RA and QA manager

Job Responsibilities:

1. Regulatory support and registration of the company product at various countries.
2. Plan, direct, or coordinate production activities of an organization to ensure compliance with regulations and standard operating procedures.
3. Responsible of establishing and maintenance of technical files.
4. Establishment, maintenance and management of QA system and document control per internal and external regulatory requirements.
5. Responsible for company's product quality and reliability to meet or exceed customer expectations
6. Responsible for company's Quality Compliance to ensure compliance with regulatory agencies and all applicable standards worldwide.
7. Develop and execute quality design and quality assurance strategy for new product development and sustaining business activities.
8. In support of the quality system, provide effective leadership support, training and guidance to all company personnel.
9. Responsible for writing/guiding employees for writing all company procedures, specifications, instructions etc.
10. Responsible for internal and external audits system.
11. Responsible for approval of finished product release.

Job Requirements:

1. Relevant education (BSc in related field and quality related education).
2. Previous experience in the medical devices or life science regulatory managements.
3. Previous experience in QA and RA of medical devices companies
4. Experience in drafting, submitting and maintaining regulatory related files (510k, technical file, etc.)
5. Experience in leading the preparation and presentation of external audits.

Please send your C.V. to Shahar.ophir@270surgical.com