TOP 100 RA ACTIVITIES WHICH ARE OUTSOURCED

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INTRODUCTION

Currently Regulatory Consultation has become a lucrative business area .Lack of Regulatory Expertise, Complex Regulations, Urgency and competitive pressures continue to motivate **Pharmaceutical Supply Chain to explore outsourcing of RA Activities.**

Many a times it has been noted that outsourcing of RA activities are much economical than employing an up-to-date manpower for the same. This article has been written to highlight the benefits of outsourcing regulatory intelligence and the whole spectrum of regulatory activities which are worth outsourcing.

REASONS FOR OUTSOURCING REGULATOR INTYELLIGENCE

The followings are few reasons for outsourcing RA activities:

1	Outsourcing ensures rapid marketing authorizations. The consultants can accomplish any typical marketing authorization within 3-6 months for which company may take 12-24 months time.
2	Outsourcing helps in meeting ever increasing regulatory expectations .The regulations are constantly amended and the consultants are specialized in mastering them in time.
3	Outsourcing facilitates overall reduction of cost and time for marketing authorizations. A good regulatory consultant costs only 25% of what one spends on entire team of regulatory and quality control personnel. Outsourcing turns your fixed costs on regular staff in into lower variable cost.
4	The regulatory consultants generally have deep and up-to-date regulatory knowledge and solid track record of regulatory compliance. Outsourcing reduces chance of redo.
5	Outsourcing helps in training to the in house regulatory staff. The regulatory staffs who work closely with regulatory consultants become trained automatically.
6	Consultants can be hired as and when needed. It saves complexity and cost of maintaining the special regulatory staff for the full year.
7	Consultants undertake liability to do right in the first attempt whereas the regulatory staff may require repeated attempts.
8	The outsourcing organizations have the proper SOP and contacts in place with key regulators.
10	Outsourcing helps to meet advanced regulatory norms which require deep knowledge and experience to interpret.
11	Outsourcing help is acquiring competitive knowledge, practices and regulators expectations for their kind of products.
12	Outsourcing also simplifies tasks such as Complaint handling, CTD filings, Variation Filings, Renewals of marketing Authorizations, Closure of Registrations, Recalls , training on complex regulations etc.

13	Outsourcing Prevents the errors, redo, loss of time in regulatory compliance.
14	Outsourcing helps in associated functions such as QC/QA, Validation, Internal Audits , OOS, Document Planning and management, APR ,Supplier audits and Development of New Products
15	Outsourcing avoids costly penalties, cancellation, and hold of marketing authorizations
16	Outsourcing allows the available staff to concentrate more on quality control, quality assurance and production activities
17	Outsourcing helps in Priority approvals resulting in increased market share and additional revenue from gaining in stock price and/or investor funding
18	Outsourcing is an effective risk management tool. It prevents loss from product approval delays or recalls. It also helps in preventing fines, penalties and loss of reputation.

TOP 100 RA ACTIVITIES WHICH ARE OUTSOURCED

The broad categories of RA activities which are outsourced are: Regulatory Planning, Preparation and submission of dossiers, Liaoning with regulators, accelerating Approval Process, Solution to the Queries, Post Approval Changes, Training/Guidance to regulatory staff, Audit of manufacturing site, Maintenance of Marketing Authorizations, filing variations and amendments, Expert Report of submissions.

Followings are the top 100 specific regulatory activities which are outsourced by Pharma world

No	ACTIVITIES WHICH ARE OUTSOURCED
1	Follow-up with MOH till the registration documents are accepted and approval letter is issued
2	GMP Audit/Gap Analysis/Gap Closures services.
3	Guidance on Filings Variations/Amendment for the registered products
4	Guidance on Labeling and advertising of Medicinal Products
5	Expert reports on Regulatory Submissions
6	Guidance for Planning, Preparation and Delivery of regulatory submissions throughout the product's life cycle with regional perspective.
7	Guidance for Response Documents for health authority
8	Guidance on Briefing Documents for health authority
9	Liaison with Health Authorities on regulatory issues on routine and non-routine basis
10	Management of Complex Regulatory submissions
11	Preparation, Mainainence and delivery of Regulatory Operational Plans
12	Review of Annual Reports on Regulatory Compliance
13	Management of PIL, SPC and Physicians Training Materials
14	Change Control to avoid non compliance to the existing Marketing Authorizations
15	The Management of audits conducted by FDA/EDQM/MHRA and other Regulatory Authorities
16	Pre submission Review of Dossiers/CTD and amendments to the same.

