QA/RA Manager

The individual will be responsible for the maintenance of our Quality Management System, creating and updating company SOP's and ensuring their correct and effective implementation across the various teams.
The QA/RA Manager will also support with the regulatory work being undertaken and be the direct point of contact for all regulatory and quality needs across the organization.

Requirements:
Bio-medical engineering BSc (MSc advantage)
· 5+ years experience as a QA Manager or similar role
· Knowledge and experience managing company ISO Audits (i.e ISO 13485)
· Experience with FDA processes, including 510k and PMA processes
· Experience with writing and implementing SOPs
· Experience initiating and completing CAPAs and reports, performing internal and external audits and trainings
· Experience effectively enforcing rules, regulations and order within a company
· Past Quality assurance experience from a medical device company
· Knowledge of regulatory requirements, and experience in drafting, submitting and maintaining regulatory related files
· Relevant education (BSc. in related field and quality related education)
· High-level English required (Native tongue preferred)

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