Advena Ltd UK - Medical Device Regulatory Consultant/Specialist

Advena are an established, respected Medical Device Regulatory Consultancy based in the heart of Warwickshire. We are a team of highly experienced regulatory professionals specialising in providing affordable, honest, medical device regulatory advice and support to small/medium sized medical device manufacturers and start-ups, to achieve EU/UK/US regulatory compliance

KEY PURPOSE OF THE ROLE:

- To provide IVD/Medical Device Regulatory and Quality Management consultancy for Advena Ltd clients and prospective clients
- Fully support the Managing Director
- Maintain clients Technical Files to ensure compliance to current UK/EU Regulations

RESPONSIBILITIES OF THE ROLE:

- To provide accurate and current medical device regulatory and quality management advice to all Advena Ltd.'s client base and prospective clients.
- Prepare, review, and approve data elements for use in regulatory technical files in accordance with UK/EU/US requirements for medical devices and IVD's
- Liaising with external regulatory authorities to ensure approvals are obtained in line with project schedules
- To perform visits to clients' premises (or other location at client's request) to conduct regulatory/ quality meetings, audits, and any other relevant regulatory requirement
- To provide support to other members of the team and Managing Director, when requested
- Oversea regular communication with clients to provide accurate and concise updates on regulatory changes that could affect their businesses
- To ensure clients comply with the organisation's ISO 13485 accreditation
- To represent the company in a professional and courteous manner.

We offer a competitive salary to the right candidate and Company Pension Scheme.
Salary Range: £45-£65k dependant on experience