Quality Assurance Engineer for Medical Device company #2224

Responsibilities:
The job holder's duties and responsibilities include any of the following:

Responsible for relevant procedures implementation
Writing and developing procedures, reports and associated quality documentation
Ensure compliance with regulatory requirements at all levels
Administration of specific quality documentation and document control
Getting and providing training in the relevant areas
Supporting Global Objectives, Improvements projects and QA plans
Supporting for data gathering, analysis and reporting, such as periodical QA and management reviews
Review and approve documentation (such as procedures, protocols and reports)
Assist in the failure investigation of product complaint and CAPA/ correction activities
Ensure DHF, DMR and DHR completeness and correctness in all product's lifecycle stages
Active participation in regulatory inspections (e.g. 21CFR820. ISO13485,MDD, CMDCAS, MDSAP, MDR), and other external and internal audits, including investigations and further CAPA/ corrections
Supporting incoming inspection, IPC, final testing, MRB/NCM processes
Supporting or leading internal and supplier audits
Provide investigative support when significant product quality issues
R&D / D&D quality guidance and support (DR/ TRR meetings, documentation review and approval)

Requirements:
Relevant formal education in quality, quality engineering, engineering.
At least 5 years of relevant previous experience in medical devices, pharmaceutical, biology or cosmetics industries.
Formal training records on QMS typical activities such as internal and supplier audit, CAPA and complaints management, documentation writing and review, management review, R&D QA support, NCM/ MRB management, etc. is a plus.
Familiar with specific standards such as 21CFR820, ISO 13485, 60601, 62304, ISO 14971 among others.
Experience interacting with operators abroad, mostly USA. Written and verbal communication high levels and skills. Other foreign languages are a plus.
Capability of carrying out technical and quality investigations, from data gathering to conclusion, including root cause analysis and action plan follow up.

Location: Haifa
CV TO: jobs1@stepup-hr.com