



BioPULSE

Importance of regulatory affairs

Regulatory affairs is a crucial function in the Indian pharma industry. **Rajashri Survase-Ojha**, Managing Director, Raaj Global Pharma Regulatory Affairs Consultants (GPRAC) and **Onkar Deshmukh**, an MS student at The University of Greenwich, UK review the situation



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In the first place, 'regulation' is the jurisdiction of human and communal conduct by dint of rules and precincts. The expression 'regulation' has not been quite novel to industries like pharmaceuticals and biotechnology. The code of practice and laws that preside over the pharma business were taken on board in interest of shielding the consuming populace by struggling to supply drugs of uniform or reliable quality, efficacy and safety. Interestingly, the prominence of the regulation and regulatory affairs professional are the intention of this article.

Industries like pharma, biologics, food and medical equipment can be uncertain if the new products and methods are not tested and checked for functionality with great vigilance before being publicised. The first and foremost factor for the pharma sector has been always in the time and occupied by the drug candidate to see the light of the day which is very in-dispensable for the product's success and for the pharma companies. Therefore, effective administration and superintendence of regulatory affairs actions plays a crucial job towards economy of the corporation.

The regulatory affairs professional is the only person who is completely responsible for such activities, as developing distinct rejoinders to regulatory authorities who want an organisation to hold products in compliance and retain satisfactory data in support of applications that have made for the registration of the products. However, failure of the same may make the company to put a stop to on-time confident appraisal of the marketing submissions.

A new entity can cost several millions of rupees or dollars to progress. Surprisingly, even a few month deferrals in taking it to the market can have substantial impact on the monetary status of the company. One of the vital activities of the regulatory specialist is to ensure that the label of the product and related information of the patient has correctly been established and even a small mistake in any of the regulatory activities can make the product to be ready for recall in addition to the loss of several millions of money which is eventually bound to give rise to fall in self-assurance of financiers, health experts and finally the patients.

The regulatory professional:

The current state of affairs. Personalities who guarantee regulatory accordance and assemble the submissions or proposals together with those whose central job role is clinical affairs or quality assurance are all taken into account as regulatory affairs professional.

Accountabilities and careers in regulatory affairs:

Regulatory affairs professionals usually have responsibilities for the following general areas:

- Ensuring that their companies comply with all of the regulations and laws pertaining to their business. They need to keep a track on ever changing legislation in all countries where the companies is looking to market their product.
- Working with federal, state, and local regulatory agencies and personnel on specific issues affecting their business.
- Advising their companies on the regulatory aspects and climate that would affect proposed activities i.e. describing the 'regulatory climate' around issues such as the promotion of prescription drugs, regulatory compliance etc.
- They are responsible for the presentation of registration documents to regulatory agencies in India and importing countries and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorisation for the products concerned in country of origin as well as importing countries.
- Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the products.

Furthermore, one of the vastly legalised industries in the world is the pharma and specialists who can bring about this regulation are in high exigency.

When we sell drugs we need to be fairly confident that they do what they claim to do, they have been through a tough testing process to get from the lab to the market and the side effects are well documented. This is where regulatory affairs come in. The Indian pharma industry has a Compound Annual Growth Rate (CAGR) of over 13 per cent in last five years and it is expected to grow at a higher rate in the coming 10 years. It is valued at \$ 8.0 billion approximately and ranks fourth in terms of volume and 13th in terms of value globally. \$15 billion market and it is estimated to reach \$40 billion by 2020. With such a high growth rate and rapid globalisation there is a substantial need for highly trained professionals ready to perform the work required within this specialised industrial sector who will keep updates with regulatory laws, policies and procedures for one or more product lines as well as maintain an understanding of the scientific and technical background of new products. As far as the needful skills are required and when it comes to the regulatory experts, it embraces project management and its configuration, nego-

tiation, communication both in written and oral as well as complete attention towards the details. Over and above, an analytical frame of mind and an ability to evaluate the strengths and weaknesses of the technical and legal options open to a company and to the agency concerned are essential.

A high degree of sensitivity is required when proposing and executing the strategy and tactics needed to obtain marketing approval in a way which will satisfy the authorities and serve the best needs of the company. Considerable care must be exercised if the best possible case is to be presented to the authorities for the company. It must be done without obscuring the facts, enabling the authorities to arrive at proper and rightful conclusions regarding safety, efficacy and quality of the product under application. Regulatory professionals must always exercise considerable judgment in the practice of their role. Integrity and the ability to inspire trust and confidence are valuable attributes. Outstandingly, a worthy regulatory affairs individual has to have a good view towards concept of quality management which delineates itself as prevention of faults is far more beneficial and costeffective than its discovery and linked redraft or amendments. Besides, coordination of scientific trials, during the course of the product's journey along with the requirements of its regulation, significantly banks upon a regulatory expert who helps the organisation expand the cost effective use of its wherewithal.

Regulatory affairs proficient is only the very connexion point in the middle of the regulatory authorities and the company whose positive or negative standpoint fosters the insight of the regulatory authority into the industry, for good or for bad. So, the better the scientific precision, the greater will be the chances for a product to come to the market within the expected time. An eminent regulatory professional is always able to work under stressed situations and inspires, motivates others to do the same. No college degree or basic seminar can 'make' an RA professional - the title is earned through continuous enhancement of RA knowledge and skills, effectiveness of training, experience and hardwork. As the profession grows and more individuals join ranks, it will be interesting to see where this diversity takes us. The long and short of it, it is absolutely essential that any product that is intended for human use or for human health must be in pure state, safe and efficient at all the time for which effectual regulation is pretty inevitable. ■

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