מהנדס.ת איכות בייצור

לחברת סטארט-אפ בתחום המדיקל שנכנסת לשלב מכירות בארה"ב
הזדמנות להצטרף לחברה עם מוצר מרתק שהייצור מתבצע בבית, ולהיות מחובר לשטח
חובה ניסיון בתפקיד איכות בייצור בחברת מדיקל

מיקום: איזור כפר-סבא
קורות חיים לכתובת: jobs2@stepup-hr.com

Roles & Responsibilities:

- Oversee and assess the quality of manufacturing process
- Support quality activities in production (in-house and outsourced)
- Data collection and analysis of trend (e.g., MRB, Yields) in the manufacturing site.
- Review manufacturing-related paperwork in the Device History Record for accuracy and completeness
- Support QC activities including in-coming, in-process and final inspection (product release), label inspections
- Participate in the resolution of all product rejections and returns, internal and external, call and follow-up on Material Review Board Meetings
- Participating in investigations in the production related to nonconforming products
- Developing and documenting manufacturing work instructions together with Engineering
- Determination of quality requirements for production and processes improvements

Requirements:

Relevant degree (e.g., biomedical, mechanical engineering or related science / technical discipline)

- At least 2 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, etc.)
- Experience with statistical techniques, risk analysis, root cause analysis, Process validation etc. an advantage
- 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