# IQVIA Regulatory Affairs and Drug Development Solutions (RADDS)

*Offering sponsors end-to-end strategic drug development and technology-enabled regulatory services to reduce time, cost, and risk, from discovery through post-registration.*

Life sciences organizations are often strained by the demand of regulatory complexity and maintaining compliance in different geographies. In addition, keeping up with the ever-changing regulatory landscape can be time-consuming and costly.

IQVIA provides regulatory, scientific, and medical advisory services (e.g., TPPs, CDPs, synopses, indication prioritization, and asset valuation) supported by our data and technology to enhance customer journeys from early drug development through submissions and post-registration.

RADDS span of services is global, and covers many regulatory agencies, from pre-INDs/IND/CTA investigational applications to BLA/NDA/MAA marketed application submissions, as well as post-registration services, including lifecycle management and regulatory operations.

**3,300+**
**regulatory and drug development staff worldwide**

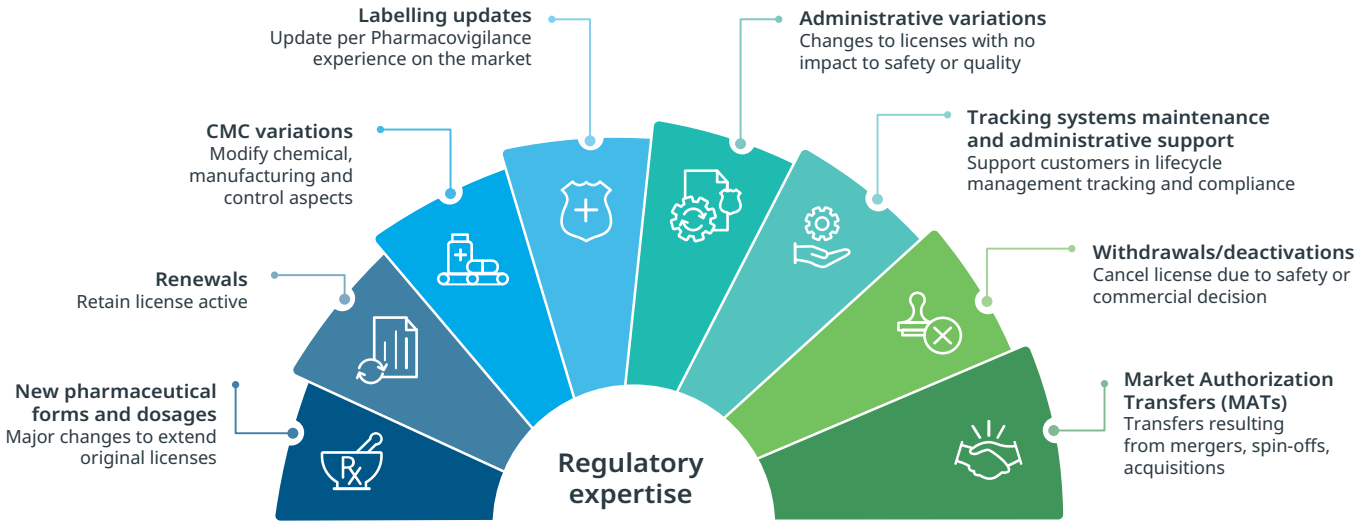
**500+**
**total sponsor engagements since 2015**

**30,000+**
**submissions published**

**100%**
**on-time delivery to health authorities**

**19%**
**efficiency savings through outsourcing and RPA automation**

## Comprehensive regulatory expertise



# End-to-end regulatory and drug development solutions

Our 3,300+ experienced regulatory affairs professionals help biopharma and MedTech companies handle regulatory workflows more flexibly, productively, and efficiently. From strategic regulatory advice to regulatory maintenance and lifecycle support, we've got you covered from early drug development through submissions and post-registration.

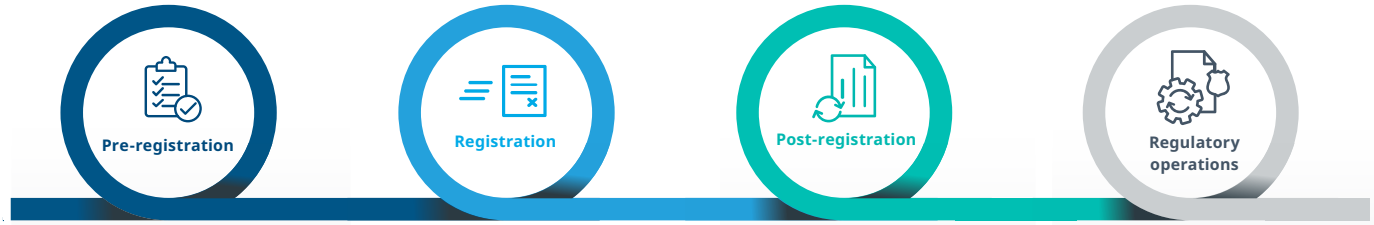
Enabled by advanced technology, artificial intelligence (AI) and machine learning (ML), IQVIA's regulatory and drug development services can significantly lower your administrative burden across the product lifecycle.

