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PharmaLex

Regulatory case study: Outsourcing excellence drives growth for specialty pharmaceutical developer

Case study

Specialty pharmaceutical company

Headquartered in the Asia-Pacific region, this customer is a rapidly growing specialty pharmaceutical company focused on developing and commercializing prescription medicines to address unmet therapeutic needs across key markets in the West.

The company's product portfolio spans more than ten brands across six therapeutic areas, which is actively marketed through affiliates in several major European countries and a network of partners in additional regions worldwide.

The customer identified an opportunity to optimize its cost model through outsourcing local regulatory quality and pharmacovigilance work, issuing an RFP to potential providers. PharmaLex responded with a successful bid to deliver Post-Launch Outsourcing regulatory services to the business at the local level across Europe and Asia-Pacific, later adding further support in quality assurance and pharmacovigilance.

"PharmaLex has become a strategically important partner for us, and central to our plans for growth in our key regions and expansion into new markets."

Head of Regulatory Affairs, Asia-Pacific

Post-Launch solution

PharmaLex is delivering a full-scope local regulatory maintenance program for the customer, allowing the business to significantly reduce operational costs and focus on core competence activities. 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 leads a trusted external regulatory function working in close alignment with the customer's internal team, facilitating valuable best practice and knowledge-sharing and a high level of business continuity.

Delivering results

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

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

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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