Job Title: Regulatory Affairs Consultant

Job Sector: MedTech and HealthTech

Hours of work: full-time, 40 hours/week

Place of work: fully-remote, must live in Ireland

Salary guide: €45,000 to €65,000.

An enhanced benefits package will be considered on successful completion of 6-month probationary period. Membership to The Organisation for Professionals in Regulatory Affairs (TOPRA) and to Team-PRRC is provided on engagement.

Travel throughout Ireland, rest of EU and UK will be required in order to attend: face-to-face team meetings; visit clients on-site; deliver presentations; attend training courses: and attend conferences and networking events as an ambassador for the company. There may be a need for long-haul travel but this is likely to be occasional only. It is anticipated that no more than 25% of the role will require travel.

Company devices are provided and a virtual ergonomic/health & safety assessment of the home workstation will be undertaken. Any additional equipment needed to ensure a safe and healthy home working environment will be provided by the Company.

The Company

Med-Di-Dia is a regulatory affairs and quality compliance consultancy focused on the Medical Device, Digital Health, Diagnostic and general HealthTech sectors. From Ireland, we provide a full range of Regulatory Affairs and Quality Compliance consultancy services to both local and international clients with the full support and guidance of the parent company, Global Regulatory Services (GRS).

We are on a mission to be the leading Medical Technology Regulatory Affairs and Quality Compliance Consultancy in Europe. Our key goal is to be the 'go to' consultancy. We are determined to cut through the maze of regulations and be a risk partner in the journey to the market never forgetting that, at journey's end, patients will be the beneficiaries.

Med-Di-Dia is a dynamic company with an adaptable and flexible approach to our clients and their projects. Invariably this means that we attract many University and Multinational spin-outs, start-ups, and SMEs by getting involved at the design stage and assessing innovative technology to determine classification and regulatory pathways to market. Currently, a large proportion of our work is strategic, helping companies to map out scale-up and commercialisation activities in order to present this information as part of their business plan to potential investors. Of course, as part of this scale-up, all companies need a good Quality Management System in order to support their future success.

Med-Di-Dia is also acting as the EU Authorised Representative (EUAR) and Person Responsible for Regulatory Compliance (PRRC) for an ever increasing number of MedTech companies.

Our consultants are both specialists and professionals with the ability to work on multiple projects simultaneously with no two days being the same. If you like variety and the opportunity to engage directly with prospective and existing clients about their innovative technology in order to scope out how you and Med-Di-Dia can support them in achieving their goals, then you are definitely well on the road to being a consultant.

The directors are warm and welcoming with an emphasis on community, family, support, and education. They provide a friendly and safe environment for consultant staff to grow and develop in areas of the business that interest them most. They encourage individual contribution and through training, career opportunities, personal and professional development, they allow everyone the opportunity to learn, become specialists and prosper.

Med-Di-Dia employees have ready access to full and comprehensive support from the parent company's worldwide network of regulatory and quality compliance specialists.

Make Med-Di-Dia's success, your success

For the right candidate, we'd love you to become an integral member of our team, helping us to continue to lay down solid foundations, to grow and develop a successful, sought after consultancy. We will provide you with the opportunity to expand the breadth as well as depth of your knowledge with respect to devices, in-vitro diagnostics, combo products (device-drug delivery), quality management systems, software/mobile apps, digital health, robotics, fitness/wellness products and more.

Role & Responsibilities

General and Routine activities

- Act as an Ambassador for the Company
- Lead, mentor, and train team members as required
- Effectively communicate to internal stakeholders
- Plan and conduct meetings, create project plans and timelines, and effectively manage projects for on-time delivery
- Help clients to classify their technology and develop their regulatory strategy (EU, UK, US and RoW), a particular challenge if a 'borderline' device
- Expertise to ensure successful EU CE Mark and/or UK CA Mark registration
- Advice, guidance, and implementation of all mandatory standards, such as ISO 13485:2016 (Quality Management Systems)
- Supporting clients to transition from EU MDD to EU MDR
- Selection and liaison with EU Notified Bodies and UK Approved Bodies
- Represent clients to the Regulators, as and when necessary
- Review, advise and/or compile Technical Files
- Support to create, implement and maintain compliant Quality Management Systems (QMS)
- Perform internal audits for clients and provide support throughout formal audits by the Regulators
- Help develop and maintain all internal company policies and procedures

