

# VP QA/RA

Biomedical Startup company is looking for VP QA/RA

## Requirements:

- University degree in Science or Engineering
- M.S. in a technical area or MBA is preferred.
- At least 8 years of experience in quality assurance, quality control / regulatory affairs, research, and development of medical devices.
- Working knowledge of FDA Quality System Regulations, ISO 13485, ISO 14971, 21 CFR 820, MDD/MDR understanding with a focus on design controls and risk management
- Familiarity with eQMS systems
- Experience in corresponding with regulatory agencies.
- Experience managing internal and external audits.
- Design Control experience and strong knowledge of risk management including generation of system risk documentation.
- Basic standards analysis capability, experience with statistical tools and techniques
- Knowledge of and experience with Human Factors & Usability engineering process, sterilization validation, biocompatibility
- Experience with multidisciplinary system including mechanics, electronics, and software.
- Hands-on approach.
- Strong interpersonal, written, and verbal communication skills (Hebrew & English)

CV to: [michal@insighthr.co.il](mailto:michal@insighthr.co.il)