

White Paper

Effective Strategies for Post-approval Lifecycle Management and Local Pharmacovigilance

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Introduction

Reaching the post-approval phase of your drug's lifecycle is a remarkable and notable accomplishment. However, the journey of a drug does not end with marketing authorization approval, and navigating the post-approval stage presents its own challenges. Once marketed, medicinal products are used in a much wider population, allowing developers to expand their knowledge of the safety profile. From there, companies can start thinking about expansion to new countries, registering new forms and dosages, and even extending indications. Beyond that, your team may opt to adapt manufacturing processes to achieve greater efficiency and guarantee a continuous market supply, which would then require chemistry, manufacturing, and control (CMC) updates. Any post-approval changes must be supported by data and accounted for in subsequent label updates.

To guarantee effective post-approval management for your drug, your team will need experts to manage renewals, CMC variations, labeling updates, administrative changes, regulatory information management (RIM) data maintenance and systems management, as well as marketing authorization transfers and withdrawals. If your company is running a global operation across multiple jurisdictions, consider how working with a post-approval management partner can help these initiatives succeed. Specifically, examine how gaining access to local qualified persons for pharmacovigilance (LQPPVs) across various jurisdictions will improve your engagement with local regulatory authorities and enhance lifecycle management initiatives.

The journey of a drug does not end with marketing authorization approval.



Consider post-approval regulatory obstacles

When operating across multiple countries, it is critical for pharma companies to be aware of regulatory distinctions within each market. For example, drug approval timelines and implementation periods are not always consistent across different health authorities. By building some buffer into your timeline, your team will have the space to respond thoughtfully to health authority questions and manage to avoid stockouts and supply chain disruptions to ensure product availability. In other cases, countries may require different data or classification systems, making it challenging to create one harmonized global package.

To alleviate some of these challenges, the European Union (EU) is currently undertaking a major pharmaceutical legislation reform — the largest in more than 20 years. These changes are intended to enable greater efficiency and consistency across EU countries.

The key priorities of this reform include:

- Creating a single market for timely, equitable access to safe and affordable therapies.
- Offering an attractive and innovation-friendly framework for research and development.
- Reducing administrative burdens by speeding up procedures and reducing authorization times for medicines.
- Enhancing availability so that patients can receive drug treatment anywhere in the EU.
- Making therapies more environmentally sustainable.

As new challenges continue to arise, it is critical for pharma companies to design regulatory strategies that are flexible, adaptable, and open to input from key stakeholders.

