ASPHALION
MedTech

Your trusted partner and EU Authorised Representative

EC REP

As your trusted partner and EU Authorised Representative Asphalion will guide you to comply with European regulations for Medical Devices and IVD:

- Contact point with EU Competent Authorities and Notified Bodies
- Support with Medical Device and IVDs registrations, as required
- Keeping Technical Documentation and Declaration of conformity available upon Health Authorities request
- Regulatory intelligence: stay always up to date on legislation changes and how they can affect your products

Why work with Asphalion?

- Expert MedTech professionals
- Good communication
- Similar business culture
- Strict confidentiality
- Full life cycle support
- Cost-effective solutions

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ASPHALION MedTech

Asphalion PRRC Services

Compliance Made Easy

What is a PRRC?

The PRRC, or Person Responsible for Regulatory Compliance, is a new role introduced by the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR).

The PRRC is responsible for ensuring that a medical device manufacturer complies with all applicable EU regulations.

This includes ensuring that the manufacturer's quality management system (QMS) is compliant, that the devices are designed and manufactured safely, and that they are properly marketed and post-market surveillance.

Key PRRC's Requirements

The PRRC must have the following qualifications:

- A university degree or equivalent in a relevant field, such as engineering or law.
- At least 3 years of experience in regulatory affairs for medical devices.
- Knowledge of the EU MDR and IVDR.
- The ability to have high communication skills.
- The PRRC must be permanently and continuously available to the manufacturer. This means that they must be able to respond to inquiries from notified bodies, competent authorities, and other stakeholders at any time.

Key PRRC's responsibilities

The PRRC have the following key responsibilities:

- Overseeing the manufacturer's QMS.
- Ensuring that the manufacturer's devices comply with all applicable EU regulations.
- Preparing and submitting regulatory documentation, such as the Declaration of Conformity and the Technical Documentation.
- Responding to inquiries from notified bodies, competent authorities, and other stakeholders.
- Participating in audits and inspections.
- Reporting on regulatory compliance to the manufacturer's management.

Why do you need a PRRC?

The PRRC is an important new role under the EU MDR and IVDR. By ensuring that manufacturers comply with all applicable regulations, the PRRC helps to protect patients and ensure the safety of medical devices on the EU market.

If you are a medical device manufacturer, you need to ensure that you have a qualified PRRC in place. If you do not have in-house resources to provide this function, you can outsource the PRRC service to a qualified consultancy firm entering into a contract that specifies the consultant's responsibilities and liabilities.

How can Asphalion help you?

At Asphalion we can help you with your PRRC needs. We have a team of experienced regulatory experts who can provide you with the support you need to comply with the EU MDR and IVDR. We can help you with all aspects of the PRRC process: from qualification and appointment to day-to-day support. We can also help you with other regulatory affairs matters, such as product registration, documentation preparation, and audit support.

Don’t navigate the complexities of EU MDR and IVDR alone. Contact Asphalion today to ensure your compliance and protect patient safety.

PRRC Trainings

At Asphalion, we organize trainings for individuals who will be appointed as Person Responsible for Regulatory Compliance (PRRC) by manufacturers or Authorized Representatives.