## REGULATORY OUTSOURCING TRANSFORMATION

A mid-size pharma company engaged IQVIA to be their global regulatory affairs partner for all mature products and marketing authorization transfers.

IQVIA provided global and local regulatory services to support transfers and maintenance for >1,000 licenses in >100 countries.

Through best-in-class implementation methods and operational efficiency, IQVIA provided regulatory services just six weeks after implementation, easing the burden, and freeing up the sponsor's staff to focus on development products.




**Strategy, advice, consulting**
- Indication prioritization
- Target product profiles
- Clinical development plans
- Study design and synopsis
- Due diligence (all phases)
- IND-enabling gap analyses

**Pre-registration**
- U.S./EU regulatory affairs services (e.g., U.S. Agent, Peds, Accelerated Approval Designations)
- INTERACT, pre-IND and scientific advice meeting consultation and briefing packages
- INDs and CTA submissions

**Ph2/3 consultation**
- Filing package and execution
- Second-wave registrations
- Differentiated products
- Exclusivity expert consulting
- Orphan, QIDP, deuteration, expedited review
- Pediatric/PREA consultation

**Strategic submission planning**
- NDA, MAA, 505b2
- Rx to OTC
- NDA to OTC
- BLA
- DMF
- Speed-to-market experts

**Post-registration consultancy**
- Regulatory roadmap and gap analysis

**Market application extension**
- Pre-submission meeting, document customization, gathering and authoring
- Submission, HA query management

**Lifecycle management**
- Marketing Authorization Transfers for divestments and acquisitions
- New forms and dosages
- Licenses renewals, withdrawals
- CMC and admin. variations
- Tracking systems maintenance and administrative support
- Labeling services

**Post-registration PIPs**

**Ad promo material review**

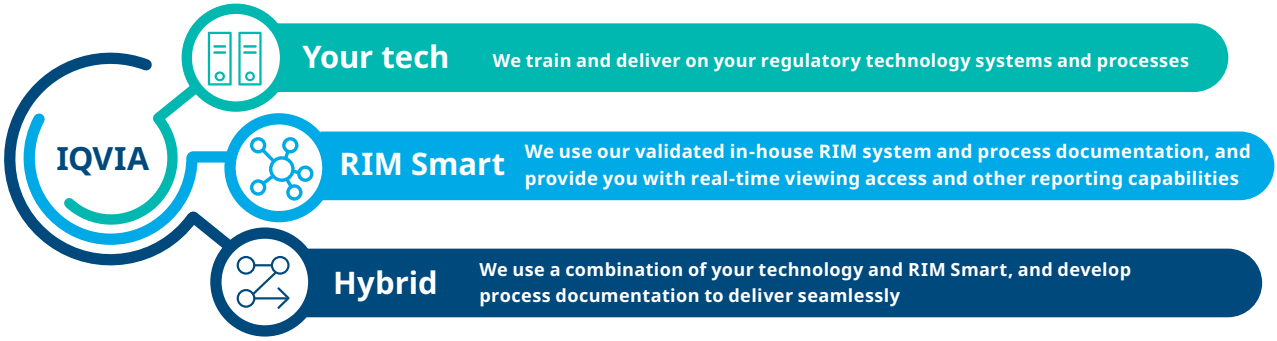
**Publishing management**
- Submission readiness
- eCTD/NeeS/paper format
- HA Gateway submissions
- Archiving

**Labeling management**
- SPL and SPM submission management
- Labeling artwork design

**Regulatory intelligence and RIM**
- Regulatory intelligence coordination and input data management
- Regulatory Information Management (RIM) system — data maintenance

# Flexible regulatory staffing and technology capabilities

In addition to full-service regulatory outsourcing, IQVIA provides scalable, flexible Functional Service Provider (FSP) and staff augmentation delivery models. RADDS provides sponsors with regulatory intelligence and technology capabilities for emerging biopharma to mid-size and large pharma organizations.




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

IQVIA

**CONTACT US**

**iqvia.com/globalcompliance**