UNIVERSITY OF SOUTHERN CALIFORNIA

Regulatory Affairs Administrator

Job Code: 133139

Grade: L
OT Eligible: No
Comp Approval: 8/8/2008

JOB SUMMARY:
Manages development and implementation of a comprehensive regulatory affairs compliance program. Drafts and ensures compliance with various standard operating procedures and policies. Develops and executes regulatory plans for design, development, and preclinical and clinical testing of medical products. Monitors applicable regulatory requirements; and assures compliance with company and external standards. Manages submission and reporting processes for regulatory agencies such as Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Food and Drug Administration (FDA) and Notified Bodies.

JOB ACCOUNTABILITIES:

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- Develops and executes regulatory plans for design, development, and preclinical and clinical testing of medical products. Maintains and ensures compliance to all quality requirements.
- Assists in preparation of Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) submissions.
- Maintains regulatory files and documents for US and international submissions for all projects.
- Interfaces with the Quality group to assist with clinical plans, Corrective and Preventive Actions (CAPA) and other quality issues as required.
- Provides input to project teams to assure that FDA and other regulatory authority requirements are incorporated as part of the product development process.
- Represents regulatory affairs during third party audits (e.g. FDA, Notified Body, etc.).
- Prepares and conducts all site visits including, but not limited to, qualification visits, initiation visits, monitoring visits, motivational visits, audit support visits, and termination visits.
- Reviews or audits study-related activities and documentation (e.g., protocol audits, crucial phase inspections, data and report audits, etc.) for compliance with protocol, standard operating procedures and Good Laboratory Practices (GLP) regulations. Issues audit statement when appropriate.
- Writes and distributes Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) audit reports that describe audit findings.
- Develops departmental standard operating procedures (SOPs), work instructions, templates, and forms. Perform vendor audits (e.g., test facilities, test sites, consultants) and internal audits of the Preclinical Sciences department, test facilities, and test sites for compliance with GLP regulations.
Performs other related duties as assigned or requested. The University reserves the right to add or change duties at any time.

*Select E (ESSENTIAL), M (MARGINAL) or NA (NON-APPLICABLE) to denote importance of each job function to position.

**EMERGENCY RESPONSE/RECOVERY:**

Essential:  
- [ ] No  
- [x] Yes  

In the event of an emergency, the employee holding this position is required to “report to duty” in accordance with the university’s Emergency Operations Plan and/or the employee’s department’s emergency response and/or recovery plans. Familiarity with those plans and regular training to implement those plans is required. During or immediately following an emergency, the employee will be notified to assist in the emergency response efforts, and mobilize other staff members if needed.

**JOB QUALIFICATIONS:**

**Minimum Education:**

- Bachelor’s Degree
- Combined work experience and education as equivalent.

**Minimum Experience:**

- 3 Years

**Minimum Field of Expertise:**

- Experience in Regulatory Affairs or Quality Assurance. Understanding of global medical device regulations and regulated environments. Understanding of FDA Quality Systems Regulations (QSRs), Good Manufacturing Practices (GMP/ISO), Good Clinical Practices (ICH GCP) and regulatory requirements. Knowledge of Good Laboratory Practices (GLP) regulations and guidelines. Understanding of the clinical research process and terminology. Demonstrated excellent written and verbal communication skills, organizational skills and negotiation and interpersonal skills.

**Preferred Education:**

- Bachelor’s Degree

**Preferred Experience:**

- 5 Years

**Preferred Field of Expertise:**

- Experience in Regulatory Affairs or Quality Assurance in Medical Devices/Pharmaceutical Development, implementing compliance programs and working in a medical device manufacturing environment.

**Skills:** **Other:**

- Analysis
- Assessment/evaluation
- Budget control
- Budget development
- Communication -- written and oral skills
- Conceptualization and design
- Consulting
- Interpretation of policies/analyses/trends/etc.
- Knowledge of applicable laws/policies/principles/etc.
Negotiation
Networking
Organization
Planning
Problem identification and resolution
Project management
Public speaking/presentations
Research
Statistical analysis

Skills: Machine/Equipment:
Calculator
Computer network (department or school)
Computer network (university)
Computer peripheral equipment
Fax
Personal computer
Photocopier

Supervises: Level:
Supervises student and temporary workers and/or resource employees.

SIGNATURES:
Employee: _______________________________ Date: _______________________________
Supervisor: _______________________________ Date: _______________________________

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

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