
Regulatory Affairs and Clinical Trials

Typical Job Description for Regulatory Affairs and Clinical Trials



Individuals who work in the area of Regulatory Affairs and Clinical Trials make sure that all the work of the company meets regulatory requirements. Under the direction of a Senior Associate or Manager, the Regulatory Affairs Associate is responsible for gathering information and assembling regulatory submissions. They are also responsible for projects such as literature searches and report preparation. Submissions may include annual reports, addition of new investigators to clinical protocols, Certificates of Analysis, amendments providing for changes in the clinical program manufacture of a product, and routine and supplemental filings. These individuals assist with and prepare for FDA meetings, inspections, and audits from regulatory agencies. Keeping current on regulations, laws, and guidelines is a very important aspect of this work. Companies rely on reports from these individuals to ensure compliance.

With respect to clinical trials, the primary focus of these individuals' work is on the implementation of clinical studies, with emphasis on study monitoring. Additional responsibilities include assisting with study drug management and reviewing data from clinical trials. These individuals may also be responsible for the review of labeling, promotional, and advertising materials in compliance with regulations and guidelines. They prepare regulatory reports and clinical documents, and coordinate data collection and reporting with other departments.

SAMPLE JOB TITLES

Regulatory Affairs Associate
Labeling Compliance Associate
Clinical Research Associate
Regulatory Affairs Specialist
Flow Cytometry Specialist
Histological Technician
Research Technician
Laboratory Aide

**Routine Scenario:
Tracking Changes in Regulations
and Guidelines**

AS A REGULATORY AFFAIRS professional, you are often responsible for tracking changes in regulatory guidelines as they may occur. In order to do this, you must take the initiative to keep current on all changes in regulations. For example, you might check the FDA Web site and read professional journals. You might also learn about new guidelines from peers at work or by attending a conference.

All changes in regulations must be documented in the manner required by the company. Changes must also be interpreted and communicated to appropriate people in the company, including management. Management may then determine what changes in company procedures and process may be required to stay in compliance. You may be involved with coordinating and implementing the changes.

PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

B. Review, process, and communicate data

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information
- B3. Flag problems and issues
- B4. Track approvals and renewals
- B5. Draft reports

C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices

- C1. Prepare updates on laws, regulations, and guidelines for distribution to company personnel
- C2. Monitor and evaluate manufacturing process changes
- C3. Review data and reports for compliance
- C4. Assist in maintenance of document control system
- C7. Support quality assurance
- C9. Assist with resolution of quality issues

D. Participate in interactions with regulatory agencies

- D1. Perform literature searches
- D2. Assist with submission preparation and international documents and licenses
- D3. Assist with regulatory document control

**Crisis Scenario:
Notified of a Product Failure**

THE COMPANY IS NOTIFIED of an adverse event at a clinical trial, which means that a patient had a potential reaction to the test article. Once notified, you collect data about the event to allow the company to evaluate the reaction. The data is turned over to a medical professional to evaluate and determine whether or not the adverse reaction may have been related to the product.

You also ask the medical professional whether he or she felt it was a severe or life-threatening reaction. If it is a severe reaction and is related to the product, then you have reporting responsibilities to FDA.

Depending on the situation and the regulatory requirements, you may be required to call the FDA or to submit a report in writing. You would also notify individuals in your company and other medical investigators at the clinical sites. These actions could lead to a decision whether or not to stop the clinical trial, or simply enter the data as part of the trial.

PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

A. Support clinical research

- A1. Perform record keeping
- A2. Assist with and coordinate development of clinical trial support documents
- A4. Report on status of clinical trials
- A5. Facilitate communication with IRB
- A6. Monitor clinical sites
- A7. Assist with study drug management
- A8. Review data from clinical trials

B. Review, process, and communicate data

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information
- B3. Flag problems and issues
- B4. Track approvals and renewals
- B5. Draft reports

**Long-Term Scenario:
Assist With Training**

THE COMPANY HAS HIRED new workers in the Regulatory Affairs Department, and you have been asked to assist with training the workers. You might be asked to give a formal presentation, some on-the-job training, or an assignment for the new individuals to learn on their own. The first step is to gather information about what the new workers will be doing and determine what the content of the training should be. The content could include information about FDA requirements and the company protocols as they apply to the work the new-hires will be doing. Often the training may include job shadowing, in which the new employee spends a few days with you to get oriented to the work in this particular company. You may be asked to monitor and evaluate the work or progress of the new employee and to determine what further training is required. If employees make errors and require additional training, you may provide one-on-one training in specific areas.

PRIMARY TASKS AND FUNCTIONS INVOLVED IN THIS SCENARIO

B. Review, process, and communicate data

- B1. Record and organize data
- B2. Conduct simple analyses of data and process information

C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices

- C8. Assist in training programs

Concentration: Regulatory Affairs and Clinical Trails

JUNE 8, 2000

CRITICAL WORK FUNCTIONS	KEY ACTIVITIES								
A. Support clinical research	A1 Perform record keeping	A2 Assist with and coordinate development of clinical trial support documents	A3 Research current literature regarding clinical trials	A4 Report on status of clinical trials	A5 Facilitate communication with IRB	A6 Monitor clinical sites	A7 Assist with study drug management	A8 Review data from clinical trials	
B. Review, process and communicate data	B1 Record and organize data	B2 Conduct simple analyses of data and product information	B3 Flag problems and issues	B4 Track approvals and renewals	B5 Draft reports				
C. Coordinate with manufacturing and other departments regarding regulatory and compliance practices	C1 Prepare updates on laws, regulations and guidelines for distribution to company personnel	C2 Monitor and evaluate manufacturing process changes	C3 Review data and reports for compliance	C4 Assist in maintenance of document control system	C5 Conduct audits	C6 Review promotional media to ensure compliance	C7 Support quality assurance	C8 Assist in training programs	C9 Assist with resolution of quality issues
D. Participate in interactions with regulatory agencies	D1 Perform literature searches	D2 Assist with submission preparation and with international documents and licenses	D3 Assist with regulatory document control	D4 Assist with preparation for FDA meetings	D5 Keep current on regulatory requirements	D6 Assist with inspections and audits from regulatory agencies			