

Regulatory Affairs Outsourcing

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Regulatory Affairs Unit in a pharmaceutical company is a vital unit that drives the R & D efforts of the company to the market successfully. Today a Regulatory Affairs department is a dynamic business unit which works with a focus to get products to the market with a commercially viable label in the least possible time and expenses.

Today the world has become a global village and many companies are in a race to place many new products in the world markets to gain market share and increase earnings. In such a scenario a small delay in gaining market access means huge loss in terms of market share and revenue generated. The key to success for pharmaceutical companies lies in obtaining timely marketing approval from regulators.

So to obtain timely marketing approval companies can either strengthen their regulatory department or outsource the same to regulatory affairs consulting firm.

With changing global regulatory norms, outsourcing regulatory affairs work seems a more beneficial option both in terms of time and money. Maintaining a large regulatory affairs department can be very expensive and scope of knowledge can be limited to certain aspects. On the other hand a regulatory affairs consultant keeps on updating himself with the current regulation and has vital experience in the field to expedite the approval process.

This article further explores the services provided by regulatory affairs professional and the key points for proper selection.

There are many regulatory affairs consulting firms providing services both at a large scale and small scale. Large scale service providers possess large ranges of expertise under one roof, operate on a global basis, some even have local presences in different countries. While small regulatory firms specialize in one or the other aspect of regulatory affairs, for e.g. compiling dossiers, Analysis, agency contacts etc.

Well established regulatory firms can provide service in the following ways

- Compiling large regulatory application for submission in different countries
- Expertise Knowledge regulatory and scientific knowledge
- Expertise knowledge and support in terms of local regulatory authority
- Expert solutions to FDA queries
- Access to Scientific and technical resources
- Formulation and implementation of regulatory strategies on a global level

A regulatory firm can surely accelerate the submission process, but this won't happen unless there is active participation of the customer (party hiring the regulatory firm).

Once it is established the service offered by regulatory affairs professional can help company save both time and money, proper selection of regulatory professional is very important. This article will explore some of the key points for selecting a regulatory affairs consultant

Experience: Experience in pharmaceutical industry particularly in drug development is an essential for pharmaceutical regulatory consultants. Consultants should have experience in preparation and submission of regulatory documents. A consultant working actively in this field for 5 -10 years will have extensive knowledge on getting approval for various drugs, he will be able to formulate regulatory strategies and implement them. His professional references, documents prepared by him, approvals obtained by him, articles published by him can be used to evaluate his experience.

Confidentiality: A Confidentiality agreement has to be in place to protect your company's proprietary knowledge. A consultant's confidentiality can be evaluated by requesting previous studies and information shared can be used to judge the same.

Staff: A company must have adequate staff to serve ongoing projects without delay. The staff must be highly skilled and trained to carry out regulatory work. Staffing capability can be judged by visiting the consultant's office, professional associations, website information and office locations.

Collaborations: The Company must have access to key technical and scientific resources at their disposal for timely completion which can be achieved by having in house facility or collaboration with other service providers.

System: Company should have in place standard system to carry out the work effectively. Initial communication with the company will give an impression of how far the company is organized and follows a standard system.

Technology: Technology has become a key part for success and timely submission today. With the introduction of eCTD it has become important for companies to integrate technology in their companies. Website of the company can be an example of adoption of technology.

There are many more criteria which can be used to evaluate and select proper regulatory affairs consultant but this article is limited to the above mentioned criteria only.

Regulatory affairs outsourcing is on a growth worldwide, many large and small companies have adopted this strategy to get a timely approval. Even multinational firms are outsourcing their regulatory work to lessen the pressure on their in house team or to support the same.

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