

# A flexible approach to Generic Product Development

**QPS IS A GLOBAL CRO WITH DIVERSE CAPABILITIES THAT CAN OFFER END TO END SERVICES 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's 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](mailto: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 Endpoint 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 Endpoint Studies
QPS Taiwan	40	Patient Pharmacokinetic Studies and Clinical Endpoint Studies
QPS Netherlands	66	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical Endpoint Studies
QPS China	160	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical Endpoint Studies
QPS Miami	95	Healthy Human BA/BE, Patient Pharmacokinetic Studies, Clinical Endpoint 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 challenging and 'hard to develop' methods, we are positioned as the ideal partner for generic product development.

with multiple inspections by various agencies including US FDA, EMA, UK MHRA, WHO and CEB, resulting in numerous product approvals 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.

## Credentials

All our global sites have an excellent regulatory track-record

**AGILITY. FLEXIBILITY. SPEED**

# Generic Product Development

**CALL** +1 512 350 2827  
**EMAIL** [infobd@qps.com](mailto:infobd@qps.com)

**QPS is a Global CRO**  
with locations around the world  
to serve the evolving needs of the  
Pharmaceutical and Biotech industries

