



Location: Tel-Aviv, Israel

Datos Health is growing and looking to add a QA/RA Manager to our team!

About Datos Health:

Datos Health offers a fully automated remote care platform designed to directly connect patients with medical sources of care from the comfort of their own homes, for improved quality of life. The platform makes it possible to safely monitor, detect, analyze and predict adverse events or other changes in patient conditions – enabling care teams to communicate and intervene in real-time and to successfully manage even the most complex medical treatment protocols.

Our full-stack remote patient monitoring solution is both device-agnostic and disease-agnostic and seamlessly equips care teams with the data and tools required to manage even their most complex and chronically ill patients.

REQUIREMENTS:

Oversee all QA/RA activity for a fast-growing company, focused on Software, both in Israel and US:

- Implementation of QMS and SDLC
- Ensure that QMS requirements are effectively established and maintained
- Manage, maintain, and verify compliance with regulatory standards, to include: HIPPA, GDPR, ISO 27001, ISO 13485, FDA compliance
- Provide leadership, guidance, and corporate-level oversight to product quality teams, and other employees with responsibilities related to regulated products
- Create and maintain regular lines of communication and training to promote quality awareness, regulatory partnership, and harmonization of quality processes
- Conduct internal audits and lead external audits while providing guidance regarding best practices and continuous improvement
- Manage key quality and regulatory affairs initiatives to drive continuous improvement

QUALIFICATIONS:

- A minimum of 5+ years of experience in the development, implementation, and maintenance of a QMS (including SDLC) in a software company
- Broad knowledge of healthcare-related regulations focused on software
- Highest standards of accuracy and precision; highly organized, detail-oriented and mindful of deadlines
- Able to work under pressure and extensive working hours as needed, in a fast-paced and changing environment
- Able to lead processes and activate subcontractors and co-workers, as well as work independently
- Fluent written and spoken English
- Excellent interpersonal skills

Preferred Qualifications:

- Experience in FDA approval processes
- Highly proficient in MS Office

Please email us your resume to: careers@datos-health.com and mention QA/RA Manager in the subject line.