

RA Specialist

As RA Specialist, you will take part in new product submissions for regulatory approval in US, Europe, Japan, China, Brazil, Australia and more

Location: Yokneam, Israel

Scope & Responsibilities:

- Preparing, coordinating, tracking, and following up on approvals for medical device submissions
- Preparation and management of EU MDR technical documentation submissions
- Oversees of CER, PMS and PMCF activities, including customer complaints, vigilance, and recall
- Participate in regulatory inspections and audits.
- Prepare regulatory assessments for design changes
- Developing labelling according to applicable regulatory requirements

Requirements:

- B.Sc. or above in Engineering or Life Sciences
- Excellent English experience in writing regulatory and clinical documents
- 1-2 years experience in RA of medical device (preferred)
- Experience in the Neurovascular field, an advantage
- Ability to analyze and interpret standards, technical procedures, professional journals and governmental guidance and regulation documents
- Eye for detail and accuracy
- Experience working on multiple projects with aggressive timelines

Please send your CV to: danielle.elbaz@rapid-medical.com