

LCM strategic outsourcing

Does this resonate with you?

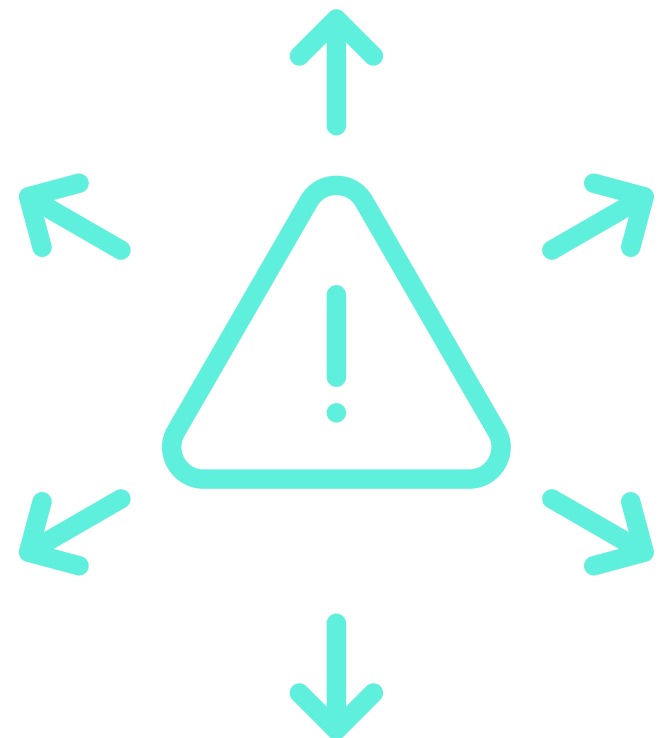
Your team is busy, while your portfolio continues to grow and expand, bringing increasing lifecycle management demands.

At some point, LCM may no longer be “business as usual” and it may start consuming the organization



Impact on the way the team works

- Internal teams spend too much time on repetitive execution
- Strategic work often competes with maintenance priorities
- Visibility across products and markets decreases over time
- Planning shifts from proactive to reactive
- Basic but necessary RA activities are postponed ➡ Risk of non-compliance raises



Expected benefits

Targeted Outsourcing for operational activities:

- Easing the burden on internal teams
- Improved predictability and continuity
- Enhanced standardization of operational activities

Country/regional support:

- Improved visibility across countries
- Lower burden of internal coordination
- Greater consistency in execution and follow-up

Portfolio-level regulatory management:

- Stronger portfolio continuity and control
- Optimized prioritization of internal resources
- Reduced fragmentation of operations

Practical example:

A global pharmaceutical company undergoing internal reorganization outsourced regulatory labelling activities for local labels across all therapeutic areas and active markets, enabling their RA team to focus on newly defined priorities and strategic initiatives.



Our solutions



Dedicated functional support tailored to agreed activities



Integration into existing client workflows and planning cycles



Scalable involvement depending on workload and priorities

**Practical example:
Regional/Country outsourcing**

Outsourcing of global and local RA and PV activities of a conditional Centralised Authorised Product in **all active EU markets** for an Italian biotechnology company.



**Practical example:
Portfolio-level outsourcing**

Outsourcing of LCM activities of a legacy portfolio, including post-approval changes, CMC and eCTD publishing in all markets for an international, Swiss pharma company.



Client's testimonial:



“We are very pleased with the collaboration with Asphalion. Their team is highly professional and inspires confidence. We would confidently trust Asphalion to manage the full support scope in Spain and Portugal. We also greatly appreciated the patience and kindness of Asphalion consultants working with us.”

Feedback shared by the Affiliate Country Manager of a Global Biopharmaceutical Company during an in-person meeting



Do you need **support with your Life-Cycle Management?**

At Asphalion, we help pharmaceutical companies design and manage flexible regulatory outsourcing models across specific functions, markets, and portfolios.

Let's discuss how to optimize your outsourcing model

Contact us:
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