



HOW TO GET A JOB IN REGULATORY AFFAIRS?

How Do I Get a Job in Regulatory Affairs?



Department of Regulatory Affairs is a crucial part of any pharmaceutical, biopharmaceutical, medical device, nutraceuticals, veterinary, and cosmetic industry. The department is focused on maintaining the quality standards and safety of medicinal products in different markets around the world. To make this possible, the regulatory professionals keep a close eye on all the products on various parameters such as development, manufacturing, testing, and distribution. This department also works closely with the government authorities to regulate the activities of the company. A career in regulatory affairs offers immense opportunities and growth for students keen to learn and acquire knowledge.

Skills Required for Regulatory Affairs

The rules and regulations around the world are different for every region around the world. These rules are much more stringent for pharmaceutical and medicinal products owing to the safety of the public. Hence, regulatory professional has to be on their toes at all times and keep themselves updated with the new norms and legislations.

A career in regulatory affairs is demanding and it asks for a particular set of skills to excel in the domain, such as:

1. Attention to Detail:

Documentation is an integral part of a regulatory affair job role. This documentation consists of hundreds of pages with pharmaceutical protocols, legislation, business, and so forth. A lot of times the professionals are also required to draft and review such documents within stringent timelines. This calls for a brilliant eye for detail.

2. Diverse Knowledge:

The department of regulatory affairs offers a diverse horizon for candidates in science, law, and business. The professionals working in the department should be well aware of the drug development process right from its inception to its marketing. At the same time, the professionals should also know the legal aspects of the drug in different parts of the world.

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3. Writing Skills:

As mentioned above, regulatory professionals are required to draft critical documents. The professionals also have to review hundreds of pages about the quality, safety, and efficacy of a medicinal product. This asks for a flair for writing.

4. Organizational Skills:

Regulatory affairs involve a variety of tasks such as coordinating application procedures for a medicinal product drafting an application and so forth. Sometimes the regulatory specialist has to coordinate with different departments to ensure the adherence to legalities. All of this calls for exceptional organizational skills.

Education Required for Regulatory Affairs

To become a regulatory affairs specialist, you will need a bachelor's degree in life science specifically in pharmacy, pharmacology, and biochemistry. A graduation or post-graduation degree is sufficient for a junior position. The senior-level, however, demands a doctorate

Concepts Which One Should Know to Get a Job in Regulatory Affairs

To become a successful regulatory specialist, you should know the following:

1. Investigational New Drug Application (IND)

An investigational new drug application or IND refers to an application that is filed with the United States Food and Drug Administration (USFDA) to get legal approval for testing an experimental drug on humans.

2. New Drug Application (NDA)

A new drug application or NDA is a key application that is filed with the USFDA to approve a new pharmaceutical product for sale and marketing in the United States. Data from the animal and human studies gathered from an IND is collated to submit an NDA.

3. Abbreviated New Drug Application (ANDA)

An abbreviated new drug application or ANDA refers to an application that is filed with the USFDA to approve the sale and marketing of a generic drug product in the United States.

4. Generic Drug Product

A generic drug product is comparable to an innovator drug product in terms of its strength, route of administration, quality, performance characteristics and intended use

5. Orange Book

Orange Book is an electronically available free database which contains a list of drugs approved as both safe and effective by the USFDA.

6. Drug Master File or DMF

A drug master file or DMF refers to submission to the USFDA. It provides confidential and thorough information about the medicinal product concerning manufacturing facilities, process, packaging, and storage of drugs. This application is submitted to the USFDA as absolute confidential information about the product.

7. 505 (b)(2) Application

A 505 (b)(2) application is also a type of NDA for which the investigations rely on the applicant. The investigation for these is carried out by the applicant but the right to approval does not lie with the applicant.

8. Common Technical Document (CTD)

A common technical document or CTD refers to an application dossier that is prepared for the registration of drug products in Europe, Japan, and the United States. The document includes detailed information about the quality, safety, and effectiveness of the drug product.

9. Marketing Authorization Application (MAA)

A marketing authorization application or MAA refers to an application filed with the relevant authority in Europe for marketing a drug product.

To Sum It Up

Regulatory affair is an interesting career option for students with zeal to learn and grow. This diverse field will give you insight into a medicinal product right from its development to marketing. If you wish to build a career in the domain, contact us here. If you want to learn more and get in-depth knowledge, try our [**drug regulatory affairs course**](#).