lead auditor covering over 200 medical companies in Europe and USA.
Anne is a member of TOPRA, (The Organisation for Professionals in Regulatory Affairs) and RAPS, (Regulatory Affairs Professionals Society) and a regular speaker at conferences world-wide.
Through close association with like minded organizations such as Medilinks, the DTI and NHS Innovations Hubs as well as biotechnology incubators around the UK, she is active in the promotion of integrated management and regulatory systems to assist the successful introduction of new products to market.
Since March 2020, she is also Vice President of Team-PRRC.
Specialties: Technical guidance on regulatory strategies and quality management systems for new medical device product commercialization, including CE marking requirements, implementation of management systems to ISO 13485:2016 and training / coaching in these areas.

Gap analysis compliance audits for manufacturers and subcontract third party auditor for Notified Bodies.

Past visiting lecturer at Cranfield University (through TOPRA) on MScs in Medical Technology Regulatory Affairs.

Vice-President of Team-PRRC, a non-profit association in EU to support those taking on the PRRC role under MDR and IVDR.

Course date

5 November 2024	**Live online** 14:00-15:30 **UK (London)** (UTC+00) *Course code 14233*	GBP **150** ~~175~~ EUR **220** ~~255~~ USD **250** ~~289~~ **Until 01 Oct**

How to book

Online:
ipi.academy/2699

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

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