

Job Title:	QA/RA manager	Reporting to:	VP Quality
Department/Group:	QA	Field:	Digital Health
Location:	TLV	Position Type:	Full time
		Version:	3

Job Description

ROLE AND RESPONSIBILITIES

Overlook all QA/RA activity of 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 process
- 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 AND EDUCATION REQUIREMENTS

- 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 medical-related regulations focused on software - A Must
- 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

PREFERRED SKILLS

- Experience in FDA approval processes
- High skills in MS Office tools

ADDITIONAL NOTES

EXCELLENT interpersonal skills and teamwork

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		Date:	7.10.20