Building a 21st-century global regulatory affairs organization

Big pharma faces an ever more complicated and high-stakes regulatory environment. Players that can’t develop new capabilities and mind-sets risk being left behind.
The pharmaceutical industry is facing an ever more complex regulatory landscape. Managing drug approvals in major developed markets such as the United States and the European Union is already an immensely challenging task, but the growth of new markets—Brazil, Russia, India, and China alone accounted for nearly a quarter trillion dollars in drug sales in 2016—means that pharmaceutical companies now must navigate the regulatory guidelines for multiple countries simultaneously to gain approval for new drugs. Emerging product categories—such as personalized medicine and diagnostics, gene therapy, and biosimilars as well as the growth of existing categories such as drug and device combinations—further highlight the need for clear regulatory guidance. Meanwhile, pharmaceutical companies must also balance more demanding regulations in the areas of advertising and promotion (particularly on social media), manufacturing, and benefit and risk management.

Despite these developments, the government regulatory affairs (GRA) organizations at many pharmaceutical companies have not kept pace. They are often perceived as purely transactional or, worse, a compulsory function that slows progress and chokes innovation. The stakes are high: global drug R&D spending reached $149 billion in 2015, so drugmakers lacking an effective GRA organization could spend significant amounts of money to conduct tests that don’t ultimately satisfy the requirements of regulators. Yet GRA organizations also face constrained departmental budgets, hiring freezes, and even downsizing or the outsourcing of key elements of regulatory affairs to third parties—a sign that they haven’t adequately communicated the value they can deliver and aren’t yet considered full strategic partners.

To meet the evolving challenges, GRA organizations must adopt new mind-sets and substantially upgrade their capabilities. In some cases, this effort may require the addition of new talent and leadership. GRA leaders should begin by comparing their own sense of mission against the four core competencies of an effective GRA organization: regulatory strategy, regulatory guidance, document management, and regulatory intelligence. Then, leaders must ensure that five vital enablers—leadership, processes, systems, organizational structure, and people—are working together so that their organization can deliver strategic counsel and support throughout the regulatory approval process. GRA leaders that do these things most effectively will not only deliver superior value to the enterprise but also be well positioned to serve as thought partners to clinical development teams long into the future.

Start by clarifying the mission

Generally speaking, the mission of a GRA organization is to provide leadership, guidance, and expertise to internal customers—including clinical development, medical affairs, manufacturing, and commercial marketing—on regulatory matters throughout the life cycle of a drug. Further, it must work closely with both internal stakeholders and regulatory bodies to influence governance and decision making. Although the exact makeup and responsibilities of a GRA organization can differ from company to company, the function typically has four core competencies that are necessary to achieve its mission (Figure 1):

• **Regulatory strategy.** Drawing on deep knowledge of the field and existing connections with agencies and relevant opinion leaders, GRA organizations must develop and recommend regulatory pathways that not only meet agency approval but also deliver a competitive target product profile.

• **Regulatory guidance.** GRA organizations provide regulatory expertise to cross-functional partners at global, regional, and local levels throughout the submissions process (and product life cycle) to achieve and maintain regulatory approval. This guidance ensures that the organization’s overall GRA strategy and compliance aligns with the company’s internal and external policies and standards.

• **Document management and submission.** This task involves the development and submission of high-quality documents for new products and product changes in a timely fashion as well as the maintenance and tracking of registration documents and regulatory commitments in compliance with agency requirements.

• **Regulatory intelligence and agency relationships.** Connections to local health authorities (for example, the European Union’s

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A target product profile provides a description of the drug under development, its anticipated characteristics, and how its attributes will make the drug a distinctive product in the marketplace, among other information.

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Figure 1: **Four competencies of an effective GRA organization**

- Regulatory strategy
- Regulatory guidance
- Document management and submission
- Regulatory intelligence and agency relationships
European Medicines Agency, the United Kingdom’s Medicines and Healthcare products Regulatory Agency, and the US Food and Drug Administration) and knowledge about their expectations of market authorization holders (such as drug manufacturers) are critical to navigating the approval process. A GRA organization’s members collect and communicate emerging regulatory trends and submission requirements. In addition, they engage with regulators to seek advice, shape regulatory policies, influence impending regulations, and, when possible, negotiate more favorable outcomes.

