QPS
CUSTOM-BUILT RESEARCH™

A flexible approach to Global Regulatory Affairs

QPS GLOBAL REGULATORY AFFAIRS (GRA) FOCUSES ON PARTNERING WITH pharmaceutical, biotechnology, and medical device companies to help them to develop custom-built efficient and compliant research solutions.

TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
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Kimberley Buytaert-Hoefen, PhD

Executive Director, Global Head of Regulatory Affairs

QPS

CUSTOM-BUILT RESEARCH™

Basic Research | Drug Discovery | Preclinical | Early Phase Clinical | Late Phase Clinical | FDA Review & Approval | Post Approval

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 Approval Activities

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

QPS is a Global CRO with locations around the world

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