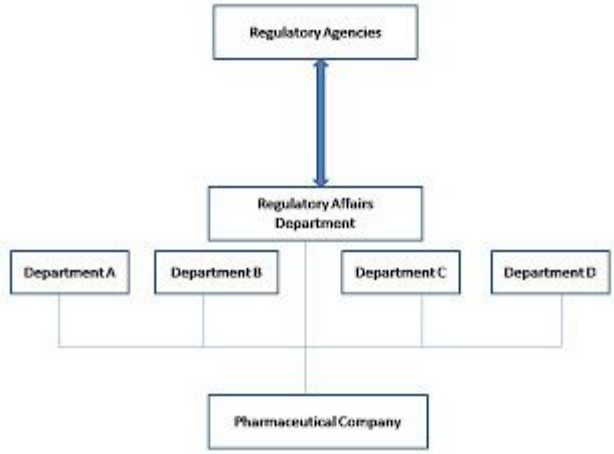
Regulatory Affairs

What is Regulatory Affairs?

Regulatory Affairs is a profession within regulated industries namely-pharmaceuticals, medical devices, energy and banking. It has specific meaning within healthcare industries namely- pharmaceuticals, medical devices, biologics and functional foods. Regulatory Affairs in the pharma industry may be defined as "**The interface between the pharmaceutical company and the regulatory agencies across the world.**"



All the departments of a pharmaceutical company, Regulatory Affairs Department acts as the interface between the pharmaceutical company and the regulatory agencies across the world. Regulatory agency in the present context may be defined as "**The competent government agency which is responsible for ensuring that medicines work and are acceptably safe**."

Origin of Regulatory Affairs-

- Elixir Sufanilamide, prepared using DEG (a poison) as solvent resulted in the death of more than 100 people in the USA in 1937. This incident led to the passing of the1938 Federal Food, Drug and Cosmetic act in USA.
- Thalidomide use by pregnant women for treating morning sickness was linked to the cause of birth deformities in more than 10,000 children in late 1950s and early 1960s.
- This incident led to the **Kefauver-Harris Amendment** in USA-it is a 1962 amendment to the Federal Food, Drug and cosmetic act.

Similarly, other tragic incidents led to various acts/amendments.

Goals of Regulatory Affairs as profession-

• Protection of human health

• Ensuring safety, efficacy and quality of drugs

• Ensuring appropriateness and accuracy of product information

Roles of Regulatory Affairs professionals-

• Act as a liaison with regulatory agencies

• Preparation of organized and scientifically valid NDA, ANDA,INDA ,MAA,DMF submissions

• Ensure adherence and compliance with all the applicable cGMP, ICH, GCP, GLP guidelines, regulations and laws

• Providing expertise and regulatory intelligence in translating regulatory requirements into practical workable plans

• Advising the companies on regulatory aspects and climate that would affect their proposed activities

What work is done in Regulatory Affairs Department?

• A new drug/generic drug manufactured by a pharmaceutical company just cannot be released into the market for human use.

• Here the Regulatory Affairs Department comes into play.

• Regulatory Affairs Department of a pharmaceutical company files all the information related to the development, manufacture, control, stability studies, packing, labeling, safety and efficacy studies of drugs with the Regulatory agencies in a prescribed format as ANDA/NDA/MAA/DMF etc.

• The Regulatory agency reviews the information provided in accordance with regulations, guidelines and if they are satisfied with information provided, approval will be granted for marketing of the drug by pharmaceutical companies for human use.

General work profile of a Regulatory Affairs professional in an API (Active Pharmaceutical Ingredient) manufacturing company-

• Filing a DMF/ASMF with regulatory agencies in support of the NDA/ANDA/ INDA/MAA filed by a Formulator (Drug Product manufacturer who uses API of that particular API manufacturing company).

• Filing dossier of API with EDQM for obtaining CEP.

• Assessing and filing amendments/variations to the information (which may be related to manufacture, control, stability studies etc) in DMF/ASMF/Dossier of particular API with the Regulatory agencies. Major amendments are to be reported prior to their implementation while minor amendments may be reported annually. The classification of amendments will be dealt in the later posts.

• Taking approval of customers of API before implementing any major changes regarding the information mentioned in DMF/ASMF/Dossier. The updated DMF/ASMF may be submitted to the customer simultaneously along with amendments/variations filed with the agency.

• Preparing and submitting Open part/Applicant's part of DMF to the customers of API (Drug products manufacturer) which may be filed by customer with the Regulatory agency.

• Preparing and submitting the LoA (Letter of Access/Letter of Authorization) to the API customers and Regulatory Agencies. LoA is the letter which authorizes the regulatory agency to review the DMF /ASMF of the API manufacturer against the NDA/ANDA/MAA of the API customers (Formulators).

• Preparing Technical Packages for existing/prospective customer for initial assessment of the API.

• Filing Annual/Biannual/Quinquennial reports (Which contain list of changes to the DMF/ASMF/Dossier) with the regulatory agencies.

• Maintenance of the complete history of each API (Filing history with agencies/customers, amendments, annual reports).

• Taking part in the drug development process by advising the R & D scientists regarding various guidelines, laws and regulations.

General work profile of a Regulatory Affairs professional in a Drug Product /Finished product/ Formulation manufacturing company -

• Filing a NDA/ANDA/MAA of drug products with regulatory agencies for getting marketing approval.

• Assessing and filing supplements/amendments/variations to the information (which may be related to manufacture, control, stability studies etc) in NDA/ANDA/MAA with the Regulatory agencies for prior approval or after their implementation.

Major supplements/amendments are to be reported prior to their implementation while minor supplements/amendments may be reported annually. The classification of amendments will be dealt in the later posts.

• Filing Annual/Biannual reports (Which contain list of changes to the NDA/ANDA/MAA) with the regulatory agencies.

• Reporting any adverse effects which have occurred/may occur due to the use drug products.

• Maintenance of the complete history of each Drug products (Filing history with agencies/customers, amendments, annual reports)

• Taking part in design and revision of drug product labels, packing leaflets.

• Taking part in the Formulation development process by advising the R & D scientists regarding various guidelines, laws and regulations.