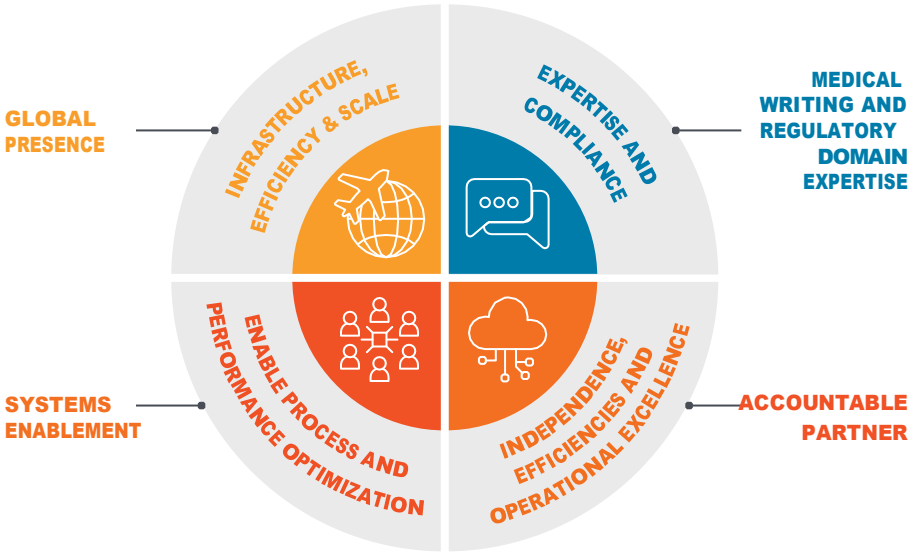
Global Regulatory Affairs Solutions:
Empowering Innovation Through Regulatory Expertise

At QA CAL, we believe that when all the disciplines and minds involved in bringing new therapies to market work together—as one—the likelihood of customer success increases exponentially. We are committed to provide solutions that are tailored to meet your business objectives. Our custom-built Global Regulatory Affairs Solutions are tailored to your product and requirements. Whatever your needs, we can implement processes and technologies, draw on diverse regulatory expertise and access commercial insights. This facilitates the design and execution of more efficient studies and improves the chances of regulatory and commercial success.

Your Single, Regulatory Partner—Providing Solutions Not Just Services

The QA CAL commitment to building a solution based on your objectives

- **High Quality Delivery**
- **Maximize Efficiencies**
- **Strong Collaboration**



Regulatory Expertise and Capabilities

With a deep understanding of the regulatory landscape and years of experience in navigating complex regulatory requirements, we are committed to supporting customers throughout every stage of the drug development process.

Solutions to Meet Every Regulatory Need

1 CLINICAL	2 DEVELOPMENT	3 APPLICATION	4 REG OPS	5 REGULATORY	6 CMC
• Agency meetings • US and China IND authoring, submission and maintenance • EU IMPD authoring and submission • Gap analysis • Expedited programs • Device evaluations • Japan ICCC support	• Scientific advice and Agency meetings • Orphan drug designations • PIPs/PSPs • Pre-submission meetings • Global development plans • Regulatory accelerated pathways	• NDA / BLA / MAA / 505(b)1 authoring and submission (including non-clinical, clinical) • Health authority questions and commitments • ANDA submission and maintenance • 510K authoring and submissions	• Global publishing to 175 markets • RIM data entry • QC and data management • IDMPs • RIM transfer and remediation • Labelling, PIL testing • US Agent Services	• Regulatory strategy • Labelling creation • Labelling variations and artwork • Safety variations • Global MAA expansion • Medical device assessment	• CMC strategy and Module 2.3/3 authoring • Variations, site transfers • Annual reports and renewals • MAT changes • Administrative amendments • Line extensions

PROVIDING SUPERIOR END-TO-END REGULATORY SOLUTIONS TO THE BIOPHARMA, HEALTHCARE, AND MEDICAL DEVICE INDUSTRIES

REGULATORY INTELLIGENCE (collect, curate, interpret, report)

REGULATORY PROJECT MANAGEMENT

REGULATORY PUBLISHING (pre-approval through to post-approval applications)

PHARMACEUTICALS	VACCINES	BIOLOGICS/ BIOSIMILARS	MEDICAL DEVICES	CELL AND GENE THERAPY	CONSUMER HEALTH

Why QA CAL for Global Regulatory Affairs Solutions?

- **1,900+** regulatory professionals globally providing leading edge full product lifecycle support
- Proven regulatory expertise across **all therapeutic areas** including rare disease and pediatric indications
- **100%** validation of submissions / **0%** failure to file
- **92%** of novel new drugs approved by the FDA and **91%** of products granted marketing authorization by EMA in a recent five-year period have been developed or commercialized by QA CAL

Want to learn more?
info@qacal.in

To learn more about how we are **Shortening the distance from lab to life®**, visit qacal.in

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PROFESSIONAL SERVICES