

## Role of regulatory affairs in the pharmaceutical industry

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Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. Regulatory Affairs plays a crucial role in the pharmaceutical industry and is involved in all stages of drug development and also after drug approval and marketing. The drug development process is a lengthy, complex and extremely costly albeit necessary process. Pharmaceutical companies use all the data accumulated during discovery and development stages in order to register the drug and thus market the drug. Throughout the development stages, pharmaceutical companies have to abide by an array of strict rules and guidelines in order to ensure safety and efficacy of the drug in humans. In this highly regulated environment, regulatory affairs plays a critical role not only as the interface with health agencies and as a link between different departments in the company but also as the leading department to provide strategic advice on extremely difficult decisions through the life of a drug. Regulatory professionals keep working with the authorities and different departments within the company in order to meet regulatory commitments with the health authorities. Regulatory Affairs also ensures the maintenance of the marketing licence and leads life cycle extension activities such as broadening the indication of the drug, change of formulation, changes in the dosage etc.. Regulatory Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work, are comfortable with multi-tasking and are eager to expand their knowledge in the wide realms of the Pharmaceutical world. Regulatory Affairs is a rewarding, intellectually stimulating and highly regarded profession within pharmaceutical companies.

### Biography

I am Jony Mallik. Student of M.Pharm (Thesis) at Southern University Bangladesh (SUB). I have also going to take Masters of Public Health (MPH) from ASA University Bangladesh. I have more than 10 Pharmaceutical publications at different national & international journal. Some are- Journal of pharmaceutical research & opinion, International journal of pharmaceutical & biological archive, International journal of pharmacy teaching & practices etc.. I participate in various pharmaceutical & medical seminar at home & abroad (Gujrat-India, Nepal). I have researched on Phytochemistry, Pharmacology, Pharmaceutics, HPLC Technique in Pharmaceutical Analysis. Nowadays I am researching on Clinical Pharmacy (Cancerous Patient). In future I want to research on Combinatorial Chemistry & NMR technology at abroad. Finally, I Love Field of Pharmacy.

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