**RA Consultant Bio-pharma or Medical devices**

A regulatory consultancy firm supporting startups specializing in drugs, Bio-Pharma therapeutics, and innovative medical devices is seeking a new team player for the RA department with experience mainly in the medical device field but also familiar with the pharmaceutical development processes and regulations.

The candidate will provide RA consulting services to meet client expectations through supporting the design and development of products from a regulatory perspective, actively contribute to the development of regulatory strategies for product development and approval as well as product lifecycle. Reporting to RA Director.

**The candidate will need to:**

·Demonstrate a rapid learning curve and will be required to write English proficient regulatory documents.

·Product submissions, global registrations, and communication with authorities

·Coordinate and prepare document packages for US FDA and EMA regulatory submissions, EU MDR Technical Files, and international packages.

·Interacting with CROs both on a local and global level

·Acting as an operational delegate of the customer for diverse activities

**Required Knowledge, Skills, and Abilities**

· Enthusiastic and eager to learn and expertise in regulatory affairs of medical devices

· Ability to work in Multidisciplinary work opposite various stakeholders internally and externally

· Excellent verbal and written communication skills enabling interacting with customers with a service-oriented attitude, understand customer needs and challenges, and adapting accordingly

· Self-learner and team player.

· Ability to establish and maintain effective working relationships with coworkers, managers, and clients.

· Experience in interacting with QA, QC, and CMC teams.

· Ability to capture both the "big picture" and technical details

·Ability to adhere to timelines, act with a sense of urgency in an environment requiring rapid and prompt responses

**Occupational background:**

* M.Sc. or Ph.D. in Life Sciences/Biotechnology & food Engineering with 3-5 years of experience in medical device regulations
* M.Sc. or Ph.D. in Life Sciences/Biotechnology & food Engineering with 4-6 years of experience in the regulation of biological/drug products – Advantage
* Experience in AI as a Medical device - Advantage
* Experience with non-clinical and clinical studies design and/or monitoring – Advantage

Full-time job in Rehovot

**Job Description – RA Consultant Bio-pharma (Digital health)**

A regulatory consultancy firm supporting startups specializing in drugs, Bio-Pharma therapeutics and innovative medical devices is seeking for a new team player for the RA department.

The candidate will provide RA consulting services to meet client expectations through supporting the design and development of products from a regulatory perspective, actively contribute in the development of regulatory strategies for product development and approval as well as product lifecycle. Reporting to RA Director.

**The candidate will need to:**

* Demonstrate a rapid learning curve and will be required to write English proficient regulatory documents.
* Product submissions, global registrations and communication with authorities
* Coordinate and prepare document packages for US FDA and EMA regulatory submissions, EU MDR Technical Files, and international packages.
* Interacting with CROs both on a local and global level
* Acting as an operational delegate of the customer for diverse activities

**Required Knowledge, Skills and Abilities**

* Enthusiastic and eager to learn regulatory affairs
* Excellent verbal and written communication skills enabling interacting with customers with a service oriented attitude, understand customer needs and challenges and adapting accordingly
* Self-learner and team player.
* Ability to establish and maintain effective working relationships with coworkers, managers and clients.
* Ability to capture both the "big picture" and technical details
* Ability to adhere to timelines, act with a sense of urgency in an environment requiring rapid and prompt responses

**Occupational background:**

* M.Sc. or Ph.D. in Life Sciences/ Biotechnology & food Engineering
* M.Sc. in Digital Health - Advantage
* Experience with In Vivo and In Vitro studies design
* Excellent Scientific writing - Must

Full time job in Rehovot

תהליך גיוס עובדים חדשים –

לינקדין, יריד להכוון תעסוקתי במוסדות אקדמאים/אוניברסיטאות,

יועץ רגולציה 1 –

DH – רקע במדיקל דיווייס עם גישה/יכולות של דיגיטל

Valu for the candidats

הלמידה וההתפתחות...

כדאי לכם לבוא כי זו הזדמנות מאוד טובה

סינון ראשוני – טופס מילוי שאלון