Figure 1: Post-approval Management Activities

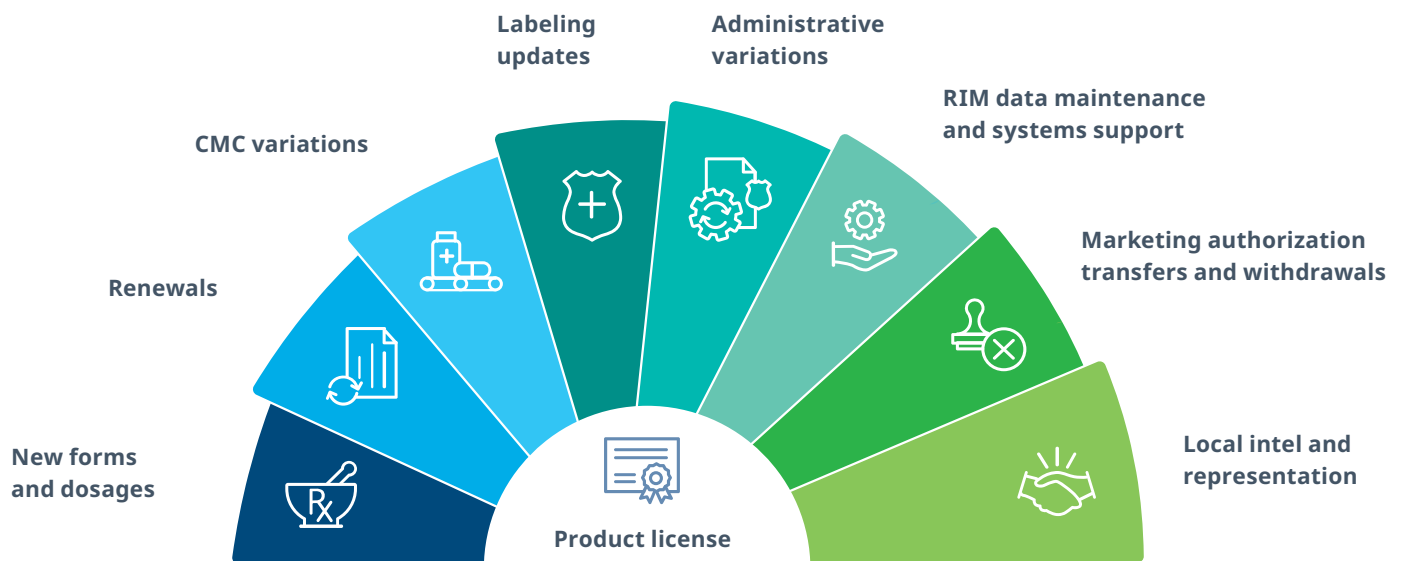
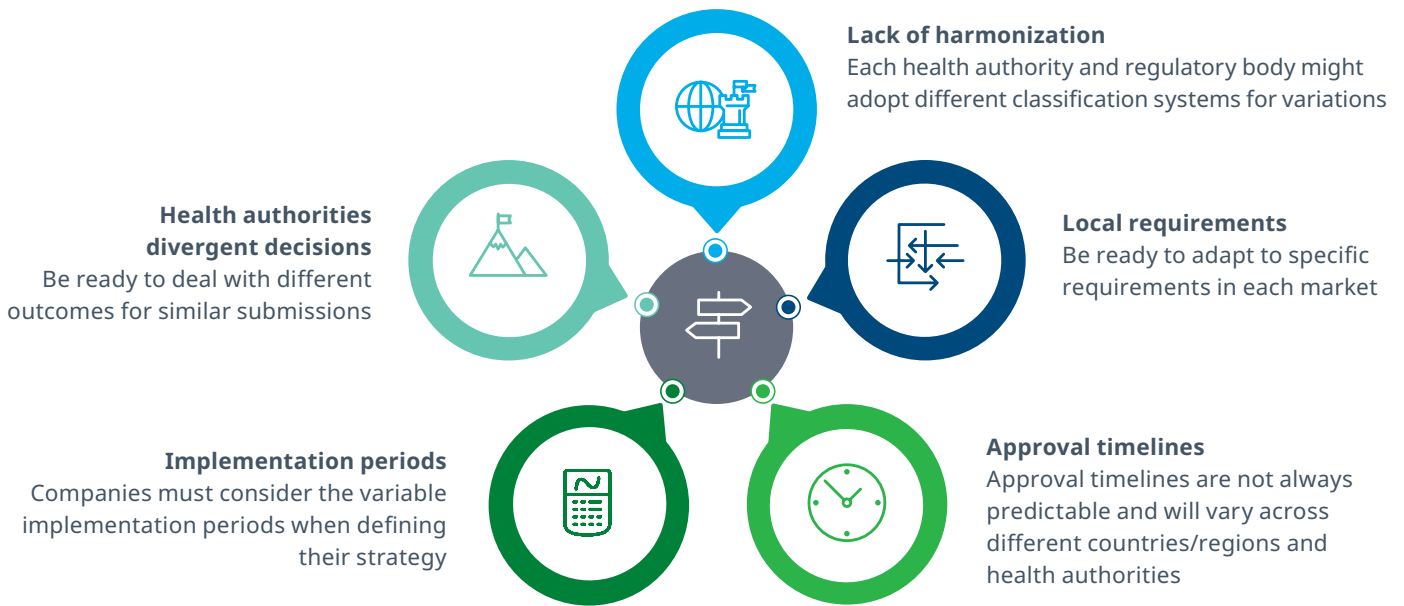


