IPI Academy

MANAGEMENT forum



Presented by
Management Forum

The Role of the Person Responsible for Regulatory Compliance (PRRC) Under the MDR and IVDR

This one day course will cover the role of the Person Responsible for Regulatory Compliance (PRRC) introduced by the implementation of the Medical Device Regulation 2017/745 and the In-Vitro Diagnostic Device Regulation 2017/746. The course will review Article 15 from the regulation in detail to enable understanding of the intent of each requirement. It will also present the UK Medical Device Regulation requirements and discuss the proposed Qualified Person role with current information.

Format:
Bespoke training

CPD:
6 hours for your records (depending on your requirements)

Certificate of completion

Course overview

Attend this one-day course to gain a comprehensive understanding of the critical role of the Person Responsible for Regulatory Compliance (PRRC) introduced by the Medical Device Regulation 2017/745 and the In-Vitro Diagnostic Device Regulation 2017/746.

In the evolving landscape of medical device regulation, understanding and complying with new roles and requirements is crucial for maintaining market access and ensuring patient safety. The introduction of the Person Responsible for Regulatory Compliance (PRRC) role mandated under the Medical Device Regulation (MDR) 2017/745 and the In-vitro Diagnostic Device Regulation (IVDR) 2017/746 has created a pivotal position within organisations, necessitating a deep understanding of its responsibilities and integration into existing systems.

This course is designed to address these challenges and provide participants with the necessary knowledge and tools to effectively implement the PRRC role within their organisations.

This comprehensive one-day course will delve into Article 15 of the regulation in detail, ensuring a thorough understanding of each requirement's intent. Participants will also be briefed on the UK MDR requirements and the proposed Qualified Person (QP) role, based on the latest information.

A key focus will be the integration of the PRRC role into the Quality Management System, supported by real-world examples to illustrate practical applications. The course will explore the provision of PRRC services by third parties, addressing how to meet all requirements remotely from the manufacturer.

This course offers an excellent opportunity to grasp the significance of the PRRC role and its critical place in your organisation, equipping you with the insights and practical strategies to ensure compliance and regulatory success.

Benefits of Attending

- **Understand** the role and responsibilities of the PRRC
- **Identify** ways of incorporating the PRRC role into your organisation and Quality Management System
- **Compare** the EU PRRC role with the proposed UK MDR Qualified Person role
- **Gain** a clearer understanding of the PRRC role for those considering whether they should undertake this

Who should attend?

This course is ideal for those seeking to understand the role of the Person Responsible for Regulatory Compliance (PRRC), and those currently holding or considering the PRRC designation within medical device companies, including:

- Quality managers/specialists
- Regulatory affairs professionals
- Start-up organisations with a need to understand where the PRRC role is required
- Compliance engineers
- Medical device manufacturers
- Those considering undertaking the PRRC role

Reviews

★★★★★

I accomplished a better understanding on the role of the PRRC. Very knowledgeable [speaker] with a good presentation style.

Adrian Dunleavy
UK Quality & Regulatory Manager
Freudenberg Performance Materials LP
May 22 2025

★★★★★

The content was structured logically and could be followed easily. The atmosphere was friendly and inviting to participate/ask questions. [Speakers were] competent, very helpful, friendly and patient with us.

Elena Louisa Lange
Quality Management Officer
Farstar medical
Jan 23 2025

★★★★★

The training successfully addressed Learning more about the role and responsibility of the PRRC. Content and presentation all good. Not too formal, not too informal. Just right. Speakers [have] Great knowledge about the subject.

Wessel Nomen
PRRC/Engineer
Enraf-Nonius
Jan 23 2025

★★★★☆

I was hoping to gain a better understanding of the role of the PRRC, in particular the expectations placed upon them. This was achieved. Overall a very good training session.

Chris Hooper
Qualified Person and Group Quality Manager
Diomed
Sep 22 2025

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:



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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.

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