CITELINE

Biotechnology And Pharmaceutical Companies Are Embracing Regulatory Technology Outsourcing

Blending Human Regulatory Expertise With Technology Increases Efficiencies While Reducing Risks

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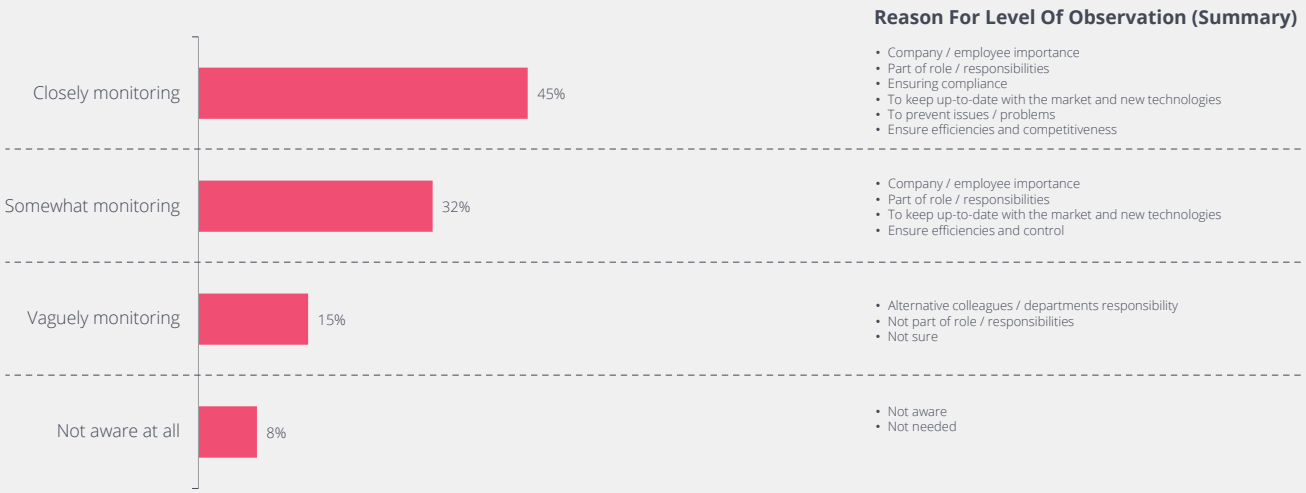
Keeping pace with the constantly evolving regulatory requirements for biotech and pharmaceutical products is always challenging, particularly for smaller enterprises that may lack the capacity or expertise to manage these issues in-house. Even for larger companies, the risks involved in steering development programs from discovery through to marketing authorization and beyond, as well as the time, effort and expenditure involved, may be too demanding to handle on their own.

If the benefits of outsourcing regulatory services extend across the biopharmaceutical industry, they may apply to different phases or elements of the regulatory process. This, in turn, depends on the stage of product development and the size of the company concerned. For all types of companies, though, access to innovative technology is a key driver of regulatory outsourcing. At the same time, companies need support and guidance on how to use the expertise and technology available through outsourcing. They also want reassurance

that outsourcing will be a constructive investment in optimizing regulatory capability rather than just an additional cost.

The level and breadth of interest in regulatory outsourcing were evident from a recent survey of biotechnology and pharmaceutical companies conducted by Citeline on behalf of IQVIA. In total, 45% of respondents said they were watching closely the development of the latest technologies for regulatory outsourcing. Respondents cited reasons such as corporate focus, obligations of their role, efficiency and cost-efficiency, compliance, staying competitive and avoiding problems. A further 32% of respondents were "somewhat" monitoring the situation (Figure 1).

Figure 1: Technologies Training



Question: How closely do you follow the development of the latest technologies affecting outsourcing regulatory activities?
Base: All respondents (n=110).

Question: Please explain the reason for your answer?
Base: All respondents (n=76).

