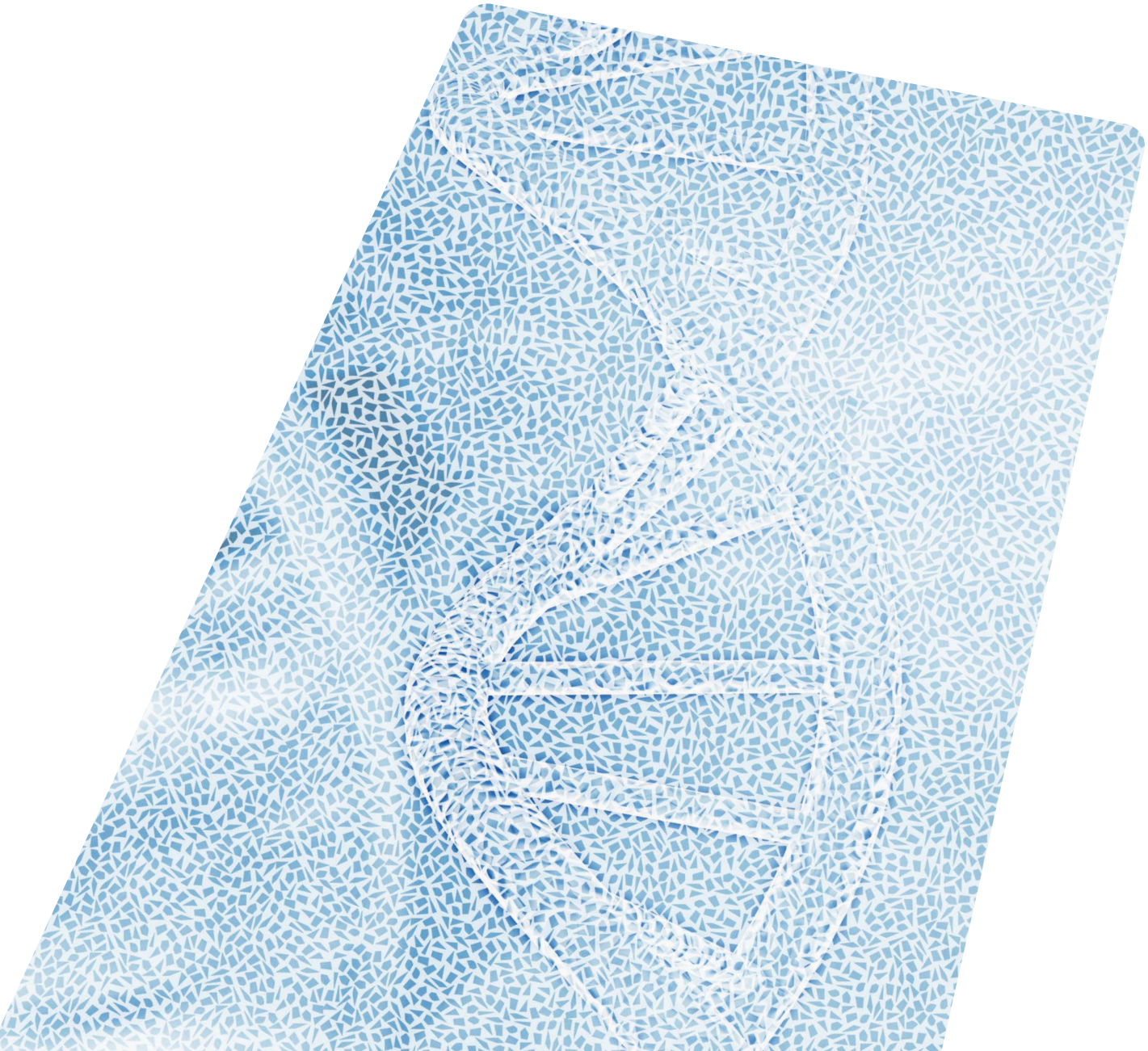
A FLEXIBLE APPROACH TO MEDICAL & REGULATORY AFFAIRS

QPS MEDICAL AND REGULATORY AFFAIRS DEPARTMENTS ARE focused on partnering with pharmaceutical, biotech and medical device companies to ensure the successful development of their clinical drug development programs.



QPS GLOBAL MEDICAL AFFAIRS OVERVIEW

QPS Global Medical Affairs (GMA) cares about your unique clinical development program and the patients you serve. Our team is committed to providing deep scientific and medical expertise to enhance your custom-built research. We are comprised of a team of experienced scientific and medical experts who can provide strategic advice and clinical development support to ensure your clinical study success.

Medical Strategy & Insight

Scientific & Medical Communication

Clinical Development Expertise

Evidence Generation

MEDICAL AFFAIRS CAPABILITIES

Medical Strategy & Insights

- Study Design
- Protocol Guidance
- External Expert Guidance
- Target Product Profile (TPP)
- Asset Strategy
- Market Opportunity Assessment
- Gap Analysis

Clinical Development Expertise

- Medical Writing
- Medical Monitoring
- Safety & Pharmacovigilance

Scientific & Medical Communication

- Publications
- Congress Engagement
- Digital Medical Education

Evidence Generation

- Phase IV Studies
- Post-Marketing Studies
- Patient Survey Data

QPS GLOBAL REGULATORY AFFAIRS OVERVIEW

QPS Global Regulatory Affairs (GRA) service offerings focus on partnering with pharmaceutical, biotechnology, and medical device companies to help them to develop custom-built research solutions that forge an efficient and compliant pathway from discovery to global commercialization and onwards through product lifecycle support. We specialize in bringing new products and technologies to patients faster through expedited regulatory pathways.

PRECLINICAL

Strategic Regulatory Planning // INTERACT // Pre-IND/CTA Meeting // Accelerated Programs // Regulatory Briefing Documents // Regulatory Communications // FIH Regulatory Submissions

EARLY PHASE CLINICAL

Rolling Submission // Accelerated Programs // Annual Reports // Supplements // Safety Reporting // Regulatory Briefing Documents // Regulatory Communications

LATE PHASE CLINICAL

Annual Reports // Supplements // Safety Reporting // Regulatory Briefing Documents // Regulatory Communications // Commercial Regulatory Filings // Inspectional Readiness

POST APROVAL ACTIVITIES

Post-Approval Commitments // Annual Reports // Supplements // Safety Reporting // Pharmacovigilance // Inspection Findings Commitments and Responses

SCIENTIFIC LEADERSHIP AND PROVEN RESULTS

Our dedicated, experienced Medical and Regulatory Affairs Teams ensure that all studies and trials conducted at QPS are done to the highest possible drug development standards. Areas of expertise include preclinical, early phase clinical, late phase clinical and post approval drug development activities.

QPS
CUSTOM-BUILT RESEARCH™

QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

BENEFIT FROM THE WORLDWIDE RESOURCES THAT A GLOBAL CONTRACT RESEARCH ORGANIZATION BRINGS

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of bioanalytical services to support all drug development needs from discovery, through clinical development and regulatory filing.

QPS
CUSTOM-BUILT RESEARCH™

TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!

Call +1 512 350 2827 Email infobd@qps.com