Emerging Trends in Regulatory Outsourcing

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You are not alone in the quest for bringing your products to market and improve the quality of life for millions! MakroCare brings you the insight on how a drug/device development partner can help you navigate the regulatory hurdles, from Concept to Market, and various emerging partnership models.

Regulatory Landscape

Today Pharmaceutical Industry is passing through a very challenging period in its evolution as the traditional approaches to drug development constantly expanding. On one side there is tremendous pressure on the Industry and Medical Fraternity to reduce the cost of prescription drugs and on the other, operational costs are skyrocketing. In addition to these are complex regulatory requirements, declining revenues from the lost sales of blockbuster drugs going off patent and pressure from governments as well as health insurers for a reduced healthcare cost. Given these difficulties pharmaceutical companies across the world have realized the need to leverage resources, and the expertise provided by specialist external sources.

In the last ten to fifteen years Big Pharma has outsourced almost all processes Chemistry, Clinical, Non Clinical, Logistics, IT, Marketing, and all other non core processes. In spite of the cost and business benefits, companies were cautious in outsourcing some functions like IP, Regulatory Affairs, etc. as they are the most vital functions that drives R & D efforts of the company to the market successfully.

However with companies expanding into global markets and with changes in the clinical landscape, most companies have tested unknown destinations. This has turned into a positive note as it not only reduced the clinical cost but also shortened the R&D cycle and hence, bench to market. Companies have realized that the key to success lies in obtaining timely marketing / clinical approvals from regulators. Therefore to obtain timely marketing / clinical approvals companies have either strengthened their regulatory department or outsourced this to regulatory affairs consulting firm.

Many high end regulatory consulting companies have come on the global screen offering their expertise across the product life cycle; however they have certain limitations such as appropriate expertise, geographical reach, etc. As a result pharmaceutical companies were forced to maintain large regulatory affairs departments across the geographies. This has proved very expensive.

Over the period it had become a daunting task for Pharmaceutical Companies to address local regulatory challenges as well as constant changes in the regulations of major markets such as US, Europe and Asia. Staying in compliance with existing regulations has become an overwhelming chore, leave alone trying to stay current with developments across the globe. Amendments to existing regulations promise to further complicate the regulatory path for the industry. As a result, demand for outsourced regulatory expertise is rising. Whether the need is simply to procure more able consultants to help with submissions or surveillance efforts or the need is for deeper regulatory knowledge in specialty areas such as (Clinical Regulations, Dossier Requirements, Quality System Requirements, CMC, Labeling, etc)

While many regulatory consultants are familiar with preparing submissions, auditing quality systems or conducting clinical trials, those who can develop and improve a company’s regulatory strategy are even more valued because they can often save their clients time and money by leading them to the path of least resistance.

Trends in Regulatory Outsourcing:

Today firms of various sizes are becoming more comfortable in exploring the RA Outsourcing options, at various functional and strategic levels. Some of them include

Large Firms: These are the big boys and they used to have very traditional RA department. These are the ones that are really changing and increasingly outsourcing various RA functions, activities, and projects.
Bigger companies have strong technology infrastructure and ability to attract qualified, experienced employees. Also, these firms’ portfolios, pipelines and resources make keeping Regulatory in-house practical and feasible. So regulatory outsourcing in large companies is mostly about addressing capacity problems, they typically outsource regulatory work when they need additional capacity as all these companies have full complement of regulatory staff; outsourcing is seen more as a supplement to their internal capability than as unique expertise they lack. In addition, when companies cut back on their internal regulatory staff, they end up outsourcing the additional workload. Another interesting factor is that most of these companies are trying to consolidating their regulatory departments to avoid duplication of activities.

**Mid-Sized Firms:** Anywhere from 500 to 2,000-3,000 employees - have a larger, more "usual" RA department make-up. Outsourcing is likely to be very task /project-oriented (e.g., Dossier Assembly or individual clinical trial oversight from an RA standpoint).

Most mid sized firms have decently large regulatory departments. However they have limitations in reaching global markets because most of them are confined to few markets. As they are constantly expanding they are looking for regulatory consultants who can manage their submissions and management of applications.

**Small Firms:** Startups or companies with approximately 100 people or less in size – Most of, their RA department might just be 1 person in-house. Outsourcing is likely to be End to End.

Most of the smaller companies depend on external consultants for host of services as they either don’t have the expertise or the manpower. “Many of them have a really good Regulatory / Medical director with good experience but whose staff isn’t big enough to support his or her needs”. They are the companies who largely depend on external consultants for End to End services.

**Emerging Regulatory Outsourcing Models:**

As the regulatory requirements are different, challenges and goals too are different. It’s very rare to find a consulting company to address the challenges of Big, Mid Sized and Small Pharmaceutical Companies. Only a consulting company which has built its capabilities around these models can address the challenges of the pharmaceutical companies of different sizes.

