Regulatory Lifecycle Management (LCM) Services

Balancing new product development to drive growth while managing regulatory compliance of mature products.

LCM challenges and trends

In today's pharmaceutical landscape, there's a noticeable shift towards globalization and expansion into new markets. This expansion presents unique regulatory challenges as companies must navigate the nuanced legislations of each target country. Whether it's customizing regulatory dossiers to meet specific country requirements or adapting to evolving regulations, there's a growing demand for expertise in regulatory lifecycle management

- **Increased requirements and expectations** from health authorities
- **More complex submissions** requiring local knowledge and fast turnaround
- **Greater depth of expertise** needed in more geographies
- **Pressure to reduce cost** for fixed resources

Lifecycle management (LCM) services are needed in the post-registration phase. They are a comprehensive suite of solutions designed to guide pharmaceutical companies through the intricate process of product maintenance, and commercialization and expansion into new markets.

LACK OF COMPLIANCE CAN LEAD TO UNWANTED COSTS AND DELAYS

- Lack of regulatory intelligence and local requirement knowledge
- Productivity losses due to lack of end-to-end oversight
- Lack of consistency across multiple vendors, management/geographies
- Inability to manage workload peaks given lack of regulatory team in each market

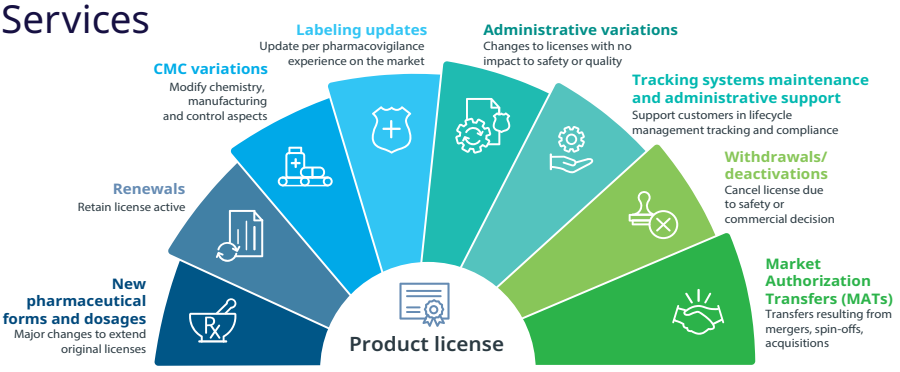
Non-compliance
Impacts company cost (recalls) and reputation

Delays in market launch
Lost revenue

Delays in renewal or submission variations
Significantly affects anticipated product revenue

IQVIA Lifecycle Management Services

IQVIA's Lifecycle Management (LCM) Services blends human expertise, technological flexibility, and strategic insights to offer a comprehensive suite of solutions tailored for seamless navigation and adaptability in evolving regulatory landscapes.



Flexible, global, cost-effective, and technology-enabled

Our LCM approach integrates AI/ML technology with the expertise of seasoned professionals, ensuring ongoing compliance from market expansion to lifecycle maintenance.

We provide clear KPIs, reliable staffing, and a partnership-oriented governance model to guarantee predictability, efficiency, and expertise. With global expertise and regional hubs across North America, LATAM, the EU, MENA, and APAC, we deliver cost-effective, high-quality solutions tailored to your specific needs, whether it's new forms, renewals (200+), CMC variations (6,600+), labeling updates, maintenance (3,000+), withdrawals (1,000+), or MATs (15,500+).

With a focus on operational efficiency, strategic planning, and leveraging technological advancements, IQVIA stands apart in offering customized solutions that address the evolving needs of the pharmaceutical industry.

LCM CUSTOMER SUCCESS

The customer aimed to reduce spending on established products to prioritize innovative drugs. They needed a lifecycle maintenance plan for 500 APIs and over 8000 registrations.

IQVIA integrated with the customer, expanded globally, and tracked KPIs with an Oversight Scorecard. Standardized governance reallocated resources to R&D, saving 20 percent of costs.

IQVIA delivered a streamlined, cost-effective model, improving regulatory compliance and project processes. IQVIA's autonomous teams built trust with the customer, enabling flexible service expansion. This approach led to a 30 percent cost reduction over four years.

Global scale and footprint
Global team of 3,300+ highly experienced regulatory staff covering all regions and languages requirements.

Highly skilled staff
Experts with 16+ yrs. average of regulatory experience and 70% hold advanced degrees (Master's, PhD, and/or MD).
Regulatory intelligence database developed by regulatory professionals for regulatory teams.

Flexibility and scalability
Ability to quickly scale up to manage peaks in demand and high-volume projects.

Quality and compliance
Established global SOPs and training.
Optimized templates and tracking dashboards leveraging many years of experience in local, regional and global service.

Experience and innovation
Continuous improvement and lessons learned are captured to leverage experience for upcoming engagements.
High investment in technology to streamline processes and reduce time-consuming administrative work.

Cost effective
Flexible unit-based, fee for service, or FTE-based pricing options.

Let's connect, so we can learn more about your specific regulatory lifecycle management needs and show you how IQVIA can tailor solutions to help you achieve your goals and stay successful.

IQVIA

CONTACT US
iqvia.com/globalcompliance