AD-TECH MEDICAL INSTRUMENT CORPORATION

Job Description
Regulatory Affairs Analyst

Department: Regulatory

Education and/ or Experience Required:

1. Minimum: Bachelor's Degree in Science, Health Care, Engineering, Mathematics, Statistics or other technical field; or five years related experience and/or training; or equivalent combination of education and experience.
2. Previous job in Regulatory Affairs/Quality Assurance within the Medical Device Industry preferred
3. 2+ years working in area quality assurance or regulatory industry; 1+ more years conducting quality audits in a regulated medical company
4. Experience communicating with customers preferred.

Job Information

Perform Compliance management, Regulatory functions as listed in job description and perform other related miscellaneous tasks/duties as assigned and required.

Qualifications

The following qualifications are preferred:

- Active Learning
- Active Listening
- Critical Thinking
- Learning Strategies
- Self-Assessment
- Excellent communication and listening skills
- College level Reading, Writing and Speaking (English)
- Problem Solving
- Attention To Details
- Proficiency in MS Programs
- Professionalism
- Handles Pressure
- Knowledge and understanding of FDA and international regulations as well as other quality standards (e.g. ISO9001, ISO13485).

Essential Duties and Responsibilities - *Duties may include but are not limited to:*

1. Regulatory Affairs:

- Lead or assist with medical device license registrations
- Lead or assist international customers with international registrations
- Lead or assist in the development of product and regulatory documentation (Technical Files, etc.)
- Assist with identifying and ensuring compliance with applicable quality-related standards and assessing and implementing any required changes.
- Assist with ensuring Regulatory requirements are met via creating, reviewing and/or maintaining all "REGU-related" materials (Operating Procedures, Work Instructions, labeling, etc.).
- Member of Regulatory Team. Responsible for ensuring that:
    - the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;
    - the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;
    - the post-market surveillance obligations
    - the reporting obligations with competent authorities.
- Collaborate with applicable functions to support:
    - Pre- market notifications, registrations and licenses.

    - Regulatory authority applicable notifications for product changes resulting from Deviations and/or Change Orders (COs).
    - Notification of customers, distributors and regulatory authorities of related notifications of regulatory concerns (Example: FDA Warning Letter).
    - Issuance of advisory notices.
- May serve on internal committees related to customer complaints, recall, recovery, CAPA, field correction boards, etc.
- Completes and submits any supplementary documentation/forms to applicable countries or in country sponsor as required by country regulation.
- Attend Design Meetings representing the Regulatory Department.
- Participate and assist with internal and external audit activities, as needed.
    - Complete documentation for internal and external audits.
- Perform other related duties and responsibilities, as assigned.

2. **Additional Duties:**
    - Participate in various meetings as needed.
    - Member of the Quality Steering Team as needed.
    - Perform other related duties and responsibilities, as assigned.

Supervisory Responsibilities: None

Work Context

Body Positioning

- Requires repetitive movement
- Requires bending or twisting
- Requires using hands to handle, control, or feel objects, tools or controls
- Requires walking
- Requires sitting

Physical Demands:

- Requires repetitive movement and sitting for long periods at the desk
- Requires working indoors in environmentally controlled conditions
- Job tasks are performed in close physical proximity to other people

Desktop Computer Skills/ Tools

- Microsoft Programs (Excel, Word, Publisher, PowerPoint)
- Internet/Email (Microsoft Outlook)

Communication

- Requires face-to-face discussions with individuals or teams
- Requires contact with others (face-to-face, by telephone, or otherwise)

Impact of Decisions

- Requires making decisions that may impact co-workers, clients and the reputation of the company.
- Opportunity to make decisions without supervision
- Includes responsibility for work outcomes and results
- Interpreting the meaning of information for others

Level of Challenge

- Freedom to determine tasks, priorities, and goals
- Requires repetitive activities (physical and/or mental)
- Requires a high level of accuracy

Pace and Scheduling

- Requires meeting strict deadlines

Personal Interaction

- Requires work with others in a group or team
- Requires coordinating or leading others in accomplishing work activities

Responsibility for Others

- Includes responsibility for work outcomes and results

Work Attire *(When entering CEMA)*

- May requires wearing common protective or safety equipment
- Clothing must be neat and clean
- Clothing or shoes cannot be made of shedding material (wool, angora)
- No sweaters are permitted
- Jewelry is discouraged in the clean areas
- coverall or a disposable coverall