

Outsourcing Regulatory Filings with an FTE Model: Five Keys to Consider

As an increasing number of drug and device developers focus their efforts on reducing costs so they can invest more heavily in their core R&D functions, it's no surprise that the outsourcing market for healthcare regulatory affairs is predicted to expand at a rapid pace over the next decade. Some estimates say the market will reach \$200 million by the end of 2025.

While some sponsors choose to outsource regulatory affairs when they are seeking approval for their product, the benefits of regulatory outsourcing can extend far beyond approval. Even when companies have a strong regulatory team in-house, they may find outsourcing can drive cost efficiency and scalability — particularly when the focus is ongoing regulatory maintenance or publishing and chemistry, manufacturing and controls (CMC) activities.

For mid-size and large manufacturers with many products, hiring a full-time staff to manage regulatory filings through the product life cycle can be costly and unwieldy to manage. A Full Time Equivalent (FTE) outsourcing model can help to streamline post-approval regulatory filings, enabling sponsors to maintain compliance and reduce overhead costs without compromising quality or risking deliverables.

If you are considering outsourcing post-approval regulatory work, here are few keys to help you choose wisely:

1. Seek experts with deep experience: The regulatory strategy, including writing key communication and submission documents, is critical in achieving approval and maintaining compliance.

Each therapeutic area and each approval pathway has its own regulatory nuances and special requirements. The last thing a sponsor needs is to lose time, or dollars, funding an outsourcing partner's learning curve. The more in-depth experience your regulatory partners have with your product's therapeutic area — and the specific pathway — the more able those partners will be to hit the ground running.



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2. Look for flexibility to integrate with your team: In an ideal FTE outsourcing model, the consultants will have the flexibility to work independently or under the direction of a manager on your team. Additionally, they should be able to operate within your company's established requirements, or bring expertise to help develop those processes and templates if they are not already in place.

Essentially, your outsourced team should have the flexibility to ebb and flow to meet the unique needs of your company — and fill in gaps if any exist.

Some FTE models have a hybrid built in — meaning they can shift from FTE to hourly at times, allowing manufacturers to scale their work up and down quickly.

3. Remember that depth matters: When it comes to the most complex and nuanced components of regulatory affairs, particularly strategy development and regulatory writing, there's no substitute for proven, hands-on experience.

Some potential partners may boast significant experience at the senior-most levels of the organization, then pass your day-to-day project work on to a team with much less experience. That's why it's important to ask potential outsourcing partners to share the average years of experience of the specific team that will be working on your product. An experienced FTE leader, who can anticipate manufacturers' needs and who knows which levers to pull to keep the model at 100% capacity, is also critical to success.

4. Consider your outsourcing partner's employee and customer longevity: Years and depth of experience are critical, but so are team and customer longevity. It can take years to map out and steer successfully through the drug development and commercialization process — and team turnover is a sure-fire way to slow that process down. That's why it's critical to ask potential regulatory affairs partners about their staff turnover rate. It is also helpful to know what percentage of their work comes from customer referrals and repeat business.

The answers to these questions will indicate each potential partner's reliability and whether the staff that works on your product is likely to remain consistent.

5. Request case studies: Anyone can claim to deliver results, but few companies can demonstrate it. Be sure to ask your potential partners to share case studies of how they have helped companies like yours reach regulatory milestones, maintain high quality and achieve cost savings through outsourcing.

Choosing the Right Partner is Key to Success

As sponsors focus on cultivating their own internal R&D talent and expertise, they'll continue to seek out regulatory affairs experts who can help them contain costs while expediting approval pathways and maintaining compliance. However, choosing the right outsourcing partner, from the start, is key to the success of this approach. Sponsors must be thoughtful and strategic in engaging early with partners who have not just the therapeutic and pathway approval experience, but also the depth and breadth of experience needed to remove potential roadblocks and streamline the regulatory process. **PV**

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