Attention to new outsourcing technologies was fairly consistent across industry segments. For example, among emerging and small biotech/pharmaceutical companies, 46% and 32% of respondents, respectively, were closely or somewhat monitoring the latest technology in regulatory outsourcing. On the other hand, in mid-size and large biotech/pharmaceutical companies, 49% and 32% of respondents were watching new technologies closely or to some extent.

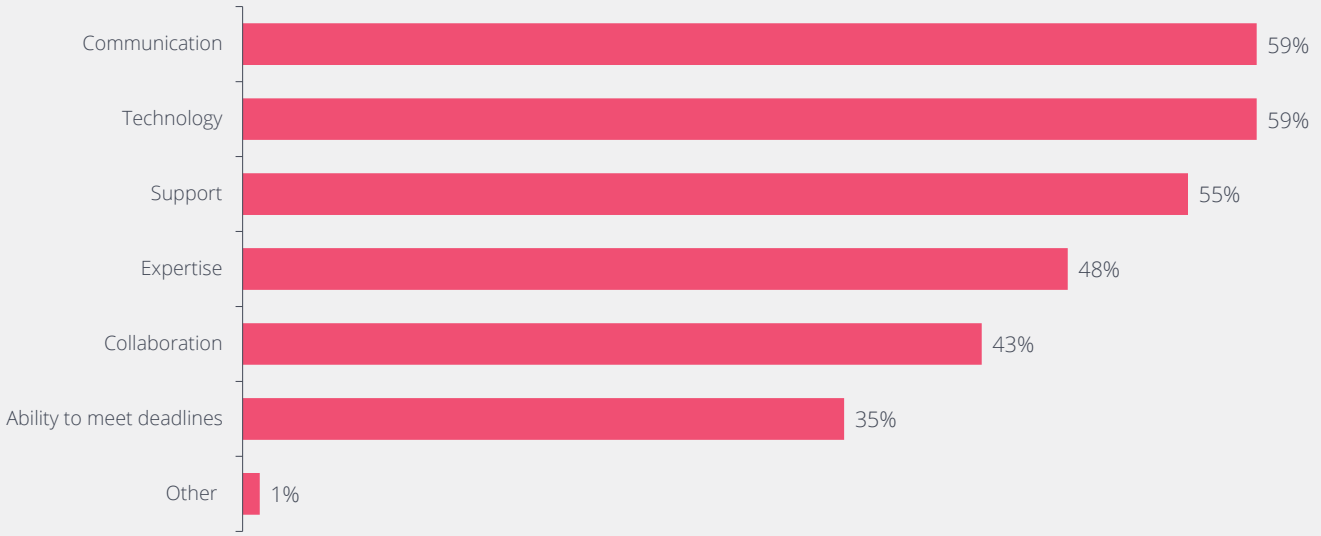
Some survey participants explicitly linked awareness of new technologies with their ability both to stay abreast of regulatory developments and to retain their competitive edge. "In our business strategy high-tech progress is crucial to stay up to date with novel regulations," one respondent commented. Another underlined the need to "stay ahead of the game and above the current, in order to stay relevant in our current field."

Awareness And Implementation

Most survey respondents were keeping an eye on evolving technologies for regulatory outsourcing, and they did not generally feel ready to implement those technologies without some help from outsourcing partners. In fact, 81% of survey respondents saw a need for additional education or training before they put the latest technologies to use. That need was slightly higher for mid-size and large biotech/pharma (81%) than for emerging and small biotech/pharma (78%). The latter segment is already significantly more reliant on regulatory outsourcing than their mid-size/ large counterparts (see next paragraph) and therefore more likely to be familiar with enabling technology.

Technology (59%), along with communications (59%) and support (55%), also emerged as one of the three main considerations when companies were selecting an outsourcing partner for regulatory activities (Figure 2). Among mid-sized/ large biotech/pharma companies, the emphasis in selecting partners was more on communications (59%) than technology (53%) or support (51%), while collaboration (53%) was a more urgent consideration than for the industry overall (43%). Responses from emerging/small biotech/pharma again reflected stronger reliance on outsourcing, with technology (62%) and support (57%) as the chief considerations in vendor selection, followed by communication (54%), expertise (51%) and collaboration (38%).

