

we are hiring Medical Product Regulation Officer

Biomedical Engineer / Electronics Engineer / Biophysicist

AJM Med-i-Caps Ltd is an innovative medical technology startup company based in Nicosia, Cyprus. We are working on the development of a colon cancer screening capsule and are inviting applications from high-performing candidates for this immediate opening.

We are seeking for Medical Product Regulation Officer to join our team. Candidates should have a Biomedical Engineering / Electrical Engineering / Biophysics, Medical Physics or equivalent degree. Having a MSc or PhD or industrial experience in the area will be considered an advantage.

RESPONSIBILITIES

Responsibilities cover the preparation of a roadmap for regulatory approvals for the company's products, in order to:

- ✤ to analyze and correct any deficiencies in the product design and production routes
- study scientific and legal documents
- gather, evaluate, organize, manage and collate information in a variety of formats
- ensuring compliance with regulations set by the FDA, EMA and MHRA.

The roadmap will include studying and following guidance documents for multiple markets, e.g. ISO 14971:2012- Medical Device Risk Management, ISO 60601-1 -Safety of Medical Electrical Equipment, ISO 11137 – Sterilization of healthcare products, ISO 11607 – Packaging for terminally sterilized medical devices, EMA/FDA/MHRA guidance on clinical evaluation of diagnostic agents, EU Medical Devices Regulation 2017/745, etc.

REQUIREMENTS

- Degree or MSc in Biomedical Engineering, Electrical or Mechanical Engineering, Biophysics, Medical Physics or equivalent
- > Quick to learn and comfortable with pushing their boundaries
- Attention to detail
- Self-motivated, ambitious and strong team player
- > Able to work under pressure and meet strict deadlines
- Excellent knowledge in both written and oral English

NICE TO HAVE ONE OR MORE FROM THE BELOW

- Experience in medical device quality assurance processes
- Experience in conducting medical device experiments
- > Experience in working with optic and optoelectronics
- Experience with nanotechnology
- Experience with AutoCAD, SolidWorks
- > Experience in Electronics Circuit design and Printed Circuit Board design
- > Experience with Analog Integrated Circuit design in the Cadence design environment
- > Experience with VHDL/Verilog in the Cadence in the Cadence design environment

REMUNERATION

Competitive salary based on qualifications and experience. The appropriate candidate will be eligible to participate in the company share option plan after a probation period. In-house and external training will be offered.

Please send your resume with a short cover letter in English stating the relevant job title in the subject to: contact@ajmmedicaps.com

All applications will be treated in strict confidence. The position is open until filled. (Only Cypriots or European Citizens will be considered)

www.ajmmedicaps.com