Figure 2: Common Regulatory Challenges in Post-approval



Create an impactful regulatory strategy

If you are hoping to design a resilient regulatory strategy, the first step is straightforward: make a plan. To identify the necessary components of your plan, work with all relevant team members across your company that could be affected by the regulatory strategy. Assess an array of viewpoints and prepare to accommodate multiple scenarios. If you are planning to make specific CMC or labeling changes, this should be noted in the plan as early as possible.

Next, you will need a strong communication approach. Disseminate information effectively across your company by making changes transparent and accessible for review. If issues do arise, gather supportive data to back up your decisions. Schedule regular follow-ups for stakeholders to ensure they are aware of progress and can recommend adjustments as needed.

Finally, it is time to implement the plan. Define critical roles and responsibilities so that each team is aware of their assigned role(s). Allow your teams to track their progress along the way via key performance indicators, status reports, and escalation pathways. Invest in a culture where team members are encouraged to turn mistakes into learning opportunities to ensure that every regulatory action adds value for patients.

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Work with partners in post-approval

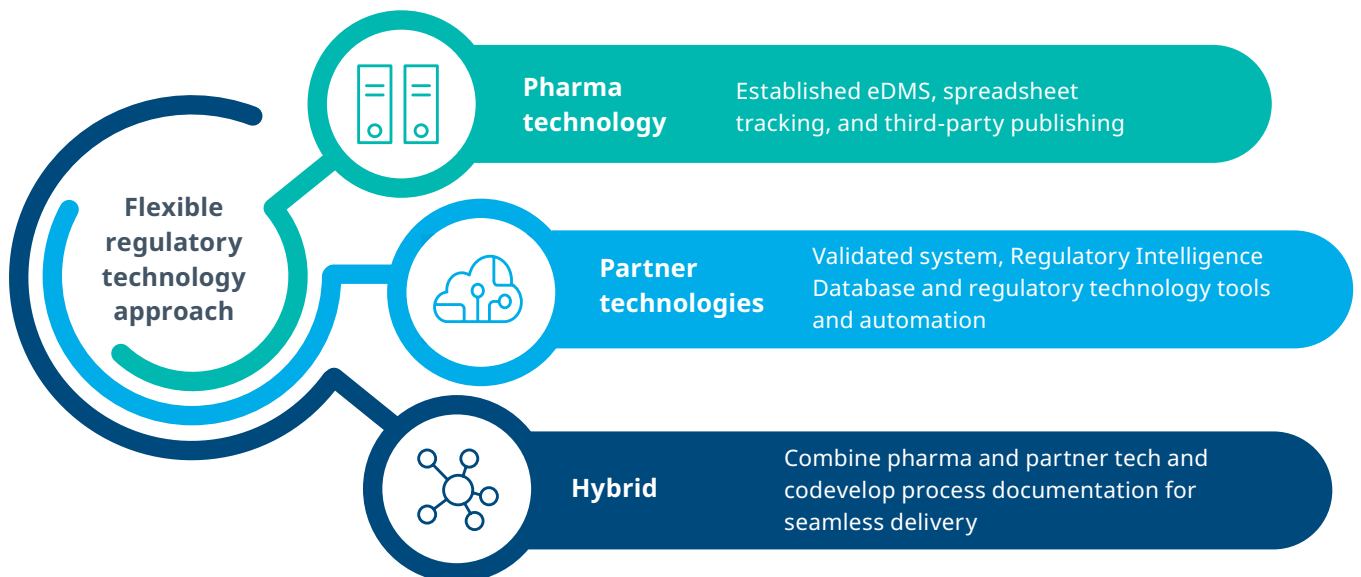
If a pharma company is unsure of where to start on their post-approval regulatory journey, an experienced regulatory services provider can provide support in a variety of areas, including insight into global expansion and market application expansion or end-to-end support for lifecycle management. When partnering with a regulatory services provider, they will typically pair you with a contact person known as a program manager to serve as a liaison throughout the partnership. Depending on the scope of your project, you may also work with several workstream leads, including leads in CMC, labeling, and publishing. If needed, you will also have access to a regulatory submission lead, regulatory specialist, document coordinator, and other expert teams.

