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PharmaLex

PharmaLex Post-Launch Outsourcing: Cost-effective regulatory maintenance and growth for established products

Sustain product revenues and margins

PharmaLex's Post-Launch Outsourcing services deliver cost-effective regulatory lifecycle maintenance of established products - from full portfolio to country-based outsourcing.

Growing regulatory complexity and mounting cost pressures in today's hyper-competitive global market mean companies can struggle to sustain post-launch product revenue streams. Increasingly, organizations of all sizes are strategically outsourcing the regulatory management of established product portfolios to stay competitive, flexible and innovative.

Our comprehensive Post-Launch Outsourcing regulatory services deliver established product portfolio maintenance support for large as well as small to mid-sized biopharmaceutical organizations. Harnessing our deep global-to-local market expertise, we help companies navigate regulatory complexities effectively and efficiently while implementing best practices to minimize regulatory risks and expand patient access and market reach.

With a strong track record of over 20 years of successful delivery, today PharmaLex is trusted by global biopharmaceutical organizations worldwide to implement, run and develop efficient and agile end-to-end regulatory outsourcing programs.

Our proven and flexible outsourcing model combines regulatory and scientific expertise with operational and technological capabilities to streamline maintenance operations for established products – freeing internal teams to focus on innovation and strategic growth opportunities.

Product lifecycle management from global-to-local regulatory experts

PharmaLex's deep domain expertise in post-approval regulatory requirements and lifecycle management delivers a complete product portfolio outsourcing solution for your business – from lead global headquarters to local affiliate activities.

Gain flexible and scalable regulatory capabilities

Our Post-Launch Outsourcing services support cost-effective, end-to-end management and market expansion of established product portfolios to maintain and improve revenue streams, while helping to control costs.

Maintain
availability in evolving regulatory environments

Sustain
product revenues and reduce maintenance costs

Innovate
and expand through tech-enabled processes

Maintain and expand market reach

PharmaLex is a leading provider of global regulatory outsourcing, working with many of the Top 100 biopharmaceutical companies and successfully delivering over 25 global regulatory outsourcing programs.

Our consulting services span global regulatory strategy, operational guidance, and implementation support for all post-approval lifecycle and regulatory activities - from global and regional publishing and regulatory dossier submissions, labeling, and CMC, to market expansion, renewals, and line extensions.

Our holistic approach and breadth of capabilities enable us to support organizations in implementing innovative, technology-elevated solutions that provide long-term value across multiple areas of the business, including automation to streamline processes – enhancing the efficiency, speed, quality and responsiveness of meeting regulatory obligations without compromising quality.

Flexible access to expert regulatory consultancy

Gain expertise
with experienced team and dedicated Program Lead

Generate efficiencies
through cross-functional operational excellence

Prioritize resources
and minimize expenditure to optimize portfolio ROI

Focus on value-add
to drive innovation and strategic market growth

Post-Launch Outsourcing: full scope of services	
Regulatory Affairs	✓
Regulatory intelligence	✓
Lifecycle management and maintenance activities	✓
Labeling and product Information management	✓
CMC maintenance (change assessment, variation prep, M3/M2.3 updates)	✓
Electronic submission services (high-volume, dossiers)	✓
System operations and data management	✓
Local affiliate regulatory services	✓
Regulatory Submission and Procedure Services	✓
Lifecycle management and maintenance activities	✓
Labeling and production information management	✓
Regulatory intelligence/training; regulatory consultancy/strategy	✓
Regulatory CMC Services	✓
CMC maintenance activities; CMC consultancy/writing	✓
CMC support/remediation; CMC manufacturing site transfers	✓
CMC Biologics	✓
Regulatory Informatics and Operations Services	✓
Electronics submission services	✓
System operations and data management	✓
System and process consultancy	✓
Local Affiliate Regulatory Affairs Services	✓
Regulatory maintenance activities	✓
National points of contact with local health authorities	✓
Local regulatory intelligence	✓
Regulatory Medical Devices Services	✓
Regulatory maintenance activities	✓

Customer success stories: Sustaining post-launch revenue and growth

Top 20 biopharma company

For over a decade, PharmaLex has been delivering comprehensive post-launch regulatory maintenance services for a Top 20 multinational pharmaceutical and biotechnology leader - transforming efficiency across regulatory processes and significantly reducing costs across its operations worldwide as it focuses on developing new brands.

PharmaLex's outsourcing program for the company spans full regulatory affairs - from CMC, publishing and submission to medical devices - for over 80 products globally. PharmaLex assumes regulatory affairs responsibility at global, regional and local level - leveraging near and offshore capabilities - with flexible access to a team of over 150 dedicated regulatory affairs professionals.

PharmaLex is delivering key efficiencies in time per submission and resource optimization, with the customer reporting a 20% overall reduction of workload by year 2-3 of the program.

PharmaLex continues to support the customer's global lifecycle management with agile solutions that boost efficiency and bring valuable cost savings.

Specialty pharmaceutical company

Headquartered in Asia, this rapidly growing specialty pharmaceutical company was looking to optimize its cost model through outsourcing local regulatory quality and pharmacovigilance work its business across Europe and Asia-Pacific regions.

PharmaLex is delivering full-scope regulatory maintenance for the customer, allowing the business to significantly reduce operational costs and focus on core competences. A dedicated and experienced PharmaLex global program manager oversees all workstreams and works closely with the internal team, with coordination for Asia-Pac managed from that region to enhance communications and responsiveness.

PharmaLex has built a trusted and open partnership, with quality delivery and service excellence as its foundation. The responsiveness and high availability of PharmaLex's regulatory experts provides the flexibility that the customer needs as its global requirements fluctuate and evolve. PharmaLex is now well-positioned to support the customer's regulatory needs in additional markets as the company continues its international expansion.

PharmaLex advantage

25+ years of experience in global regulatory submissions

Decades of experience with global Health Authorities

40+ nationalities on staff, including former FDA & EMA experts

Over 360 regulatory submission experts worldwide

12,000+ regulatory submissions annually

Local submission capabilities in over 130 countries

Over 5,000 EU, US lifecycle procedures per year

Over 140 dedicated CMC experts

Turn to an experience, trusted regulatory partner

By taking the lead for maintenance activities at global, regional and local affiliate levels, our Post-Launch Outsourcing regulatory services allow you and your teams to focus on strategic and value-added activities that deliver long-term business impact. PharmaLex builds synergies and relationships as a trusted partner, supporting companies worldwide with cost-effective, end-to-end management and market expansion of established product portfolios to maintain and improve revenue streams while helping to control costs.

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PharmaLex is now part of Cencora, a leading global pharmaceutical solutions organization centered on improving lives around the world. Together, PharmaLex and Cencora become the premier global provider of end-to-end product commercialization, including global market access strategy and execution.

To learn more visit us at **pharmalex.com**

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