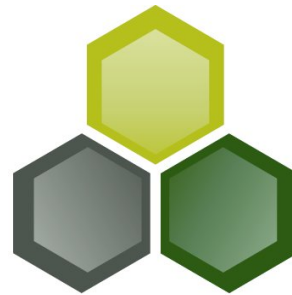


Kinapse



Life Sciences Consulting and Outsourcing

Kinapse White Paper

Offshore outsourcing in Regulatory Affairs and Pharmacovigilance

Expertise ► Collaboration ► Innovation ► Results

Offshore outsourcing in Regulatory Affairs and Pharmacovigilance

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Kinapse Consulting, 2010



Based on Kinapse's direct experience, we explore the emerging environment for regulatory and pharmacovigilance offshore outsourcing within the biopharmaceutical industry and predict the evolution of sourcing from emerging markets for these skill sets. The ideas in this paper build on a Kinapse editorial, published in September 2010, which proposed that partnering between client and service provider allows cost reductions and quality benefits while creating value for both organisations.

Sourcing opportunities in a challenging regulatory and commercial environment

Today, all life sciences businesses need to evolve to succeed and grow in a challenging external environment.

For instance, governments, payers and patient groups are demanding greater stringency on quality, safety and efficacy and have been demonstrating increased risk aversion in granting approvals and in management of in-market safety signals. In addition, as European and other markets strengthen access controls at the 4th hurdle and beyond, more effective strategies to support both regulatory approval and reimbursement are required in parallel. Importantly these strategies need effective cross-functional working between regulatory, medical and market access (health outcomes, government affairs and advocacy) experts.

Harmonisation of regulatory requirements is also enabling the globalisation of regulatory affairs activities. Many of the global pharmaceutical companies are publicly pursuing aggressive growth strategies in commercially important emerging markets including the BRIC countries as well as others such as Mexico, South Korea and the Middle East region. In this respect, a truly "global" regulatory affairs organisation needs to foster local knowledge, cultural understanding and personal contacts in these markets to support ambitious commercial strategies through achieving timely and full approvals, and ultimately market access.

Equally, as electronic submissions continue to replace paper, companies can now be more flexible about where they locate the resources delivering business processes. Moreover, with eCTD, E2B and other forms of electronic submission becoming commonplace in the core ICH countries and beyond, leading global regulatory affairs groups can take

advantage of these trends to diversify and reduce their cost base through offshoring strategies.

While several functions in major global life sciences companies such as IT and data management have a significant track record of offshore resourcing, perceptions of intellectual property risk and regulatory compliance concerns have seen regulatory affairs and pharmacovigilance organisations only just start the process of offshore resourcing of core Regulatory Affairs processes. However, these concerns are mitigated by growing confidence in patent protection in markets such as India and China and a relatively positive acceptance of offshore resourcing models by Health Authorities for instance in clinical trials execution and adverse event case processing. In this respect, Kinapse has recently been retained by the European Medicines Agency to undertake a major project in EudraVigilance.

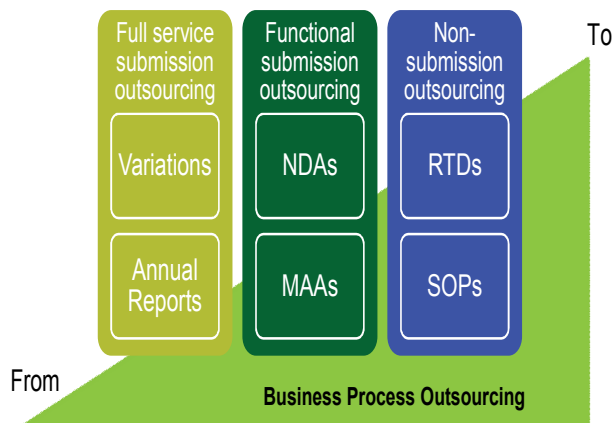
Additionally, commercial strategies targeting these markets and their growing middle classes for sales of patented products mean that multi-national companies need to transfer intellectual property to these markets and the relevant government stakeholders in these markets often actively encourage the establishment of operations groups in their respective countries. The arguments against resourcing regulatory activities in low cost countries are therefore rapidly diminishing.

