

## Responsibility of Regulatory Affairs in Pharmaceutical Industry

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### Importance of Open access and special features of OMICS Group

Open access plays a pivotal role in disseminating information. It is user friendly and poses no problem for any one to get an access to it. It contains translational feature that covers 50 worlds leading languages and enhanced feature of this is its audio version. There are digital articles that invite one and all to share and explore new frontiers and ignite new possibilities. As it is social networking enabled it can cater to the hopes and aspiration of the youth. One striking dimension of it is that authors, reviewers and editors are provided with scientific credits. Pharmaceutical research in the current scenario needs a new approach. The researchers and pharma professionals can hone their skills by harnessing this channel. This platform provides a lot of useful information in the field of regulatory affairs and thereby enriches the domain of intellectual property rights. The moral fiber of industry gets strengthened and its growth chart gathers a new momentum.

### Structure of the Editorial

The field of regulatory affairs has become increasingly more science- and issue-based and less routine and bureaucratic. A regulatory professional now spends more time on substantive scientific and medical issues and on planning for the experiments and clinical studies to achieve approval.

Regulatory department is responsible for providing strategic advice and proactive input to multi-disciplinary international project teams for the life cycle management of products. They are responsible for all regulatory aspects including the development of global regulatory environment, coordinating regulatory submissions, leading the interactions with regulatory agencies, gaining a rapid and successful approval and maintaining drugs in the market.

Regulatory affairs professionals perform a wide range of activities

in the drug development process, which vary depending on the product line and size of the company.

The main responsibility of the DRA professional within a pharmaceutical industry is to secure approval of drug submission and to ensure regulatory compliance of marketed and investigational drugs with the Food & Drug Act and Regulations. Keeping up-to-date on regulations is essential in regulatory affairs as changes in regulations can affect the clinical trials process, regulatory strategy, decisions on what kinds of trials are needed, and so forth.

The regulatory department has a multifaceted task to perform right from the pre-marketing development to the regulatory submissions and the post approval product life cycles of pharmaceutical products.

The regulatory department act as a focal point of information, both incoming and outgoing. The various sources of information that should be looked on by the regulatory authorities include published guidelines, public presentations, weekly industrial newspapers, informal conversations, emails. A good regulatory personnel must see, hear and talk with a regulator, a more experienced drug development expert, a colleague and any other person well conversant with regulatory affairs to gather information.

There is a loose translation of Buddha claiming to have once said, "Man must first direct the way he should go; only then can he instruct others." I believe you will agree that this special pharmaceutical regulatory affairs open access issue is a good start for the changes that lie ahead.

On behalf of the editor and editorial board for this special issue, I would like to thank the OMICS publishing Group 5716 Corsa Ave., Suite 110 Westlake, Los Angeles, CA 91362-7354, USA for giving me this opportunity.

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