

Outsourcing regulatory activities in pharma

Here, *EPR's* Caroline Peachey explores some key considerations, approaches and strategies for pharmaceutical companies looking to outsource regulatory activities.

OUTSOURCING has become a necessity for many pharmaceutical companies; even the outsourcing of regulatory functions has grown over the past several years and is expected to increase steadily in future. The pharmaceutical regulatory affairs outsourcing market is thus projected to rise from $7 billion in 2022 to $15 billion in 2032,[1] driven by the growing number of clinical trial applications (see **Figure 1**)[2] and product registrations. Clinical trials are expected to account for the largest share of the market – approximately 46 percent.[1]

Collectively, Europe and the US are anticipated to account for 60 percent of the global outsourcing regulatory affairs demand to 2032. However, the Asia-Pacific region is set to be the fastest growing, driven by rapid expansion, particularly in India and China.[1]

In the regulatory space, the trend is typically to subcontract about half of the work and do the other half internally, explains Olivier Saslawski, an expert in chemistry, manufacturing and controls (CMC), regulation and pharma outsourcing. Saslawski has over 30 years' experience in the industry in various companies, having served most recently as Head of Global Regulatory CMC, Worldwide Regulatory Affairs at Servier, an international pharmaceutical company, headquartered in France. Servier is active in cardiology, metabolic diseases, oncology, and neuroscience both in medicinal chemistry and biotechnology.

Saslawski's perspective is reinforced by a recent industry survey of biotechnology and pharmaceutical companies,[3] which found that 54 percent currently outsource their regulatory activities, while 46 percent do not.

Regulatory functions that are commonly outsourced include medical writing/dossier development, submissions planning and co-ordination, regulatory data and information management, local regulatory applications, agency liaison and regulatory strategy.

Regulatory strategy development was found to be outsourced by 46 percent of companies surveyed in 2023.[3] Precisely what 'regulatory strategy' encompasses can vary depending on the size and stage of the organisation. Emerging or smaller pharma/biopharma companies are likely to focus on clinical-development planning and prioritising the best indications, so work could involve gap analysis or determining success criteria.[3] Larger or more established pharma are likely to put the emphasis on regulatory submission strategy, global market expansion or technology automation.[3]

Five drivers for outsourcing regulatory activities

There are several reasons why pharma companies look to outsource regulatory activities.

Cost savings: Outsourcing can potentially lead to savings on infrastructure, staff and training. It also allows pharmaceutical companies to focus their resources on their core business activities, thus improving productivity. Cost savings (31 percent) was found to be the main reason companies surveyed were looking to outsource regulatory activities in future.[3]

Expertise: Keeping up to date with ever-evolving regulatory requirements is a significant driver for outsourcing regulatory activities, particularly for smaller organisations that may lack the capacity or expertise to manage these complex issues in house. Larger companies may opt to outsource to reduce internal workload, enable strategic focus on core activities and expertise, or to reduce overheads, Saslawski explains.

Flexibility: Outsourcing provides the flexibility to scale regulatory activities up or down, as needed; something that is especially valuable for pharmaceutical companies facing fluctuating workloads due to changing market/regulatory demands. A survey of pharmaceutical companies operating in Finland, Sweden, Estonia, Germany and Spain found that 91 percent of respondents outsourced regulatory tasks because they want to gain greater flexibility.[4] Flexibility remains important today and Saslawski recommends finding a partner that can respond rapidly to peaks and troughs in the industry.

Speed: Some 13 percent of those surveyed[3] said speeding up of regulatory approvals was the main reason for outsourcing regulatory activities. Expanding into new international markets often involves navigating unfamiliar regulatory landscapes. Outsourcing regulatory affairs to firms with global reach and expertise can help companies access new markets efficiently, while they focus on key strategic areas or markets, Saslawski notes.