Med-Di-Dia's legally responsible services

- For micro and small companies, appropriately qualified Company consultants are named as Person Responsible for Regulatory Compliance (PRRC) for both the Company and our clients
- For non-EU and UK companies, we function as the Authorised Representative within Europe
- For UK institutions running EU-wide clinical trials, we are the Legal Representative to ensure continuity of company trials post-Brexit
- For non-EU Health and Beauty manufacturers, we are their EU Responsible Person

Promotional activities

- Attend conferences and networking events as an Ambassador for the company
- Deliver presentations (face-to-face or online) for training purposes or to raise the profile of the company
- Support the Marketing Department in the creation of educational blogs and posts and any other promotional literature, as and when required

This is a forward-facing, fast-paced role where you will:

- Create and maintain a positive working relationship with clients to facilitate efficient accomplishment of regulatory goals
- Respond to queries from all clients and prospective clients
- Provide services to clients with guidance and support from the parent company, GRS (if needed), including liaison with regulatory authorities as and when necessary
- Conduct due diligence to bring all clients into full compliance with the appropriate regulations and guidelines
- Actively participate in internal and external project teams, as required
- Maintain current knowledge of regulations, standards, and guidance documents by gathering, monitoring, and analysing regulatory information and data to track developments in the changing regulatory environment to maintain Subject Matter Expert status
- Promote Med-Di-Dia through networking, workshops, and presentations etc
- Liaise with and engage support of management on all leads and activity

Our best people

- Enjoy juggling multiple projects and supporting clients through the maze of challenges along the journey towards regulatory compliance
- Embrace variety, are flexible and adaptable – no two days are the same!
- Have a 'can do' attitude where no job is too big or too small
- Are happy to 'muck in' for the reward of completing projects on time so that innovative devices can be commercialised for the benefit of patients and clinicians
- Are able to combine knowledge of scientific, regulatory and business issues to ensure compliance with evolving regulatory requirements
- Have a proven track record of effectively communicating, liaising and negotiating with various regulatory authorities
- Effectively and accurately write and edit technical documents
- Have demonstrable prior management and positive mentorship experience
- Bachelor's degree in science, engineering or medical fields
- Significant experience in regulatory affairs and quality management systems relating to Medical Devices or Diagnostics (with exposure to Pharma a bonus)
- Expertise with Software as a Medical Device (SaMD) and IEC 62304, a bonus
- Software development experience including Agile and traditional development methodologies as well as embedded software and PC/Mobile applications will be a bonus
- Good problem-solving skills a must
- Excellent knowledge of European medical device or diagnostic regulatory requirements
- Familiar with medical device technical files and all inputs, including biocompatibility, shelf life, bench testing, etc
- Experience writing clinical evaluations and risk management reports a plus
- Knowledge of ISO 13485 and other quality systems
- Knowledge and experience of auditing quality systems a bonus
- Ability to self-manage multiple projects, workload, and timelines in order to consistently meet deadlines

- Remote working means being able to work on your own but must also maintain awareness of the needs and objectives of the Team and, therefore, must be able to work effectively and proactively in cross-functional teams
- Clear and effective verbal and written communication skills with diverse audiences and personnel
- Strength of character, knowledge, and confidence to be able to inform clients, with diplomacy and respect, what they need to do rather than what they want to do
- Good listener with mutual respect for colleagues and clients
- Logical approach to work, views problems as challenges, calm under pressure

<u>NOTES</u>:

- *This job description is not intended to be all-inclusive.*
- *Employee may perform other related duties as assigned or negotiated to meet the ongoing needs of the organisation.*
- ***Applicant does not need to meet all requirements. If they have the right character and 'can do' attitude, this is more important than meeting all requested qualifications and criteria as stated in this document.***