Transforming the Regulatory Affairs function: Rational options for outsourcing and value retention

Regulatory Affairs functions are increasingly under pressure to do more with less and to demonstrate their value. Outsourcing is becoming more common in addressing resource demands to deliver perceived lower-value tasks. Without considering a holistic target operating model for these functions, Regulatory Affairs leaders may adopt a piecemeal approach that does not address the challenges in establishing an operating model that consistently adds value. A strategic approach can determine what core activities must be retained within an organization and where outsourcing fits as part of an overall strategy for delivering maximum value.
Today’s Regulatory Affairs functions are a challenging place in which to be. Many continue to experience cost pressures and headcount restrictions. Competing demands to secure new product approvals, maintain compliance, and do more with less have grown during the last decade. At the same time, investments in people and regulatory information systems have increased significantly to keep pace with the need to automate activities such as regulatory operations and publishing. As belts tighten in the industry, finance and procurement functions see opportunities for cost reduction in Regulatory Affairs, and the imperative for Regulatory Affairs functions to demonstrate the value they deliver has never been greater.

In this environment, outsourcing is becoming an increasingly important part of the regulatory capability mix. Our experience shows a pronounced move toward sustainable outsourcing for activities such as CMC remediation work through to the management of an entire portfolio. Regulatory Affairs outsourcing decisions, however, still tend to be reactive and based on the premise that only operational activities can be outsourced.

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One impediment to Regulatory Affairs outsourcing lies in the complexity and diversity of the activities involved in regulatory. But more intangibly, and perhaps more importantly, there is an inherent reticence to embarking upon outsourcing. Outsourcing means challenging the idea that Regulatory Affairs is art and not a science and that high-quality delivery can only be ensured via internal resources.

While some outsourcing arrangements might provide cost efficiency or alleviate resource crunches, they have not typically been established in a way that drives long-term and sustainable value. In short, they have not been part of a holistic strategy for organizations.

The target operating model view: A strategic approach

We are not stating that outsourcing is always what is needed, but we do advocate considering the creation of a clear target operating model, in which outsourcing can form part of a comprehensive solution to maximize the value of the Regulatory Affairs function. A strategic approach will ensure that the function focuses on higher-value activities and that there is clarity about the role of an embedded partner and the return on investment of this relationship. A successful strategy must address these key requirements and concerns often voiced by Regulatory Affairs leaders:

- “I would like my best people and most competent regulatory resources focused on the highest-value task.”
- “I need oversight and control of an outsourced provider so I can ensure quality.”
- “How should I manage the turmoil for people and processes that outsourcing might create without diminishing compliance?”

Step 1 – Mapping Regulatory Affairs on a page

The first step is to plot the Regulatory Affairs function on a single page. This high-level landscape provides objectivity on the scope of the function. It enables a considered determination of what is core and non-core, where internal resources should focus to deliver the most value, and where outsourcing and other sourcing options fit as part of an overall plan for the function. This does not mean simply “throwing tasks over the wall” to a third-party provider. Maximizing value from an outsourcing relationship requires the investment of resources, time, and an end-to-end process view of performance. It enables the function to communicate its span of activities to other functions and stakeholders while avoiding the perception that Regulatory Affairs is a “black box.”

Figure 1 shows a “helicopter view” of logical groupings of activities that are in the scope of a typical Regulatory Affairs function.

Step 2 - Make or Buy

Fundamentally, deciding what you keep inside the organization or what you outsource is a make or buy decision. On one hand, this should consider the proximity to customers and whether the
activity is repeatable, as well as the relative level of performance on the other. A short, independent evaluation of the function will determine this. That is, a focused exercise using a range of diagnostic tools that identify functional activities as either core, turnaround, outsource, or value trap and provide initial indications of subsequent strategies and the target operating model, as shown in Figure 2.

If relative performance and strategic impact are both high, these activities are core and should be retained and invested in. Activities of high strategic impact but where relative performance is low are areas where turnaround is needed and which need to become core. If the strategic impact is low and the activity repeatable, then this type of activity could be considered a target for outsourcing. For example, delivery of routine life cycle submissions or mature brands’ regulatory submission support. Other activities are where delivery is good but value is low, such as desk-side support for department IT systems not supported by corporate, or reformatting of documents because other functions cannot or will not follow templates. These are examples of the value trap and could be handed to external service providers to release valuable internal resources to core activities.

**Step 3 – Defining an appropriate target operating model**

Applying these criteria to the one-page view of Regulatory Affairs can be revealing and can provide a rational basis for creating a value-generating target operating model for the function. Ensuring that the focus is on core activities releases resources from more routine operational tasks. Let’s imagine that the Regulatory Affairs function has decided to focus internal resources on regulatory strategy and to outsource all life cycle management work. Successful implementation requires effective management of change for those directly affected and mechanisms to ensure adequate control for the retained organization while providing clarity and certainty for the outsourcing partner.

If we assume that such a move will meet resistance, explanations of value drivers and cost reduction, while they may be highly relevant, will only address a proportion of stakeholders. Those most affected will want to know about job security and how this will affect the scope and intrinsic interest of their role. In short, is the new proposition attractive? Otherwise, attrition of key staff can be anticipated.
Activities requiring high-levels of judgement and organizational understanding need to be retained in-house and may require investment in strategic regulatory capability. Other roles in the retained organization will also need to change to reflect the move; managing outsourced partners is not resource free. Adequate governance, control, oversight, and an end-to-end process view will be needed to drive additional performance.

**Conclusion**

Doing more with less through outsourcing is an increasing reality for many Regulatory Affairs functions. A strategic approach to outsourcing that is proactive and considered provides insights and decisions about department strategy and capability development.

Such an approach begins with a straightforward analysis of the function, which provides the context for any decision on which an effective change management and stakeholder communication plans can be built. This initial analysis will drive significant additional work to firm-up recommendations, and also to manage the changes that any resulting strategy will bring about.

Most importantly, it places the regulatory function in the driving seat in determining a target operating model for delivering the most value and will clearly identify those areas where alternative sourcing arrangements can be an effective part of the mix.

*Figure 2. Impact and performance determine appropriate improvement and make vs. buy strategies*