

Position: Regulatory Officer

Are you a commercially focussed and experienced compliance professional who can support creative design projects? If so, we have an exciting opportunity to join i4PD as a Regulatory Officer. You will thrive being in a fast-paced environment that requires proactive people who are comfortable acting on their initiative and able to guide and navigate the compliance industry with technical and non-technical stakeholders alike.

i4PD are undergoing an exciting period of growth. You will join our existing regulatory team here at i4PD to support multi-disciplinary projects involving product design, mechanics, electronics and software. With a continual focus on quality, you will liaise not only internal teams but our clients and engineering partners to support full-lifecycle product development. Your client engagement skills will be honed to enable you to define clients' regulatory strategy and compliance requirements in order to bring a project through gold standard design & development in line with ISO 9001 & ISO 13485 and set them up for future certification.

As an employee-owned business, i4PD has a focus and commitment to nurturing inclusiveness and a desire to succeed as a collective. We boast a diverse team of people with a wide range of personalities who are attracted to the:

- involvement in a variety of exciting technical projects.
- the chance to consistently learn new skills.
- the fast pace and stimulating daily challenges presented.

Success brings rewards, and on top of a great working experience with a diverse range of interesting technical projects, on offer is a competitive package which is complemented by way of a company performance profit share (up to tax free limit).

We recognise the value to our staff of maintaining a strong work/life balance which we foster through flexible and hybrid working arrangements, while also supporting continual training and development. You will undertake a 37.5 hour week of flexible hours Monday to Friday (around core hours of 10am to 3pm).

Requirements & Skills

- Form a key part of our product design & development team, coordinating compliance activities within our projects alongside our clients and internal i4PD personnel.
- Ensure that work carried out by yourself and the i4PD team is conducted to a consistent and high standard in accordance with our ISO 9001 & ISO 13485 Quality Management System.
- Have minimum 3 years' experience within medical device, machinery, low voltage, electromagnetic compatibility regulations/directives across territories such as Great Britain, Europe and USA.
- Produce or assist in the production of high quality, accurate compliance documentation, demonstrating organisation and traceability through our development projects.
- Have strong communications skills, able to guide your project team members, clients, and stakeholders through compliance processes and requirements in a clear and concise manner.
- Have familiarity with standards, tasks and documentation required to meet risk management processes, usability engineering and software development along with other typical standards for medical and electronic device development.
- Have experience working on your own and with multi-disciplinary teams and be able to demonstrate a deep understanding of how projects should be planned, organised, and executed as you will be managing compliance tasks with your own projects with budgets & timelines, preparing proposals and supporting business development activities.
- Need to demonstrate that you are personable and approachable to both clients and our internal team alike. You should be able to listen to others and respond to their questions or concerns in a way that makes them feel heard and that improvements/feedback is implemented as required.

Key Responsibilities

- Following the company's QMS to ISO 9001 & ISO 13485 as applicable.
- Maintaining your knowledge in the regulatory compliance industry.
- Analysing project briefs, identifying and clarifying issues for the creation of project proposals.
- Providing guidance to i4PD personnel, clients, and stakeholders on regulatory aspects of the project as required.
- Drafting, signing and delivering regulatory documentation as required by the project plan including regulatory strategy reports.
- For communicating with clients: presenting deliverables, challenges, risks on regulatory aspects of the project as required.
- For supporting or chairing workshops relating to the project plan as required.
- Leading discussions with test houses.
- Alerting team leads/PMs to requests from customers that were not part of scope of work assigned.
- Capturing project change requests and assisting with assessment of regulatory impact.
- Financial administration with regards to regulatory aspects of the project as required.
- Contributing to continuous improvement of the regulatory team and the quality of their output.

Package

This is a superb opportunity to join a forward thinking and successful employee-owned SME business. In return you can expect a highly competitive salary & company workplace pension within a challenging and supportive culture and the opportunity to grow your career.

- Industry competitive salary.
- Enhanced 10-week full Maternity Pay / 4-week full Paternity Pay.
- Full time employees receive 30 days holiday (including public holidays which can be taken at any time).
- Enhanced holiday entitlement (up to 40 days) dependant on years of service.
- Holiday purchase scheme (you can "buy" up to 10 additional days holiday).
- Hybrid working - office based for minimum 3 days/week
- 7.5hr days with flexibility in working hours.
- Tax free bonus (up to £3,600 for those that have served a minimum of 12 months continuous service)
- Cycle 2 Work Scheme
- Electric Vehicle Scheme.

How to Apply

Email jobs@i4pd.co.uk quoting job reference '**RO0424**'.

You must include the following:

- Your CV.
- A covering letter describing what you would bring to the team and highlights experience of your compliance role within product development projects.