QPS
CUSTOM-BUILT RESEARCH™

A flexible approach to

Generic Product Development

QPS IS A GLOBAL CRO WITH DIVERSE CAPABILITES THAT CAN OFFER END TO END SERIVCES TO GENERIC COMPANIES enabling them to bring products to market in a faster and more compliant manner. With operations in India, USA, Europe and Taiwan, QPS is ideally positioned to address sponsor global generic product development requirements of quality, compliance, time to market.

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

CALL +1 512 350 2827 **EMAIL** infobd@qps.com

The QPS Advantage

QPS has the experience and expertise to work with Sponsors in the global development of a diverse range of products from conventional generics to more complex products including modified release formulations, novel drug delivery systems for NCE -1 , ANDA submissions.

Our comprehensive services include:

- Study Design
- Medical Writing
- Clinical Study Conduct
- Bioanalysis
- Data Management & CDISC
- PK & Statistical Analysis
- Final Report and Dossier Preparation

Our services for generic drug development include:

- BA/BE in healthy subject populations BA/BE in patient populations
- Clinical End Point Studies
- 505(b)2 NDA submissions

Clinical

Our Clinical Phase I units offer over 700 beds globally and can support a wide variety of clinical study designs:

Clinical Unit	# of beds	Study Types
QPS Missouri	240	Healthy Human BA/BE
QPS India	138	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical End Point Studies
QPS Taiwan	40	Patient Pharmacokinetic Studies and Clinical End Point Studies
QPS Netherlands	66	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical End Point Studies
QPS China	160	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical End Point Studies
QPS Miami	95	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical End Point Studies

Bioanalysis

We offer state of the art GLP compliant bioanalysis at multiple global locations including India, USA, the Netherlands and Taiwan.
With over 46 LC-MS/MS systems installed globally and 800+ validated assays spanning all therapeutic areas including challeng- ing and 'hard to develop' methods, we are positioned as the ideal partner for generic product development.

Credentials

All our global sites have an excellent regulatory track-record with multiple inspections by various agencies including US FDA, EMEA, UK MHRA, WHO and CEB, resulting in numerous product approv- als for our sponsors.

QPS is your ideal CRO partner for generic product development and can also assist in understanding the regulatory requirements of different countries for generic drug approval. QPS can partner with your product development groups in taking you from study design to providing a final dossier for regulatory submission.

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QPS is a Global CRO

with locations around the world
to serve the evolving needs of the
Pharmaceutical and Biotech industries

WWW.QPS.COM