contact@lne-america.com 1-301-495-0477 lne-america.com

LNE/G-MED North America, Inc.
Development and Certification Department - Medical Division
3930 Knowles Avenue, Suite 306 - Kensington, MD 20895 USA

Certification Project Manager
Active Medical Device

Join the LNE/G-MED team today
and work on the frontier of Medical Device Innovation!

Location(s): North Bethesda, MD
Contract Type: Perm Full-Time
Fields: Medical Device, In Vitro Diagnostics – Healthcare
Salary: Competitive Salary

About G-MED North America, Inc

G-MED NA is the North American subsidiary of the National Metrology and Testing Laboratory, LNE, a leading Certification Body established in 1901. We serve the Medical Device Industry with offices in Europe and the United States. Our goal: Provide the best in Product Certification and Quality Management Services for Medical Device Manufacturers worldwide.

In addition to our CE marking, ISO 9001:2015 , ISO 13485:2016 and MDSAP certification services, **LNE/G-MED** is accredited by the Standards Council of Canada SCC under the Canadian Medical Devices Conformity Assessment System CMDCAS and is an Authorized Organization for the Medical Device Single Audit Program MDSAP. Our full range of technical conformity services, from Diagnostic audits to Training services, allows the convenience and efficiency of a local based team of Technical Experts, Assessors, Auditors and Certification Program Managers.

LNE/G-MED North America is an Equal Employment Opportunity. For the US, we offer excellent benefits package including a group-sponsored health, dental and vision coverage, short-term and long-term disability, a company-matched 401k plan, a company paid life insurance, paid holidays and time off.

About the Certification Project Manager:

The **Certification Project Manager – Active Medical Device** is the technical go to person and the main contact for the company. His/her main mission is to coordinate all of the certification activities required for the project and ensure that the communication between the client, the auditor(s), and the certification committee is performed adequately. The **Certification Project Manager – Active Medical Device** is very familiar with the medical device technology he manages and available for the client's certification process and needs. He/she can be a qualified Lead Auditor and must know the auditing and certification processes inside and out.

The successful candidate will manage and conduct certification activities in accordance with LNE's procedures, processes, policies for:

- Quality Management Systems according to ISO Standards ISO 9001:2015 and ISO 13485:2016
- CE Marking certification under the applicable European Medical Devices Directives:
  - ✓ Medical Devices 93/42/EEC (MDD),
  - ✓ Active Medical Device Implantable 90/385/EEC (AIMD)

- Quality Management Systems under the requirements of the Canadian Medical Devices Conformity Assessment System (CMDCAS)
- Quality Management Systems under the requirements of the Medical Device Single Audit Program MDSAP

Role and responsibilities:

- Comply with LNE's procedures, processes, policies for management of clients and projects.
- Manage a portfolio of active medical device certification projects: act as the technical point of contact for the customer, project manage certification files from A to Z; evaluate the need for follow-up audit(s); oversee the audit planning; schedule, lead or actively participate to certification committees; issue reporting in a timely manner, manage results and correspondence with the customer and LNE/G-MED operations (Audit team, Scheduling and Finance department).
- Comply with the training plan defined by the Regulatory, Quality and Education Department to maintain and/or increase qualification(s).
- Embody LNE's values and commitment in both internal and external communication to organizations (client communication, events, conferences etc.).
- Any other assignments as needed to meet assessment delivery business objectives

About the candidate's profile

- At least a Bachelor degree in **Life science** (Biology, Chemistry or Physics) or **Engineering degree** (Biomedical or Bioengineering, Electrical, Mechanical)..
- At least **2-3 years of work experience in the Medical Device Industry** in one or more of the following roles: Quality Assurance/Regulatory Affairs, Research and Development R& D, Design, Manufacturing etc.
- Knowledge of and experience working with Quality Management Systems specifically with ISO 13485 and ISO 9001.
- Knowledge of the **European Medical Device regulatory scheme** : Medical Device Directive 93/42/EEC including the Active Implantable Medical Device Directive 90/385/EEC, and In Vitro Diagnostic Medical Device Directive 98/79/EC, and understanding of the European Regulations
- Preferred: trained as QMS auditor
- **Outstanding critical thinking and analytical skills**
- Process orientated to deliver business success
- **Sensitivity to detail with excellence in accuracy will be critical** to job performance success.
- Excellent writing, editing and time management skills
- Possess interpersonal skills, both oral and written, and the ability to work well with all levels of internal and external management and staff
- Ability to coordinate and participate actively in meeting presentation and events (including clients' visit and conference)
- Experienced in Microsoft Office Suite (Outlook, Word, Excel, and PowerPoint)
- Ability to handle confidential and sensitive information with the utmost professionalism
- Must be flexible and able to work independently and execute projects with minimal supervision.
- Team player and excellent communicator
- Fluency in English is essential and other language skills desirable (French or Spanish)
- **Authorized to work in the US**

This position has an education requirement. You are strongly encouraged to submit a copy of your diploma(s) together with a resume and cover letter.