

# A FLEXIBLE APPROACH TO BIOMARKER CAPABILITIES

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TO SUPPORT RESEARCH AND DEVELOPMENT IN DIFFERENT STAGES OF BIOPHARMACEUTICAL COMPOUNDS AND PRODUCTS, QPS offers biomarker services in different global competence centers using a wide range of technology platforms to support programs in any therapeutic area.





## FDA BIOMARKER DEFINITION

The FDA defines biomarkers as “a characteristic that is objectively measured and evaluated as an indicator of normal biologic or pathogenic processes or pharmacologic response to a drug”.

### RELEVANCE OF BIOMARKERS TO DRUG DEVELOPMENT

In drug development, there is an increasing interest in the identification and use of biomarkers to aid in the association of signals for safety and efficacy. The goal is to eventually deliver on the promise of personalized medicine by understanding a patient’s unique clinical and genetic information. Incorporating a biomarker strategy through all phases of development can lead to quicker decisions and improved commercial viability.

At QPS, we seek to provide our customers with state-of-the-art services to deliver on the promise of biomarkers in different therapeutic areas. This is accomplished from preclinical studies through late phase global clinical trials, utilizing a broad range of bioanalytical techniques, from elemental analysis via small molecule biomarkers to single cell characterization.

QPS specialists are adept in the development, optimization, validation and application of biomarker assays. Similar quality systems for GLP and methods validation are applied for biomarker studies, as well as for DMPK bioanalysis. In close consultation with the Sponsor, the degree of qualification or validation is determined, and may be extended along with the flow of the candidate throughout the development pipeline.



## Analytical Techniques and Capabilities

| Technique   | Origin and classification of biomarkers that can be quantified  |
|---|---|
| LC-MS/MS  | Small molecule biomarkers including hormones and peptides.  |
| LC-MS/MS  | Biomolecules including large peptides and protein biomarkers.   |
| ICP-MS  | Trace and essential elements, total or freely circulating and bound.  |
| LC-ICP-MS   | Trace and essential elements for speciation, free, bound and total; Biomarkers with specific elemental content (e.g. Metalloproteins, Transferrins, Vitamin B12).   |
| ELISA, EIA, ECL (MSD), enzyme assay, nephelometry | Custom assays developed for biomarkers and implementation and optimization of commercially-available assay kits for large molecule biomarkers (e.g. phospho-proteins/ signaling molecules, growth factors, cytokines, complement factors).  |
| ECL (MSD), Luminex                                | Multianalyte applications (e.g. Simultaneous measurements of multiple growth factors, cytokines, signaling markers (e.g. pAKT/tAK, pERK/tErk)).   |
| Gyrolab Immunoassay Platform                      | Rapid development of custom biomarker assays using nanoliter volumes of reagents. High throughput, automated biomarker measurements.  |
| TaqMan (Real-Time PCR)                            | Gene expression analysis (relative and absolute quantitation) and SNP genotyping analysis.  |
| Flow Cytometry                                    | Cell phenotyping, Intra- and Extra-cellular markers, Cell Cycle Analysis, and Cytometric Bead Array (CBA) for soluble biomarker measurements.   |
| Cell-based Assays                                 | Cell growth/survival, cell stimulation with biomarker release or cell-surface marker changes.   |
| <i>In Situ</i> Hybridization                      | Fluorescent DNA <i>in situ</i> hybridization (FISH) can be used in medical diagnostics to assess chromosomal integrity. RNA <i>in situ</i> hybridization is used to measure and localize RNA expression (mRNAs, lncRNAs and miRNAs) within tissue sections, cells and circulating tumor cells (CTCs). |
| Immunohistochemistry                              | Localization of proteins in cells or tissue sections.   |

Offered also in combination with different types of LPS-challenge testing studies (ex vivo, *in vitro* and also *in vivo* in close collaboration with QPS' Phase I units).

## Analytical Platforms Per QPS Site

| Platform                        | Delaware | Netherlands | Taiwan | Austria |
|---------------------------------|----------|-------------|--------|---------|
| ELISA/EIA                       | X        | X           | X      | X       |
| ECL (MSD)                       | X        | X           | X      | X       |
| Luminex (BioPlex)               | X        |             | X      |         |
| Gyrolab                         | X        | X           |        |         |
| Cell-Based Assay                | X        | X           | X      | X       |
| Flow Cytometry                  |          | X           |        |         |
| HPLC                            | X        | X           | X      |         |
| LC-MS/MS                        | X        | X           | X      |         |
| Nephelometry                    |          | X           |        |         |
| ICP-MS                          |          | X           |        |         |
| Western Blot                    | X        |             |        | X       |
| Enzyme Assays                   | X        | X           |        | X       |
| RIA/SPA                         | X        | X           |        |         |
| TaqMan (genotyping and qRT-PCR) | X        |             |        | X       |
| RNA/DNA Sample Prep & Analysis  | X        |             |        | X       |
| PCR                             | X        |             |        | X       |
| <i>In Situ</i> Hybridization    |          |             |        | X       |
| Immunohistochemistry            |          |             |        | X       |
| Colorimetric Assays             | X        | X           | X      | X       |
| Wes™                            |          |             |        | X       |
| ddPCR                           | X        |             |        |         |
| ELISpot                         | X        |             |        |         |



## QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

### BENEFIT FROM THE RESOURCES OF A GLOBAL CRO



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



NETWORK USA / Austria / Australia / Argentina / Belgium / Bosnia / Brazil / Bulgaria / Chile / China / Croatia / Czech Republic / Denmark / France / Germany /  
LOCATIONS Hungary / India / Italy / Lithuania / Netherlands / Poland / Romania / Serbia / Slovakia / South Korea / Spain / Sweden / Taiwan / United Kingdom



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

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