Associate Regulatory Affairs Consultant

This position is for individuals eligible for full-time employment in the USA, and they must live in the USA. We are not interested in sponsoring a VISA at this time.

General Job Description

The associate regulatory consultant will work under the direct supervision of a more experienced regulatory consultant and receive training from multiple people within the company. This person will work with various medical device company clients to prepare regulatory submissions for various international markets. The consultant may also support Quality Management System implementation and training. Consultants may sometimes serve supporting roles in client company QMS operations, typically in the areas of CAPAs, Complaints, Mandatory Reporting, Recalls, etc.

You will be responsible for the following activities:

1. Identifying the regulatory pathway for a medical device (USA, Canada and Europe)
2. Preparation of classification rationales
3. Preparation of draft testing plans
4. Preparation of pre-submission meeting requests
5. Preparation of regulatory submissions, such as: 510(k), De Novo, Canadian License, and CE Marking TF

The associate regulatory consultant will NOT be responsible for the following:

1. Preparing regulatory or quality system documentation without any review or input from an experienced regulatory consultant or quality system consultant on our team
2. Leading teleconference meetings with regulators (FDA, Health Canada, or NB), unless their supervisor has prepared them for this and their supervisor is also involved in that call
3. Preparing proposals or invoices for clients

The associate regulatory consultant may have experience in one of our three primary markets (i.e. USA, Europe, or Canada), but we expect there to be gaps in your training. Our firm specializes in training people on QA and RA requirements for all three markets. Therefore, we have dozens of recorded webinars available on-demand for you to take at no cost. Any self-training should be planned with the direct supervisor, documented in Asana, and training records should be created--including corrected quizzes whenever possible. We encourage associate regulatory consultants to recommend improvements to our training content, and to take the initiative to make corrections and work with an experienced consultant to record updated webinars with updated quizzes whenever possible.

An associate regulatory consultant should have exceptional oral and written communication skills. Consultants must listen well and be able to effectively communicate with regulators, clients, and our team. They must be extremely competent with remote communication software tools (phone and video conferencing), organization, and self-motivation. Prior experience with medical device start-up companies is a huge plus. 100% of our customers are small medical

device companies, and many do not have adequate experience or prior training. Patience with clients is paramount. The goal is to have clients that are so thrilled with your service, that they will become your raving fan and refer future clients to work with you. The ability to most efficiently navigate the appropriate regulatory pathway will ensure customer satisfaction. Accurately estimating the duration of the associated tasks and scopes of projects along with clear and honest communication regarding potential risks and hurdles associated with their device and regulatory strategy is extremely important. Despite balancing multiple clients and projects, the goal is to make each client feel like they are your most important client. Communication and openness is key to achieving this objective. Outstanding service is an expectation at Medical Device Academy, which has even resulted in consultants receiving $ tips for outstanding service (it's happened twice in our company).

Work Environment

All employees work from home. If you need to purchase any office furniture to establish a suitable work environment, you will be reimbursed for those purchases. If you choose to sublease office space instead of working from home, we can discuss reimbursement of a reasonable office lease or potentially sign and pay the lease agreement for you.

Software & Hardware

All full-time employees will receive the following (or equivalent):

- Company mobile phone of your choice from Verizon
- New high-speed laptop
- Headset with microphone & HD webcam for video conferencing
- Adobe Acrobat Pro
- Dropbox Business (unlimited space)
- Microsoft 365
- Company email account (yourname@fdaecopy.com)
- Google Suite Account (unlimited space)
- Zoom Account

Work Schedule

- 100% Flexible as long as you are able to meet the needs of clients (50% international & 50% USA clients)
- Total - 40 hours per week (32 hours is the minimum required for a full-time employee)
- You establish your availability for clients using Calendly or a similar application.
- PTO based upon our company policy manual and company calendar (15 days plus 10 national holidays)

Compensation $

- $24.00-34.00/hour - Salaried Exempt (depending upon experience)
- $100 on 10th of month for utilities, etc. (no receipts required) if you work from home
- Reimbursement for expense receipts on 25th of month

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- 100% of Premium for Platinum Insurance Plan from MVP Healthcare (Eligible on 1st day of employment)
- Payroll is every 2 weeks on Fridays - last was 1/22/2021 (no delay in receiving your first check, it will be prorated if you start in the middle of a payroll cycle) All checks are direct deposit.

Interested candidates must submit a resume and cover letter to Sharon Morrow:

Sharon Morrow
Regulatory Consultant
Medical Device Academy, Inc.
sharon@fdaecopy.com
Tel | +1.865.705.4400

If Sharon is interested in speaking with you, she will ask you to schedule a video conference call with her using the following calendly link:

https://calendly.com/sharon-1211

You will have 30 minutes to convince her that you are a great fit for the company. She may also ask for a follow-up call to gather more information and to answer more of your questions. If she decides you are a fit, then she will coordinate your next call with Mary Vater or Matthew Walker. If you are successful, you will speak with other employees in the company remotely and finally get to interview with Rob Packard if everyone in our company thinks you are a great fit.