Figure 2: Selecting An Outsourcing Vendor



Question: What are the top 3 considerations you have when selecting an outsourcing vendor for regulatory activities? (Please select your top three considerations)
Base: All respondents (n=110); top three answers permitted.

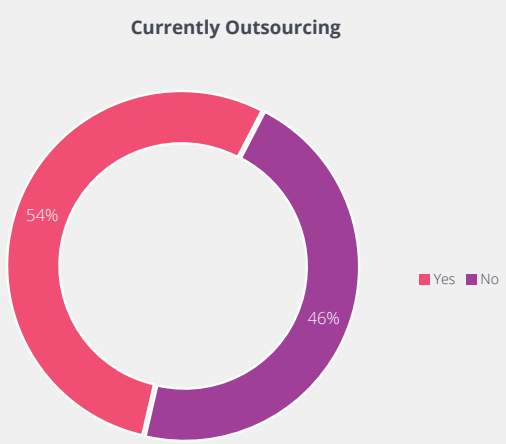
These disparities seen between industry segments are a reminder to vendors that service offerings in regulatory affairs must be tailored to the type, size and stage of development of the potential partner. Those criteria will determine to some degree the kind of expertise, involvement and support companies are looking for from their outsourcing partners, and the most important touchpoints and emphases for any ensuing relationship.

Regulatory Concerns, Strategy Development

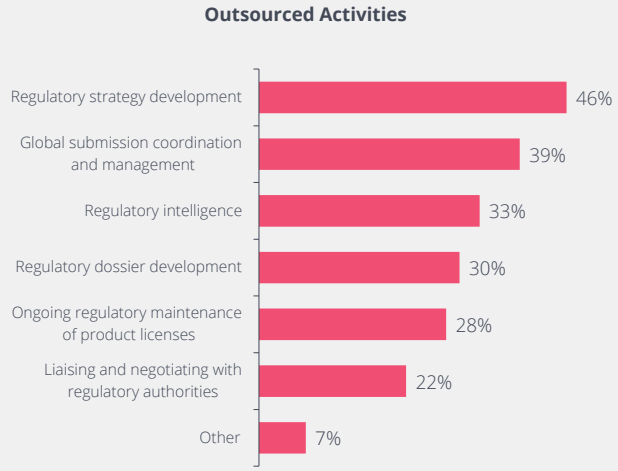
Other than highlighting the importance of access to technology and associated support, the Citeline/IQVIA survey provided general insights into current trends in regulatory outsourcing. Many of the respondents, who were largely based in North America or Europe, had concerns about the regulatory environment for the industry worldwide, with particular emphasis on the US (53% of respondents), China (40%) and Japan (30%).

A majority of survey participants were addressing these challenges through outsourcing, with 54% of respondents already farming out regulatory activities (Figure 3). Regulatory-strategy development was the most commonly outsourced activity, followed by coordination and management of global submissions, regulatory intelligence and dossier development.

Figure 3: Outsourcing Regulatory Activities



Question: Do you currently outsource your regulatory activities?
Base: All respondents (n=100).
Note: 'Don't know' not included (n=10).



Question: What activities do you outsource? (Please select all that apply)
Base: Respondents outsourcing regulatory activities; multiple answer permitted (n=54).

Regulatory-strategy development can mean different things according to the scale and stage of the enterprise. For example, emerging/small biotech/pharma may be more focused on getting the clinical-development plan right or prioritizing the best indication(s). They may prioritize activities such as gap analyses or determining success criteria for their asset. In mid-sized/large biotech/pharma, there is likely to be more emphasis on issues such as regulatory submission strategy, global market expansion, operationalization, or technology automation.

While the survey found that a significantly higher proportion of emerging/small biotech/pharma (62%) were outsourcing regulatory activities than mid-sized/large pharma (46%), regulatory-

strategy development was outsourced more than any other sub-activity in both segments (52% of mid-sized large companies, 43% of emerging/small companies). Across the industry, regulatory-strategy development (61%), program management (52%), auditing of the outsourcing partner (52%) and regulatory intelligence (48%) were the main functions of internal regulatory departments working with outsourced partners.