**Business Models**

- Big Pharma: FSP
- Mid-Sized: Hybrid
- Small Pharma: End to End

**FSP Model**

The major outsourcing with Big Pharma has been seen in FSP models only. This model helps in reducing the cost, while improving the resource flexibility and still maintaining quality. Outsourcing parts of the RA function, has proven to be a profitable strategy in addressing this challenge. This generally involves most of the tactical work like:

- Conformance guides
- Review of CMC documentation
- Drug Master Files
- Technical Writing
- eCTD conversion
- Conversion Dossiers from old format to CTD/eCTD formats
- Annual report & Variations preparation
- Query Management
- IND maintenance
- Serious Adverse Event reporting
- Drug shipment approvals for clinical trials
- Labeling
- SOP writing and training
- Coordinating with contract vendors in Clinical / Nonclinical / CMOs
- Review of GMP / Validation documents
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Best Practice includes, developing a outsourcing strategy. The due diligence should be done and cost-benefit analysis should be made, to list the work, which should be retained in-house, and work which can be outsourced. This also allows the companies to increase efficiency by allowing their internal resources to focus on highest priorities.

Vendor Evaluation: For companies looking to select Regulatory Consulting firm, for outsourcing services on FSP model basis, the most important factor to evaluate should be the vendors’ resource strengths, and their expertise. And another factor should be a strong IT infrastructure, which should enable the companies to have a clear visibility on the progress of the task assigned, while maintaining the data confidentiality.

End-To-End Model

Start-up or Small companies have a great option of opting for end-to-end model to take care of their regulatory requirements. Companies offering this model should have deep expertise across the drug development cycle. Most of these consulting companies interact with the regulatory bodies on behalf of the sponsor company, manage training requirements, coordination, consulting and support for other functions in product development and commercialization operations. In addition they also assist in preparation, management and filling of all the related documents, including management of the Application.

During the early stages of the product development, the primary challenge can be identifying of the right service provider. Companies who may not have the capability or who wish to reduce the risks due to the burden of maintaining dedicated teams choose this option as it allows them to move light and fast, while having the flexibility of sizable resources and quality support.

**Strategic:**
- Competitive Intelligence
- Regulatory Strategy for Product Development
- Regulatory Management of Global Submissions (Drugs (New / Generic), Medical Devices)
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- Regulatory Authority Liaison
- Electronic Submission
- Due Diligence assessments for product licensing
- New Market Identification
- GMP audits

Vendor Evaluation: Companies looking to select Regulatory Consulting firm, for outsourcing services on End-to-End model, should focus on the consulting companies experience on the Therapeutic Areas / Technologies, and their global presence. If you are planning to commercialize the products in multiple markets, vendors’ local presence and their knowledge on local markets can play a significant role in the success of your products in those markets. A good IT infrastructure will definitely be important, for managing the project efficiently.

Hybrid Model

The Hybrid model is the most suitable for mid-sized companies as this allows them to effectively manage regulatory outsourcing. FSP model for their domestic markets, and utilize the End-to-End model outsourcing to capitalize on the consulting companies’ presence in the international markets and its understanding and reach in those markets.

Another facet of Hybrid model includes long-term partnership between the sponsor company and the consulting company, to impart services, for requirements planned or anticipated or the period of time, which include outsourcing parts of function or execution of a complete project in a particular geography. This allows the consulting companies’ to consolidate resources and timelines, and while being able to impart these services at highly competitive rates, and has been proven to be handsomely cost effective for the companies of various sizes, who have a outsourcing polices in place and considerable amount of anticipated outsourcing requirements.

Irrespective of the size of the company or the outsourcing model, regulatory department is the critical link between R&D and commercialization. Companies therefore need to evaluate the capabilities of regulatory consultants before outsourcing the project; this can be as a part of due diligence (pilot tests, face to face interviews, etc), client references, global reach and past experiences.

Vendor Evaluation: For companies looking to select Regulatory Consulting firm, for outsourcing services on Hybrid model basis, the evaluation factors will include their resource capability, expertise, global presence, local market understanding and relationships, and finally a good IT infrastructure.

Another important factor to consider here is, other than the FSP model, for most efficient and successful utilization of the partnership with the Consulting firm on a End-to-End or Hybrid model basis, the vendors should be engaged in the process from the early stages itself, which will help in defining the optimal Regulatory Strategy from the beginning, increasing the chances of Factory-to-Market Success.

All this said, the companies, should carefully review the Consulting firms’ confidentiality policy and there should be a Confidentiality Agreement in place. It is important to evaluate their capability to maintain your company’s proprietary information as privileged. SOPs might come in handy to see if the consulting company has any mechanism to protect the IP of its customer.

Conclusion

Finally, outsourcing may represent an attractive option for sponsors to gain experience, optimize cost, and enhance productivity. Equipped with real experience, a sponsor will be better-equipped to assess their requirements, select the best solution, and understand the effort associated with implementing, operating and maintaining a publishing system. Ideally companies should look for a consulting company which can also offer supporting services such as Pharmacovigilance.

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