ASPHALION
MedTech

# Are you looking for a reliable partner to help you navigate the complex regulatory landscape for Medical Technologies in the UK?

**As your UK Responsible Person we will not only assume the representative role with MHRA on your behalf, but also will provide you with:**

1. Responsiveness to any request and/or inspection from MHRA
2. Support for the Registration of Medical Devices with the MHRA
3. Regulatory Intelligence to monitor any change in local legislation
4. Management of incidents and/or complaints
5. Notification of incidents and/or complaints to MHRA
6. Support for the UKCA approval for new and CE certified medical devices

**With high knowledge and understanding of the EU and UK regulations and hence, their differences and synergies, we will assist you on establishing the best regulatory strategy considering the unique challenges and opportunities of the UK market.**



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# Are you a medical device manufacturer looking to sell your products in the United States?

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

**At Asphalion, we offer comprehensive US Agent services for medical device manufacturers looking to expand their business in the US market.**

**As your US Agent, we provide:**

1. Assistance with FDA registration and listing requirements
2. Expert guidance on US regulations and compliance requirements
3. Support for post-market reporting obligations, including adverse events, corrections, and removals
4. Coordination with FDA on behalf of the foreign manufacturer
5. Assistance with communications with FDA, including responses to inquiries and requests for information

**Our team of regulatory affairs experts has extensive experience working with medical device manufacturers and navigating the complex regulatory landscape in the US.**

**We are committed to providing our clients with the highest level of service and support to ensure compliance with all relevant regulations and requirements.**



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