

Position: Senior Development Quality Engineer

Eitan Medical is a fast-growing global medical device company, developing and manufacturing innovative drug delivery and infusion solutions across the continuum of care- from the hospital to the home. We are looking for an excellent Quality Engineer to join the team handling Sorrel product's R&D ([Sorrel™ - Wearable Drug Delivery Device | Eitan Medical](#))

Job Description:

- As a Senior Development Quality Engineer, you will provide QA oversight and guidance to R&D as to the required deliverables to ensure compliance throughout product development cycle
- You will act as a QA leader of change controls initiated throughout the project, and for changes related to the QMS.
- You will be focal point & SME for quality related aspects as part of R&D processes and will attend R&D project routine meetings as the QA representative.
- You will establish quality methodologies for the future product (control plans & quality plans), ensures that the products meet the predetermined quality specifications, customer, and regulatory requirements.
- You will be the project QA representative in front of the pharmaceutical partners
- Review and approve deliverables and additional documents which are required for the R&D projects
- Conduct QA activities relating to data analysis and statistics, SOP reviews and approvals, audit tasks and support of non-conformity investigations.
- Test method validation- TMV plan and protocols and oversight of needs activities

Job Requirements:

- **Education:**
 - B.Sc in Engineering in one of the following fields: Medical device Quality\ Biomedical \ Biotechnology or in Bioscience education – advantage
 - CQE/CMQ from ASQ – advantage
- **Job skills:**
 - 3-4 years of experience in QA, preferably with R&D projects, in a medical device or pharma manufacturing company according to GMP and regulatory requirements (FDA QSR 820, ISO 13485)
 - Experience working in medical device product development (product design) and manufacturing (process design, process validation, and production).

**We are
hiring!**



- Auditor qualification - an advantage
- Experience in supporting sterile production and clean rooms - an advantage

- **Computer skills:** Full control of all office applications
- **Language skills:** English- writing and verbal skills- advantage
- **Personality:** Excellent communication and leadership skills, organized, motivated

Send your CV to: Dor.yamin@eitanmedical.com

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