In the typical pharmaceutical company, a GRA organization will deliver its greatest value through a combination of its regulatory strategy and agency relationships. By contrast, the more transactional aspects of the job, notably document management and submission, are often outsourced to external vendors, allowing the internal team to focus on higher-value tasks.

The five enablers of regulatory success

Once a GRA organization has defined its mission and desired competencies, its leaders must develop a comprehensive approach to five organizational enablers (Figure 2): leadership, processes, systems, organizational structure, and people practices. Since these enablers are highly interdependent and complementary, GRA organizations that underperform on one or more of them may need to undertake the equivalent of a change management effort to move the needle on performance. Understanding how the enablers work together can help organizations ensure that they have the capabilities to manage the regulatory and approval process effectively.

Leadership
To ensure that functional partners in the business don’t view the GRA organization as an obstacle to progress, GRA senior leaders must clearly articulate their vision for the group in terms that create a clear business case for the value that regulatory affairs can deliver. One of the major challenges we observe in this task is the lack of leadership communication and advocacy on key initiatives, including strategic projects, organization change, and talent management. Time and again, we see GRA leaders implement major change initiatives by making grand kickoff announcements that lack any plans for sustained, follow-up communication. It is almost impossible for business partners and frontline GRA staff to grasp the importance of an initiative—any initiative—without consistent reinforcement from leadership about the function’s mission, rationale, and relevance to the larger organization.

Getting everyone on board is not an easy task, but it’s achievable. We have worked with a senior regulatory executive at a global pharmaceutical company who is a master at making the business case for GRA involvement and garnering support from the company’s executive board for key initiatives. He achieves this success through a combination of in-person storytelling that tracks progress or delays, and he connects the results directly to the company’s bottom line. At the same time, he ensures that his entire GRA organization and business partners are fully committed to the initiative through consistent and repeated communication in the form of e-mails, meetings, newsletters, town halls, and special recognition events, among others.

Processes
GRA organizations do not work in a vacuum; regulatory activities are mostly cross-functional in nature, with significant interdependence across groups such as formulation development; analytical sciences; medical affairs; chemistry, manufacturing, and controls (CMC); clinical development; marketing;
quality assurance; and manufacturing. Thus, work processes—both strategic (for example, regulatory strategy development) and operational (such as dossier submission to health authorities)—are designed to clearly delineate these cross-functional interdependencies and handoffs. Further, regulatory work processes need to clearly define regulatory roles and responsibilities in the context of global, regional, and country-level regulatory affairs to avoid gaps or overlaps. For example, more organizations are moving away from a US- and EU-centric regulatory strategy development and dossier submission model and toward a new framework that emphasizes more direct responsibility from regional and country regulatory affairs. We have seen organizations proactively seek input from as many as 20 countries when drafting a global regulatory strategy for products still in early development. In another instance, a company built a comprehensive regulatory labeling development process that depends heavily on regional regulatory affairs teams to provide not just simple oversight but also quality control of country input and implementation of labeling changes.

Most GRA organizations monitor the effectiveness of work processes—especially those related to regulatory submission and compliance—through a set of key performance indicators (KPIs). They must go a step further and connect their KPIs to the enterprise’s performance so that GRA members understand their impact on revenues and the company’s goals. The most effective KPIs are designed with input from departments that are responsible for achieving the targets; this helps ensure that adequate resources and capacity exist to implement the initiative according to each country’s regulatory requirements. Although GRA is responsible for labeling change submissions and approvals at the country level, for instance, the implementation of these changes lies with the manufacturing site. So KPIs for a large-scale label change initiative should be set in consultation with colleagues in manufacturing and quality assurance.

