Quality First International

Your stepping stone from the drawing board to the patient

Does your medical device require new or additional clinical data to be cleared for marketing?

Whether you are preparing a device for CE marking, a filing with the FDA or collecting data for post-market reimbursement or surveillance, do you know if it will require clinical data to demonstrate clinical safety and effectiveness? If so, what clinical data will be needed in Europe or the USA, and what about other countries such as Japan and Canada? Do you know which clinical sites are best for your particular study and how best to design the trial to produce reliable data? Which authorities must approve your trial and what kind of documentation will they need to process your submission without delays?

Quality First International's Clinical Trials Program

Having managed numerous clinical studies in multiple countries, Quality First International's Clinical Trials Program will fulfill all your medical device clinical investigation requirements. Regardless of the type or class of device or drug/device combination, Quality First International will conduct, monitor and manage your clinical trial to verify the performance and safety of your device.

Clinical Trial Management

What are all the steps and requirements for a Clinical Trial? Are you confident about designing a suitable study, preparing a study protocol and then managing the study? Are there new or changed requirements that must be considered? As a Clinical Research Organization, Quality First International can manage every aspect of your trial. Working to international standards, practices and regulations, Quality First International can plan, design and implement your clinical investigations and can work in several languages.

QFI has extensive experience in the following:

- **Preparing submissions to Ethics Committees/IRBs**
- **Submitting applications to the appropriate regulatory authority**
- **Performing feasibility studies**
- **Designing clinical trial protocols**
- **Preparing Case Report Forms**
- **Helping recruit an investigator and locate a suitable clinical site**
- **Coordinating the clinical trial**
- **Monitoring the trial's conduct**
- **Coordinating with core laboratories**
- **Analyzing clinical data**
- **Outlining key results in a technical summary**
- **Preparing interim and final reports**
- **Conducting post-market studies**

Study Monitoring

Quality First International offers study monitoring including data query handling, initiation visits, routine intra-study visits and close-out visits and ensures the study fulfills legal requirements and passes all quality audits.

Regulatory Assurance

What Ethics Committee and Competent Authority approvals will you require and how to obtain them? Quality First International has excellent contacts within Ethics Committees and regulatory authorities all over the world. We can ensure that your medical device achieves worldwide regulatory acceptance, irrespective of where it is to be marketed.

QFI is experienced in preparing clinical trial applications for the:

- **US Food and Drug Administration**
- **European Medical Devices Directives**
- **Japanese Ministry of Health, Labour and Welfare**
- **Canadian Medical Devices Conformity Assessment System**

Quality Assurance

Are you aware of the quality assurance requirements that will protect your time and financial investment in the clinical trial? A quality assurance failure cannot only cause a loss of the investment but can cause delays in reaching the market that may be months or even longer. Quality First International can provide you with quality assurance at any stage of the clinical trial process.

QFI provides independent audit of a clinical trial including:

- **Investigator site audit**
- **Trial master file audit**
- **Database audit**

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Quality First International (QFI) is a London-based medical devices consulting company specializing in solving its clients' regulatory, technical and compliance challenges to enable medical devices to enter the global marketplace. Since 1995, Quality First International has provided regulatory advice, quality assurance and clinical trial services, with particular emphasis on the European, USA, Japanese, Australian, Canadian and Chinese marketplaces. All submissions made by Quality First International have fulfilled compliance requirements first time round, consistently. Clients range from start-up companies to multinational organizations, primarily developing a broad range of cutting-edge, minimally invasive and cardiovascular products and implants.

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