This combination of factors makes this an ideal time for a global regulatory affairs group to seize the opportunity to reduce costs, take advantage of new lean electronic documentation and submissions processes and invest in relationships with key emerging markets. This will free up time and budget for experienced staff to focus less on document production and more on strategic interactions with health authorities externally and development teams internally, ensuring submission of dossiers that contain compelling data supporting label claims that regulators are ready to approve.

Emerging offshore outsourcing practises

We expect that offshore outsourcing in Regulatory Affairs and Pharmacovigilance will expand rapidly in three complementary approaches illustrated in the figure below.

Figure 1. Offshore outsourcing approaches in Regulatory and Pharmacovigilance services.



In full service submission outsourcing (suitable for variations, renewals, ICSRs and PSURs and Annual Reports) all activities across the document lifecycle (from requirements gathering and planning to handling HA questions) are outsourced. This approach is being followed by companies primarily for mature products in international markets.

In functional submission outsourcing (most suitable NDAs, MAAs and other major submissions) activities which are increasingly outsourced offshore include submissions project management, authoring of CTD modules and publishing.

Non-submission related offshore outsourcing (covering regulatory intelligence, due diligence, systems support, resource and performance management) includes novel areas for which the capabilities are often not required consistently within the client organisation or are more efficiently shared across organisations and cost advantages achieved through use of lower cost resources.

Organisational considerations in offshore outsourcing

In any Regulatory Affairs and/or Pharmacovigilance operating model three main organisational axes need to be balanced, depending on the specific operating objectives of the organisation – namely:

1. Geography: requirements for local presence to support commercial priorities (new launches and lifecycle management) in key markets through understanding local

requirements and managing HA and HTA relationships

2. Therapeutic Area/Franchise/Products Knowledge : requirements to build and sustain specialist expertise in therapy areas, diseases, specialist product families
3. Functional excellence: requirements to sustain deep knowledge within functional disciplines such that processes, standards and best practices and associated skills are optimized.

In this context, clearly defined, documented and measured business processes are critical for successful use of offshore outsourcing. Existing company processes often need further specification and tailoring for offshore delivery. Additionally, organisation designs which include reporting lines, roles and responsibilities, design and composition of matrix teams, modus operandi at organisational interfaces (e.g. with Commercial, R&D and Manufacturing groups) must be optimised. The location and roles of staff within Regional hubs and countries will need adjustment to allow for effective sizing and operation of the internal Regulatory & Pharmacovigilance functions with which the offshore unit works to be defined. Clear responsibilities for these groups and the offshore unit they will interact with are critical.

Conclusion

Kinapse is pursuing Regulatory Affairs and Pharmacovigilance offshore outsourcing strategies which this paper has summarized. We believe a sea change is occurring in these practices. We are therefore committed to seeking continuous improvement in the implementation in collaboration with all industry stakeholders to achieve high quality, compliant and cost-effective operations.

About the Authors

Andy Black is co-founder and Chief Executive Officer of Kinapse. In the last 20 years Andy has consulted to many of the world's leading Life Sciences Organisations.



Gavin Outteridge is a Vice President in the Kinapse Consulting practice and has led a variety of organisational design, sourcing strategy and performance management projects for Regulatory and PV groups in major Global Healthcare Companies.



About Kinapse

Kinapse works with its life sciences clients to provide value creation through information processing, business transformation consulting and asset value consulting. We provide synergistic capability to enhance value in these three areas separately or in combination. Our business model blends experienced consultants with a high caliber analytic and delivery team based in India with industry veteran Consulting Partners who bring deep experience and expertise of R&D processes and functions.

We help companies to understand the real value of their assets and develop strategies for exploiting their portfolio that best support these companies' objectives, capabilities and resource constraints. Our experience in organisation and process design and implementation, and transactions makes us well placed to support in the implementation of actions resulting from decisions on portfolio strategy. In conjunction with one of our industry partners we can offer a complete suite of services and solutions around portfolio strategy, valuation, tactics and implementation.

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