

The pharmaceutical industry, the collection of companies that manufacture, test and sell prescription medications, is the most regulated industry in the United States, according to Corinne A. Marasco of "Chemical & Engineering News Washington." Each pharmaceutical company will have a regulatory affairs department to ensure the company's procedures meet the requirements of local and federal laws. Regulatory affairs departments do this by verifying the validity of procedures and communicating standards to other departments in the companies while understanding their needs and serving as a liaison between the company and regulating authorities.

Liaison Role

Regulatory affairs professionals serve as a liaison between a pharmaceutical company and agencies like the United States Food and Drug Administration (FDA.) At the company, they interact with the Research and Development (R&D), compliance and manufacturing staff to communicate their interpretation of federal and local guidelines. Agents must be sure the actions and vision of all departments are in concert and that this behavior is in accordance with the law.

Guidelines to Follow

The bulk of pharmaceutical legislation regulatory affairs specialists must be familiar with is the 21 CFR or Code of Federal Regulations, sections 1 through 1299. The Environmental Protection Agency (EPA) , Federal Trade Commission (FTC) , Drug Enforcement Administration (DEA), Federal Communications Commission (FCC) and Occupational Safety and Health Administration (OSHA) have additional guidelines that regulate the manufacturing, testing, labeling and advertising of pharmaceutical drugs.

Knowledge Required

According to Corinne A. Marasco of "Chemical & Engineering News Washington," regulatory agencies "are responsible for keeping up with the increasing scope and complexity of regulations both here and abroad." They must be well-versed in clinical research protocols and regulations and legal and regulatory environment procedures. Knowledge of changing and international regulation help regulatory affairs employees decide what is the best strategy to remain successful and compliant in a given place and time.

Trend in Scientific Knowledge Requirement

For these employees, knowledge of the scientific and clinical process is a key strength. Sherry Keramidas, the executive director of the Regulatory Affairs Professional Society says, "Understanding the clinical process and some of the challenges of clinical care helps regulatory affairs professionals understand the clinical trials process and what is or is not possible." Bonnie Charpentier, vice president of regulatory affairs at Genitope and herself an accomplished chemist, sees a general shift in the profession toward an increased role in the exploration on "substantive scientific and medical issues and on planning for the experiments and clinical studies to achieve approval," forcing newer recruits to be cross-discipline generalists "competent in asking questions and defining answers."

Duties to the Company

Another key component to being a regulatory affairs employee at a company is implementing strategy that keeps the company out of legal hot water while also contributing to the corporation's financial bottom line and big-picture plans. A big part of this is being able to evaluate the risk inherent in a given decision and what potential outcomes would be and then deciding if the company should take that risk.

Key Concepts

- regulatory affairs pharmaceutical
- pharmaceutical industry regulatory
- role regulatory affairs

References

- ["Chemical & Engineering News"; Regulatory Affairs; Corrine A. Marasco; December 2002](http://pubs.acs.org/cen/employment/8048/8048regulatoryaffairs.html) [http://pubs.acs.org/cen/employment/8048/8048regulatoryaffairs.html]
- [Pharmet; The Role and Responsibility of Regulatory Affairs Department; Manuela Kohler; December 2009](https://www.pharmatching.com/pharmaknowhow/the-role-and-responsibility-of-the-regulatory-affairs-department) [https://www.pharmatching.com/pharmaknowhow/the-role-and-responsibility-of-the-regulatory-affairs-department]