משרת רגולציה מתחילה

הזדמנות להיכנס לעולם הרגולציה בעולם המכשור רפואי
מתאים גם לבוגרים שסיימו לימודים בתחום מדעי החיים / הנדסה, ובעלי הכשרה כלשהי בתחום הרגולציה
מיקום: רחובות
קורות חיים לכתובת: jobs2@stepup-hr.com

Main Responsibilities:
Support the preparation and maintenance of technical documentation and regulatory files in compliance with applicable regulations and standards (e.g., ISO 13485, FDA QSR).
Assist in the preparation, review, and submission of FDA supplements and marketing applications.
Collaborate with cross-functional teams, such as R&D, Quality Assurance, and Clinical Affairs, to gather necessary information and documentation for regulatory submissions.
Contribute to the development and implementation of regulatory strategies, including assessing regulatory impact on product development and market access.
Assist with the preparation and submission of regulatory documents and maintaining regulatory files and databases.
Monitor and track regulatory submissions and approvals.
Provide administrative support to the regulatory affairs team as needed.

Qualifications:
Bachelor's degree in a relevant scientific or technical field (e.g., Life Sciences, Biomedical Engineering). Advanced degrees are a plus.
Excellent written and verbal communication skills, with the ability to effectively communicate complex regulatory information.
Proficiency in using regulatory databases, document management systems, and Microsoft office.