17	Assistance for Product Withdrawals and Closure of Marketing Authorizations
18	Guidance on CFR Part 11, ISO 13485, CMDR, MDD , PAL, FMD ,ICH and other National and International Regulatory standards/laws/directives
19	Periodic appraisal of new regulations, standards, policies as issued by regulatory authorities that may impact the company business.
20	Guidance for organizing regulatory workshops for upgrading the knowledge of regulatory professionals employed at the site
21	Assistance for recruitment of top management regulatory staff as well as down line regulatory professionals
22	Assistance for Maintenance of Marketing Authorizations (Product Licenses) in chosen territories through regular updating
23	The Management of Marketing authorization under ANDA, MRP, CEP, NDA and national procedures
24	Advice and Training on new regulatory requirements
25	Responding to requests for technical support from Regional offices, Local distributors and Indenters.
26	Maintenance of databases relating to regulatory activities
27	Liaison with labeling group to generate appropriate packaging materials
28	Liaison with medical support group for Pharmacovigilance.
29	Guidance/support/training to Regulatory Affairs Team
30	Advise on the best approach to obtain regulatory approvals
31	Guidance on resolving departmental regulatory queries.
32	Preparation of product development reports
33	Formal Review and Rectification of internal regulatory documents
34	Guidance to in-house CTD writers and Response team
35	Training and mentoring of junior regulatory writers
36	Updating the regulatory team with latest regulatory information
37	Negotiation and persuasion with drug regulatory agencies on technical matters
38	Assistance to young regulatory personnel for interpreting regulatory data/information and their implications on regulatory submissions
39	Development and execution of regulatory plans for complex regulatory projects involving genotoxic studies, extensive impurity profiling , characterization of polymorphs, BE studies on patients and Multicentre Clinical Trials
40	Review and evaluation of technical and scientific data required for submissions
41	Tracking the status of regulatory submissions
42	Regular regulatory input for product lifecycle planning
43	Assistance in developing and updating based upon evolving regulations.
44	Guidance on patent issues for ANDA submissions
45	Advise on regulatory structure and system of any particular region or country
46	Advise on risk-benefit aspects on new drug products.
47	Advise on rational for drug combinations and new dosage forms
48	Overview of applications for product registrations
49	Advise on preclinical, clinical and manufacturing requirements for product development
50	Maintenance and renewal of manufacturing and marketing authorizations and product

	registrations
51	Assistance for the review of advertising and promotional activities
52	Electronic Submissions and updating of CTD documents
53	Contribution to the development and functioning of the crisis/ issue management program
54	Regulatory inputs for product recalls and recall communications
55	Solutions for resolving conflicts with regulatory bodies
56	Guidance for cultivating culture for regulatory compliances
57	Assistance for developing extensive network of mentors for regulatory guidance.
58	Guidance and active counseling of new recruits in regulatory department
59	Vendor audits and guidance for improving cGMP Compliance
60	Intelligent services for selecting innovative and practical methods to achieve regulatory solutions.
61	Assistance for the Management of Regulatory Compliance issues.
62	Participation in training programs for raising awareness of regulations applicable for designing, production, and marketing of pharmaceutical products
63	Reviewing and resolving Patient safety and/or regulatory noncompliance flagged items
64	Providing expertise on quality and regulatory issues raised by employees, management and customers
65	Representing the company on quality and regulatory matters before regulators
66	Complex data analysis and feed back for improvement on authorized products
67	Active support for verbal and written communications with FDA to resolve problems and queries
68	Audit for accuracy and scientific validity of the documents designed to meet current regulatory standards.
69	Assistance for planning submissions and regulatory documents within agreed timelines.
70	Mentoring the regulatory team on assigned projects
71	Assistance for identification and resolution of likely regulatory issues which may crop up over the time.
72	Direct communication with Regulatory Authorities to expedite review and approval of submissions
73	Assistance for conducting scientific, regulatory legal or business research
74	Assistance in the archival process of all regulatory documents
75	Assistance for authenticating the product claims in advertising & promotional and labeling materials to ensure compliance with FDA regulations.
76	Active support for daily activities that support registrations, submissions and data analysis
77	Support for on-going corporate initiatives for regulatory compliance
78	Assistance to subsidiaries and distributors for regulatory compliance under FMD act
79	Assistance for Corrective & Preventative Actions to mitigate deficiency letters issued by FDA
80	Assistance on updating current worldwide regulatory requirements

