ASPHALION MedTech

# Regulatory Representation Made Simple

## Your trusted partner for US, UK & EU Compliance

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# European Union Authorised Representative (EU AR)

As your EU Authorised Representative Asphalion **helps you achieve and maintain compliance with European Medical Device and IVD regulations.**

# How We Support You as Your EU AR

- **Primary point of contact** with EU Competent Authorities and Notified Bodies.
- **Support** with **Medical Device and IVD registrations**, where required.
- Maintain **Technical Documentation and the Declaration of conformity ,** making them available to Health Authorities upon request.
- **Regulatory intelligence**: stay up to date with legislative changes and understand how they may impact your products.

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# United Kingdom Responsible Person (UKRP)

Acting as your UK Responsible Person, **representing your company** before the **MHRA** and fulfil the **regulatory obligations on your behalf.**

**Leveraging our in-depth knowledge of UK and EU regulations**, we help you define the most effective **regulatory strategy,** tailored to the specific requirements, challenges, and opportunities of the UK market.

# How We Support You as Your UK RP

- **Primary point of contact for the MHRA,** ensuring timely responses to requests and inspections.
- Support wih the **Registration of Medical Devices** with the MHRA.
- **Regulatory Intelligence:** monitor changes in UK legislation and assess their impact on your products.
- **Management of incidents** an complaints in accordance with UK regulatory requirements.
- **Notification of reportable incidents** and complaints to MHRA.
- Support with **UKCA marking** for both new and CE-certified medical devices **transitioning to the UK market.**

# United States Agent (US Agent)

The **FDA requires** requires all foreign medical device manufacturers to appoint a **US Agent** to act as their official representative in the United States.

At Asphalion, we provide comprehensive **US Agent services** to help medical device manufacturers establish and grow their presence in the US market.

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# How We Support You as Your US Agent

- Assistance with **FDA registration** and device listing requirements.
- **Expert guidance on US regulatory** and compliance requirements for Medical Devices.
- Support for **post-market reporting obligations**, including adverse event reporting, corrections, and removals.
- **Coordination and communication with FDA** on behalf of the foreign manufacturer.
- Assistance with **FDA inquiries and request for information,** ensuring **timely** and **compliant** responses**.**

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# Why work with us?

- **Multidisciplinary team: clinical & regulatory affairs and quality assurance**
- **Pragmatic approach to guide medtech developers**
- **Experience with a wide variety of medical technologies**
- **Flexible collaboration model for start-ups, SMEs and large companies**
- **Optimization of Time to Market**

## Do you need **support with the EU, UK or US markets?**

**Contact us:**
info@asphalion.com