Regulatory Affairs Consultant (part time)-Medical Devices

Hiring organization
BioLink 360

Employment Type
Part-time, Contractor, Temporary

Industry
Medical Device

Job Location
Ventura, CA
Remote work possible

Working Hours
Varies, 20-30 Hours/ Week

Date posted
October 6, 2022

Description

Principal Regulatory Affairs Consultant

20-30 hours/week (Corp-Corp or 1099)

Remote Based

Client Location: CA

We are recruiting for one of our medical device clients that is looking to onboard a Regulatory Affairs Consultant. This is a start up company with digital visualization products for surgical procedures. This project will entail setting up an RA department to take over submissions and post-market surveillance from its customer partners, who currently own Regulatory Affairs for their devices, and to set the runway for products in the pipeline, as they expand the portfolio of products. This will require hands-on work with submissions and PMS, as well as devising strategy as the company expands.

Qualifications

- 8+ experience in regulatory affairs within the medical device industry, with experience in ground floor RA efforts with a startup preferred
- Strong experience in EUMDR Regulations (Medical Device directives (93/42/EC)
- Authoring experience in FDA product submissions (IDE, PMA, 510k)
- Experience in writing/maintaining CE Technical Files preferred
- Experience with ISO 13485:2016 and ISO 14971
- Experience in Post Market Surveillance and QMS integration