**Systems**

The assembly and submission of regulatory dossiers often involve a regulatory information management (RIM) system to support activities...
such as document creation, document knowledge management, document control (including routing and approval), and submission data tracking (for example, product approval and registration status). Due to the importance of regulatory information in managing compliance risk, a well-functioning RIM is a foundational element of all regulatory documents and data, including country-specific submissions. However, our experience suggests that, in many organizations, the RIM system has often been implemented in a piecemeal, reactive fashion to address a particular need. As a result, organizations often wind up with software from multiple vendors, some out-of-the-box and some custom built, and this fragmented approach impedes transparency and interoperability.

For example, a well-established Japanese pharmaceutical company that has expanded to a global footprint over time had three submission management groups within its GRA organization, located in the United States, the European Union, and Japan. Unfortunately, each of these three offices used its own systems—including some homegrown varieties—for submission management, document repository, and health authority response tracking. The systems’ incompatibility with each other meant that individual offices lacked visibility and access to dossiers, causing processes to move slowly and even opening the company up to potential cybersecurity risks.

When developing a new feature, the organization must consider how it will integrate with systems used by other functions. This is particularly true with respect to systems that involve new and developing technologies—such as direct data capture in clinical trials—that can accelerate regulatory submissions and facilitate faster approvals.

**Organizational structure**

Too many pharmaceutical companies make the common mistake of starting with the organizational chart when it comes to building a GRA function. Ideally, the organizational structure reflects the underlying work processes and associated roles and responsibilities, so that form follows function. Therefore, the GRA group should be organized *after* the company-specific GRA mission, core competencies, and processes have been defined. The specifics of the GRA organizational approach will depend heavily on its processes; however, each GRA organization should consider the geographic scope of the markets it supports and how the broader company is structured.

At one GRA organization that had historically focused on US and EU markets to inform its submission strategy, senior leaders decided to globalize the strategy development process in order to address regulatory requirements in key emerging markets more efficiently. After designing a process to better incorporate regional and local regulatory input earlier in the drug development process, the need to bolster regional and local regulatory capabilities became clear. This GRA organization restructured its staffing model for regional and local affiliate offices accordingly, including the addition of new, strategy-focused leadership roles. Similarly, a large pharmaceutical company with prescription pharma and consumer divisions had embedded regulatory affairs into each division. To reflect the company’s evolving view of regulatory affairs as independent strategic partners, the capabilities were combined to form a central GRA organization that could better serve the company as a regulatory center of excellence. As a result, the organization lowered costs, was able to make better use of outsourced vendors, and made the whole network more cohesive.

**People practices**

GRA organizations need to develop innovative pathways for navigating the tangled web of modern global regulations in order to help their internal partners understand what they can do—starting from the top. Regulatory affairs leaders must adopt
a different mind-set and spread that new way of thinking as they develop employees to fill changing roles in the organization. Senior leaders must clearly define desired skills and experience and ensure that these skills are aligned with the organization’s mission; failing to do so can result in poor hiring decisions, low-impact training, and incentives that do not align with the desired mission.

Making this shift requires a completely different talent profile. GRA organizations have two options: develop the needed people internally, or hire a new crop of employees. People already in the organization may also be a good fit for other roles under a new structure. To identify promising internal candidates, GRA organizations can map potential career paths by defining the knowledge, skills, and attitudes required to move from one role to another, whether upward to more senior positions or laterally to different functions. GRA organizations must also update their recruiting practices to attract individuals with the right skills. For example, so-called “behavior event interviewing”—asking candidates to explain situations or experiences from previous positions—can help recruiters gauge if a candidate has exhibited a strategic mind-set in the past and screen out prospects whose qualifications on paper may be impressive but who would not meet the behavioral expectations of a strategic GRA organization. In addition, these interviews can help GRA executives assess an individual’s ability to be a network leader ³ and to engage effectively with both internal and external stakeholders—a critical skill in regulatory affairs today.


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The shifts in the global regulatory environment are profound and comprehensive, and so must be the organizational change efforts to properly adapt to them. Many GRA organizations will need to better articulate their mission and the value they deliver, but this effort is only the first step toward building the needed organizational capabilities.
Healthcare and Life Sciences Practice

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