81	Regulatory overview and guidance for new products in various stages of clinical development.
82	Development and implementation of global regulatory strategies to enhance the potential value of company assets.
83	Guidance on regulations across various geographic regions to maximizes probabilities of success for regulatory and ethical compliance
84	Liaison with regulatory team to develop and deliver effective strategic regulatory plans to support assigned projects
85	Management of global regulatory submissions with a high quality standards in alignment with corporate timelines and objectives for assigned compounds
86	Assistance for maintaining good liaison with global health authorities to ensure outcomes is consistent with program objectives.
87	Guidance to regulatory team on latest regulatory/drug development issues so as to accelerate success in on going projects.
88	Interactions with regulatory authorities throughout the product registration lifecycle. Assistance for tactful negotiation with regulatory authorities
89	Resolution of complex legal and regulatory matters clearly and effectively through clear and effective communication both with internal and external regulators.
90	Assistance to review/ analysis of initial project execution plans and/or corrective action plans to ensure compliance with new or existing laws and regulations
91	Building and maintenance of positive working relationships with regulators
92	Coordination with new business/sales/product development team to determine and comply with regulatory requirements
93	Management and resolution of consumer complaints
94	Training for CMC/Non Clinical/Clinical component of regulatory submissions
95	Training to the staff to handle multiple tasks and work under pressure
96	Advise on art and style for dealing with regulators/health authorities
97	Guidance on Product recalls and Adverse Events
98	Development and implementation of regulatory strategies aimed at gaining the earliest possible regulatory approvals
99	Establishment and maintenance of effective relationships with regulatory agencies
100	Company representation at public forums/conferences/seminars
101	Regulatory audit for conformance to EU, Canadian and FDA legislations and directives/guidance documents
102	Assistance to FDA for compliance investigations of drug products
103	The preparation, submission and timely approval of regulatory submissions
104	Support for proper archiving of regulatory SOPs, Documents ,Directives, Rules ,Acts, Approvals, Reviews, Submissions , Response Letters and Deficiency Letters
105	Advice on new drug development, new dosage forms development and new drug combinations.
106	Advise on designing protocols for BE studies, Clinical Trials and Non Clinical Studies
107	Advise on Impurity Profiling, Stability studies, Forced degradation studies, Analytical method development, Structure Elucidation, Excipients selection for the drug products

108	Advise on selection or reagents, solvents , starting material, intermediates and route of synthesis for new active substances
109	Guidance for Characterization API for Molecular Structure, Molecular Formula, Chirality, Polymorphism, Particle size, Solubility, Molecular form and Isomerism
110	Outsourcing of peer reviewed scientific articles on Non Clinical and Clinical aspects of the drug product
111	Drafting of overviews and summaries for CTD Module3,4 and 5
112	Redesigning of regulatory submissions to meet regional or national requirements.
113	Scientific assessment and discussion on regulatory submissions specially on CTD Module 3

PN: The Consultants generally do not offer guarantees in regulatory compliance. Further, they also donor undertake any legal responsibility for authenticity of data as their advise is based on the data submitted by the customer. Responsibility for compliance with any law, directive or regulations ultimately rests with the outsourcing company.

CONCLUSION

It is always wiser to outsource the regulatory intelligence to improve efficiency and to save the cost of regulatory compliance. The regulatory consultants/professionals who ensure Confidentiality, timelines and intelligent solutions for regulatory functions always enjoy good business and professional satisfaction

About the Author:

The author of this article himself is a regulatory consultant associated with PPCPL
PPCPL is a full-service Regulatory Solutions Provider, including filing of ANDA, DMF and CTD and has processed more than a 1,000 submissions over the last 25 years.
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