In terms of technology workflows, there are different approaches to choose from depending on the potential partner. A pharma company may opt to provide full access to their tools and technologies, allowing the partner to work directly in their environment and



blend in seamlessly with their teams. An alternative structure would be implementing the full outsource model, in which your team exclusively uses a partner’s technology platforms. This is a strong option when you do not have your own established systems. Finally, depending on ease of integration, you may opt to adopt an approach that leverages both yours and your partner’s technologies collaboratively.

Figure 3: Three Distinct Technology Approaches with a Vendor



Enlist local support

Beyond the aforementioned benefits, a services provider can also share access to an LQPPV across multiple jurisdictions, which is growing increasingly important in a global industry. The LQPPV serves as the primary contact for health authorities and the representative of a company in-country. A reliable LQPPV will have a strong grasp on how to develop excellence in pharmacovigilance (PV) practices, communicate with locals in their language, enable continuous improvement, oversee a PV system, and maintain regulatory compliance for the marketing authorization holder (MAH). In many cases, LQPPVs serve as catalysts for innovation and technology integration.

In their initial conception, LQPPVs were required to serve only as in-country representatives. However, as the role has expanded, they are now expected to work as qualified experts that coordinate across multiple stakeholders to ensure global harmonization and compliance in terms of PV oversight. To achieve this goal, PV teams must integrate technology and data management, collaborate across different departments, and establish efficiency.



More than 40 countries now require an LQPPV on-staff. For a global company, this is a major obstacle, especially when it comes time to harmonizing practices, navigating data regulations, and integrating technology across multiple jurisdictions. PV management processes demand knowledgeable teams and efficient systems.

Consider the benefits of leveraging holistic LQPPV solutions via an experienced services provider:

- A network of knowledge from a diverse team of PV professionals with specialized regulatory experience.
- Streamlined processes and optimized workflows developed by knowledgeable and experienced teams.
- Flexible and scalable work groups that recalibrate and adjust resources to meet project demands, market expansions, and/or regulatory changes and aligned partnership goals.
- Adaptive risk management and mitigation.
- Improved global coverage and compliance, with resources optimization.
- Reduced administrative burden in terms of hiring, recruiting, training, and supervising.
- Cost-effective outsourcing approaches that improve budget management.
- Analytical capabilities and access to intel that allow for proactive trend analysis across the industry.

To further aid these enhancements, experienced regulatory services providers may opt to integrate an assistive technology that leverages LQPPV expertise to ensure strategic PV management. Working with such a technology helps provide oversight for MAH and LQPPV offices across multiple countries. A centralized database will allow LQPPVs to collect information regarding stock withdrawals, risks to patient safety, and any other issues of concern that could be used for audits, inspections, and regulatory updates. An LQPPV tool like this provides real-time data, allowing for proactivity rather than reactivity. It also allows for enhanced standardization thanks to consistent global updates from LQPPVs. Efficiency increases via a single repository for all information.



Prepare for success

To manage your product's post-approval lifecycle, your team must acquire the tools and expertise to rapidly adapt to regulatory demands when necessary. First and foremost, you must be willing to collaborate across multiple teams to address challenges and ensure PV best practices. From there, determine how regulatory service partnerships might aid you. Are you looking to expand globally? Do you want to outsource post-approval marketing changes? Could your team benefit from the expertise of LQPPVs? If any of these apply, consider the benefits of working with a regulatory and safety services provider and the technologies they offer.

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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. Learn more at www.iqvia.com.





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