There is some room left to pursue new outsourcing relationships for regulatory services, with 38% of survey respondents saying they planned to outsource regulatory activities in the future. Cost savings (31%) were the principal reason, followed by improving productivity and operational efficiency (22%), reducing internal workload (16%) and speeding up regulatory approvals (13%). Prioritization of cost savings above all other reasons to outsource in the future was consistent across industry segments. However, fewer emerging/small biotech/pharma companies (33%) planned to outsource regulatory activities than mid-size/large pharma (36%), suggesting again that outsourcing is already more advanced in the former segment, with its comparative lack of internal resources for regulatory affairs.

Barriers To Outsourcing

While the survey outcomes presented a strong case for putting some key regulatory activities in the hands of outsourced partners, they also made clear that companies still have some qualms about handing over too much responsibility. Budgetary restraints and systemic risks were the main worries, despite the strong emphasis on cost savings as a driver for regulatory outsourcing (Figure 4). Budgetary limitations were the number one barrier to outsourcing for both emerging/small biotech/pharma (62% of respondents), and mid-size/large pharma (63%).

Figure 4: Barriers For Outsourcing Regulatory Activities

Question: What are your top 3 major barriers for outsourcing regulatory activities? (Please select your top three barriers)
Base: All respondents (n=110); top three answers permitted.

Mitigating Risks

There are also worries ("major" for 39% of respondents, "some" or "slight" for 50%) about cybersecurity in the context of regulatory outsourcing. Understandably, the sharpest concerns were in organizations that had previously experienced cybersecurity breaches. Conversely, cybersecurity was less of an issue for respondents who trusted the safety systems and measures their organization had put in place.

Nonetheless, there was general recognition of cybersecurity as a growing problem for industry, one that can also be difficult to monitor. "No matter how well protected and careful an organization is, there is always a risk of cyber threats, and we must remain vigilant at all times," one respondent warned. For another, the greatest risks in this area were "associated with the dependence on third parties (longer response times, service hours), the confidentiality of the data and compliance with regulations."

Given the various barriers and risks taken into consideration by survey respondents in determining whether to farm out elements of regulatory affairs, it is not surprising that many of these companies want to incorporate mitigants and exit strategies into their relationships with potential outsourcing partners. In the survey, 61% of respondents said they applied these conditions in partner selection, whether because they were a company requirement, already incorporated into partnerships, a means to simplify switching, or a risk-reduction strategy that enabled companies to duck out of unhealthy relationships.

How IQVIA Can Help

The survey results suggest there is a strong and sustainable appetite across the biopharmaceutical industry for outsourcing regulatory services, with access to technology as one of the main reasons to consider an outsourcing partnership. At the same time, enthusiasm for new technology is qualified by the need for guidance and support on how best to leverage technological advances, and by concerns about staying within budgetary limits. In addition, companies seek a partner who takes an above standard approach to digital security through detailed business continuity procedures.

IQVIA's end-to-end outsourcing model for regulatory strategy, operations, compliance and quality assurance can help to streamline regulatory activities, while anticipating and addressing hurdles to the timely and effective fulfillment of regulatory milestones. In addition, it is adaptable to different outsourcing needs and priorities, depending on the partner's stage of evolution and how far product-development programs have advanced.

Its unique blend of regulatory services and technology, including cutting-edge AI/ML and NLP tools, along with the ability to incorporate both its own Connected Intelligence™ and customer technology into partnerships, positions IQVIA ideally to address the growing demand for regulatory outsourcing. With the right expertise, guidance and support to make the most of technical innovation in the field, while mitigating any associated risks or cost concerns, partners can feel confident of a more efficient, productive and effective journey through the regulatory maze.

Pink Sheet
Pharma Intelligence

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About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. With approximately 86,000 employees, IQVIA conducts operations in more than 100 countries.

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