
A flexible approach to
Female Healthcare
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

QPS Expertise in Clinical Trials Involving Female Healthcare

Knowledge of sex differences as a key biological variable in product development must be considered at every step in the development of drugs, devices and biologics. Failure to consider sex differences during data collection and analysis will severely limit the usefulness of clinical data in the regulatory evaluation of product safety and efficacy, and may jeopardize the applicability of study results to clinical practice and personalized medicine. This is particularly important for studies of diseases or therapies that exhibit a known sex difference. QPS provides all of the clinical, bioanalytical and gynecological experts to fulfill your clinical development needs in the field of women's health care.

QPS conducts Pharmacodynamic and Safety Assessments in the Field of Gynecological Endocrinology

Sex differences can play a significant role in how a treatment will affect a patient. QPS has deep experience in the conduct of clinical trials where women are the primary study subjects. Some of the tools and techniques that we commonly use include:

- Transvaginal ultrasonography (TVUS)
- Gynecological examination
- Cervical smear
- Endometrial thickness
- Endometrial biopsy
- Hormones/biomarkers

QPS
CUSTOM-BUILT RESEARCH™

Typical Clinical Studies in Female Healthcare

QPS conducts a wide variety of clinical studies to gather clinical evidence to document how drugs, devices and biologics will affect and interact with females. Typical study types include:

- Drug-drug interaction studies with oral contraceptives
- Trials with new contraceptives
- Infertility trials
- Clinical lactation studies i.e. trials which are designed to assess:
    - The influence of lactation on maternal pharmacokinetics
    - The extent of drug transfer into breast milk
- Bioavailability and bioequivalence studies in healthy, pituitary suppressed female subjects
- Trials requiring transvaginal ultrasonography (TVUS) assessments
- PK/PD studies in healthy pituitary suppressed women with various hormonal measurements and multiples TVUS assessments to determine follicular growth and/or endometrial thickness
- Studies in which the timing of the study drug administration is to be done menstrual cycle-dependent or, in other words, should be done dependent on follicle size.

QPS

CUSTOM-BUILT RESEARCH™

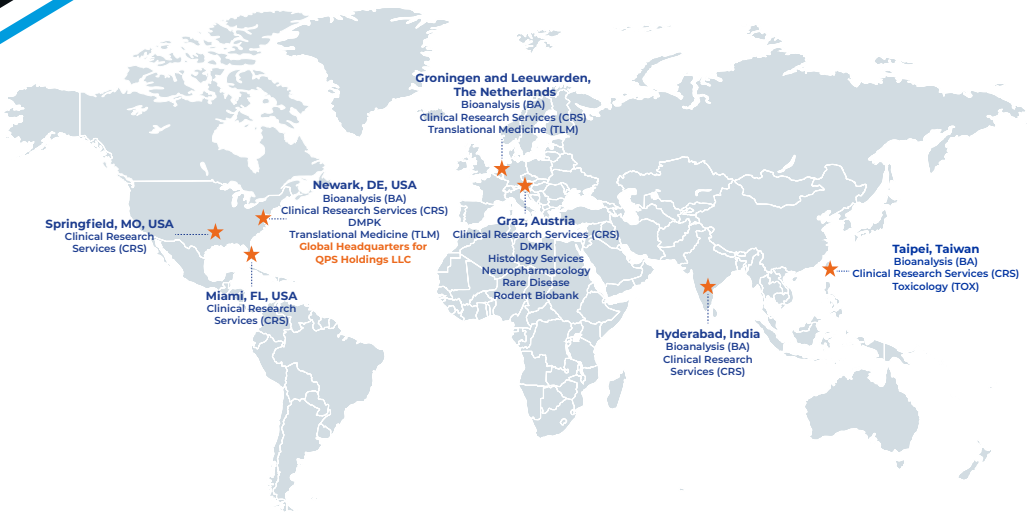
Time is of the essence in drug development. Contact the QPS business development team today!

CALL +1 512 350 2827

EMAIL infobd@qps.com

QPS is a Global CRO

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



WWW.QPS.COM