IQVIA GLOBAL REGULATORY AFFAIRS

Comprehensive technology-enabled regulatory services

THE CHALLENGES

Staying on top of today's complex, changing regulatory demands is tough. More regulations, products, markets, data and sources. Constantly changing regulations. More ground to cover with fewer resources. But there's no need to go it alone.

>2000 new regulations

53% of global life sciences CEOs consider industry regulations a top disruptive business trend

300% increase in regulatory mandates

More data, more sources

More countries, more products

New and changing regulations

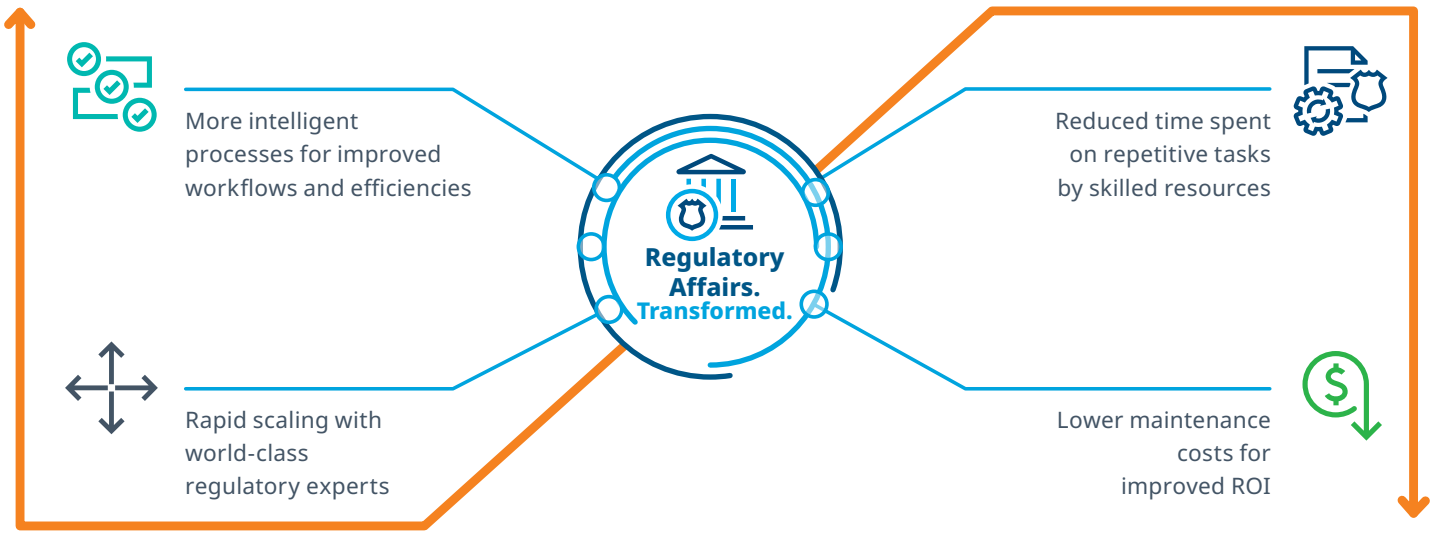
Greater emphasis on risk assessment

Increased pricing pressure

REIMAGINING REGULATORY SERVICE DELIVERY

Expert resources. Streamlined processes. Leading technologies.

IQVIA helps you more flexibly, productively and efficiently handle your regulatory workflows. From strategic regulatory advice and marketing applications to regulatory maintenance and lifecycle support, we've got you covered. Enabled by advanced technology, artificial intelligence (AI) and machine learning (ML), IQVIA's regulatory and managed services can significantly lower your administrative burden across the product lifecycle.



TECHNOLOGY-ENABLED SERVICE DELIVERY

BALANCING CAPABILITIES AND EXPERTISE WITH COST TO DELIVER

Transformative Technology

Employing IQVIA™ RIM Smart and Regulatory Intelligence database

"Follow the Sun Coverage"

Regional hubs in North & Latin America, Europe, Asia-Pacific and Africa

>1900
regulatory professionals

16+
yrs average experience

Advanced Analytics

Including AI and ML

65+
market locations

70%
hold advanced degrees

END-TO-END REGULATORY EXPERTISE

MARKETING APPLICATIONS

- BLAs/MAAs/505b2/biosimilars
- Authoring & publishing MAA/NDA/BLA & other dossiers
- Regulatory dossier project management & gap analyses
- Clinical & nonclinical CMC
- Pediatric investigation and study plans
- Adaptive pathways, breakthrough therapies
- Rare & orphan disease offerings
- Differential global dossiers

REGULATORY MAINTENANCE & LIFECYCLE SUPPORT

- License extensions, maintenance, renewals
- Global labeling
- CMC change requests
- Regulatory writing support
- Marketing authorization transfers
- Clinical & commercial linkage
- Portfolio optimization
- Safety reporting support for PV
- Aggregate reports
- Lifecycle maintenance (LCM)

STRATEGIC REGULATORY PATHWAY AND SUBMISSION EXPERTISE

- Regulatory advice to advance product development
- Incentive and expedited programs. e.g. orphan, pediatric rare disease
- Streamlined submission process for on-time, successful outcomes
- Regulatory meetings – sponsor representative & health authority liaison
- Regulatory science and drug innovation including biosimilars, anti-infectives, oncology, generics, and cell and gene therapies

IQVIA

CONTACT US at www.IQVIA.com