Vacancy For Regulatory Affairs Specialist

NIPD Genetics is a leading innovative biotechnology company active in the fields of developing, engineering, and providing genetic testing solutions, and clinical laboratory tests in the fields of haematoglogy, microbiology, immunology and biochemistry. NIPD Genetics consists of a world class dynamic team of experts with extensive experience in biotechnology, business, human genetics, molecular biology, bioinformatics, haematology, microbiology, immunology and biochemistry. NIPD Genetics is the trusted partner of labs and healthcare professionals worldwide. We provide advanced genetic and clinical testing services from our CAP-accredited, CLIA- and ISO-certified laboratories.

THE POSITION

We seek to recruit a Regulatory Affairs Specialist for full time employment. This role can be challenging since the selected candidate will need to meet tight deadlines. It can also be rewarding when a new product is successfully registered.

PROFILE OF THE IDEAL CANDIDATE

The ideal candidate will be able to provide support with the CE marking of company's medical devices by performing conformity assessment activities and preparing documentation required. You will aid with transitioning from IVDD to IVDR and the associated remediation work involved.

RESPONSIBILITIES

- Ensure that company's products comply with the regulations of the regions where they are distributed.
- Keep up to date with national and international legislation, guidelines and customer practices
- Compile and maintain regulatory documentation such as technical files/dossiers which will be in compliance with IVDR and ISO 13485:2016.
- Advise scientists on regulatory requirements and coordinate efforts associated with the preparation of regulatory documents or submissions
- Undertake and prepare for regulatory inspections and participate in internal audits
- Participate in external audits
- Liaise with regulatory authorities
- Interpret regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures
- Provide technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
- Review product promotional materials, labeling, batch records, specification sheets, or test methods for compliance with applicable regulations and policies.
- Advise project teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues.
- Desk-based role involves the close study of scientific and legal documents. You'll work closely with scientific colleagues, often on a project-team basis.

REQUIREMENTS

- BSc in Biological Sciences or related field. A Master's degree is considered an advantage.
- Understanding of both legal and scientific matters
- The ability to grasp new concepts quickly and to assimilate and evaluate scientific data
- Analytical and problem-solving skills
- Written and oral communication skills
- Attention to detail
- The ability to work under pressure and to strict deadlines
- The confidence to report to management
- Team-working skills
- Integrity and a professional approach to work

- An awareness of the IVDD and/or IVDR
- Good knowledge in both English and Greek languages

APPLICATIONS

To apply please forward your application with subject: **Vacancy For Regulatory Affairs Specialist** to NIPD Genetics at the following e-mail address: hr@nipd.com.

For further information, please contact the Human Resources Department at Tel. 22266888 or visit www.nipd.com.

All applications are strictly confidential.