



We are looking for a **Quality Engineer** to join our team!

**Location:** Tzur Yigal

**Bioprotect Ltd** developed a proprietary technology platform for biodegradable balloon. The technology suits a wide range of clinical applications including spacing for radiation oncology protection, aesthetics and general surgery. The company's first application in the commercialization stage is the BioProtect Balloon Implant™ System acting as a spacer for the protection of healthy tissue in patients receiving radiotherapy for prostate cancer.

**General description:** The candidate prime responsibility is to support quality activities for products to sustain and improve current products on market, as well as new product development (NPI). In addition, to ensure that the quality aspects related to production process control and improvement are effectively implemented.

**Roles & Responsibilities:**

- Supporting quality activities for products in production (in-house and outsourced)
- Oversee and assess the quality of manufacturing process
- Lead all quality processes and activities in the production line
- Develop, establish, and maintain quality-engineering methodologies, systems, and practices that meet company, customer, and regulatory requirements
- Performing incoming, in process and final inspection (product release)
- Participate in the resolution of all product rejections and returns, internal and external, call and follow-up on Material Review Board Meetings
- Leading all investigations in the production related to nonconforming products
- Work closely with Engineering to ensure sufficient documentation and standardization
- Developing and documenting manufacturing work instructions together with Engineering
- Determination of quality requirements for production and processes improvements
- Data collection and analysis of trend (e.g., MRB, Yields)
- Participate in pFMEA

**Requirements:**

- Relevant degree (e.g., biomedical, mechanical engineering or related science / technical discipline)
- At least 5 years' related experience, in a similar role, in a medical device company
- CQE – an advantage
- Experience and knowledge with standards and regulations (MDR 2017/745, ISO 13485, FDA QSR, ISO 14791 etc.)
- Experience with statistical techniques, risk analysis, 8D, Lean, root cause analysis, DFSS, Process validation etc.
- Ability to work under pressure to meet schedules and deadlines within quality and regulatory standards
- Strong verbal and written communication skills
- Strong analytical skills
- Strong problem-solving skills
- Excellent English language skills (verbal and writing)
- Experience with Class III implantable medical devices – an advantage
- Experience with working in controlled environment (clean room) – an advantage
- Experience in Medical Device NPD/NPI – an advantage
- Project management experience – an advantage

Cvs to Marianna: [marianna@bioprotect.com](mailto:marianna@bioprotect.com)