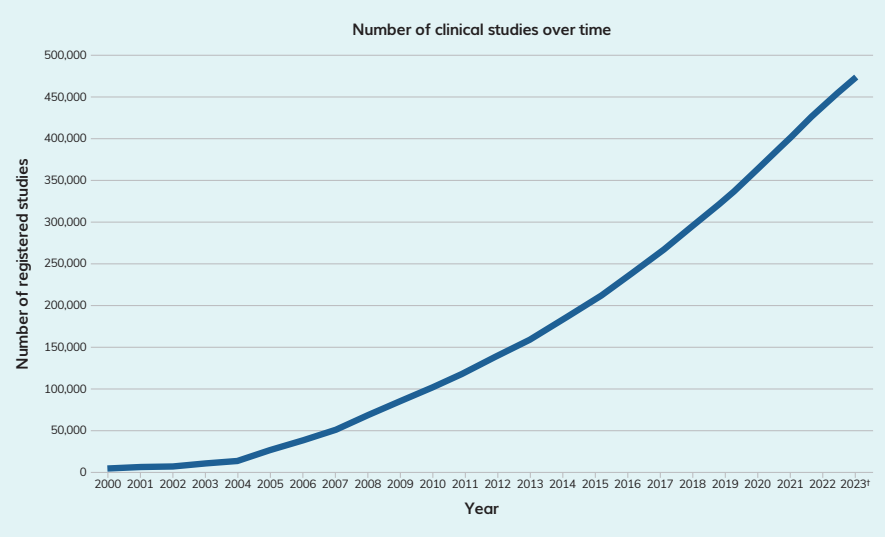

Figure 1: The number of clinical trials has been growing rapidly. (Source: ClinicalTrials.gov)
†2023 data as of 26 October 2023

Risk mitigation: Outsourcing can help mitigate compliance risks by leveraging the knowledge and experience of regulatory experts. This requires that external providers have strong quality assurance systems in place, as well as advanced technologies/tools.

Approaches to outsourcing regulatory activities

There are different approaches to outsourcing regulatory functions in pharma. Some companies outsource on a 'product' basis, says Saslawski. However, this way the company loses knowledge, history and control of its product over time given the different variations (process and analytical) submitted that is part of the life cycle management. It should be noted that the pharmaceutical company remains responsible by law for the product. Some companies outsource product management in specific markets only.

Rather than outsourcing activities on a 'product basis', an alternative is to outsource 'tasks', Saslawski explains. With this approach you subcontract tasks, releasing internal resources, but retain overall control and programme oversight.

When looking to select partners for outsourcing regulatory activities, the challenge is to identify a company able to perform a wide range of services including regulatory CMC, publishing, submission, pharmacovigilance etc. It is important for pharmaceutical companies to carefully evaluate their needs and objectives when looking to outsource regulatory activities. For smaller organisations, factors such as technology and support may be seen as major considerations. For larger pharma companies communications (59 percent) were seen as a higher priority than technology (53 percent) or support (51 percent), with collaboration (53 percent) a more urgent consideration than for the industry overall (43 percent).[3]



Carolne Peachey
Caroline is editor of *European Pharmaceutical Review*

References

1. Fact.MR. Global Regulatory Affairs Outsourcing Market Outlook. 2022. Available from: https://www.factmr.com/report/regulatory-affairs-outsourcing-market
2. ClinicalTrials.gov. Trends, Charts, and Maps. [Internet] 2023. [cited 2023Oct]. Available from: https://classic.clinicaltrials.gov/ct2/resources/trends
3. Citeline. Biotechnology And Pharmaceutical Companies Are Embracing Regulatory Technology Outsourcing. [Internet] 2023. [cited 2023Oct]. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/Campaign/2023/IQVIA-Citeline-Regulatory-Outsourcing-Research-Report
4. Gummerus A, Airaksinen M, Bengtström M, Juppo A. Values and disadvantages of outsourcing the regulatory affairs tasks in the pharmaceutical industry in EU countries. Pharmaceutical Regulatory Affairs: Open Access. 2016;05(01). doi:10.4172/2167-7689.1000161