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

Lead Auditor
ISO 13485 and CE marking

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

Location(s): This position can be remote and located anywhere in North and South America, Israel
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 Lead Auditor:

The successful candidate will conduct professional certification audits as Lead Auditor in accordance with LNE' 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)
  - ✓ In Vitro Diagnostics devices 98/79/EC (IVDD)

- 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:

- Manage assigned customers' audits: organize travel plans, conduct audit visits and assessments, issue reporting in a timely manner, manage correspondence with customer and LNE/G-MED operations (including Certification Project Manager, Planning and Financial teams)
- Attend mandatory trainings and Auditors' day
- Comply with the training plan defined by the Regulatory, Quality and Education Department to maintain and/or increase qualification(s).
- Provide training when applicable based on certification/experience and business needs.
- Embody LNE's values and commitment in both internal and external communication to organizations (client communication, events, conferences etc.).
- Lead audit team(s), and coach new or inexperienced team members if needed.
- Any other assignments as needed to meet assessment delivery business objectives
- Minimum of 70% travel to and from clients, both land (car) and air travel

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 4 years of work experience in one or more of the following roles: minimum of 2 years in Quality Assurance/Regulatory Affairs and 2 years in the Medical Device field (Research and Development R& D, Design, Manufacturing…).
- Medical Device Auditing experience, ideally with another certification body
- Certified Lead auditor for ISO 13485, ISO 13485 within CMDCAS program and/or MDSAP, ISO 9001 with a recognized certification body
- Knowledge of the European Regulations
- Good knowledge of the Medical Device industry constraints and applicable transversal standards (Risk Management, Biocompatibility, Sterilization, Packaging, Validation…)
- Recent experience as Medical Device Lead Auditor with a Notified Body
- Must be literate in the use of MS Office applications
- Strong analytical skills
- Excellent written and verbal communication skills
- Result oriented: Demonstrated ability to prioritize and focus on deadlines
- 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.