

# **Q**<sup>2</sup> Solutions<sup>8</sup>

# Q<sup>2</sup> Solutions Central Laboratory Services

Deeper science to drive tailored solutions, optimized quality systems, delivery excellence and better insights

Meeting the demands of today's drug, device and diagnostics development environment requires a next generation laboratory. When looking for a central laboratory solution, it's important to find a partner that can accommodate your diverse needs.

### What sets Q<sup>2</sup> Solutions apart?



#### **Tailored solutions**

- · Comprehensive central lab services including assay development, project management, lab data management, biobanking and more, scaled to meet your needs
- Extensive test menu and the ability to collaborate on developing customized tests to meet your drug development goals

Access to constantly expanding menu of



**3,500** 

- Integration with IQVIA and clinical trial services for a streamlined clinical delivery model to get your product to market faster
- Innovative partnership models to allow our customers to focus key internal resources while we provide the operating and governance models to ensure your success
- Scientific acumen and resources to supplement and enhance your internal capabilities so you can execute smarter trials

 $Q^2$  Solutions has 40% of all FDA-helped develop approved breakthrough/first-in-class drugs since 2011

· Early engagement scientific specialists for feasibility and methods review, assessment of regulatory requirements, and application of best practices for global scale-up and optimized deployment



#### **Delivery excellence**

- Our focus on quality Each of our central laboratories delivers excellence through our Six Sigma quality systems encompassing harmonized processes, instrumentation, tests and reagents, and integrated LIMS systems to support your development and regulatory submission goals
- Comprehensive logistics capabilities Our scientists, project managers and logistics experts understand your needs and are committed to helping you navigate this complexity to improve your probability of success



on-time logistics performance

- Client-focused project management engagement dedicated to making the entire process - from startup to timely database lock seamless and simple for you
- **Global delivery** The right footprint in the right geographies with the right systems and technologies to deliver top-quality services and innovations that turn hope into help.



#### **Shaping outcomes**

 Industry-leading scientific expertise – Applying our experience and expertise to your study and execution strategy, to ensure our wealth of knowledge and best practices translate into optimized delivery of your study

Doctors and experts seasoned at managing very large clinical trials >10,000 subjects

- Innovative technologies Advanced analytics technology and reporting to give you near-real-time data access and analysis, allowing you to quickly make important connections and proactively address issues to optimize drug, medical device and diagnostic development
- · Comprehensive integration of third party labs allows our customers to stay lean internally and remain focused on science, patients and strategy, while aligning with Q2 Solutions' global expertise and execution to achieve better outcomes
- **Therapeutic expertise** Understanding the unique laboratory needs of your therapeutic area's clinical trials for clear results and improved probability of success

Q<sup>2</sup> Solutions helped develop **93%** of the Top 30 best-selling

oncology products of 2016

Turning Hope Into Help

# **Testing capabilities**

Below is a representative sampling of the depth and breadth of Q<sup>2</sup> Solutions' testing capabilities.

Discipline	Methodology	Example biomarkers/assays
Automated chemistry / urinalysis	<ul><li>Enzymatic analysis</li><li>Colorimetry</li><li>Turbidimetry</li><li>Spectrophotometry</li></ul>	<ul> <li>Routine chemistry</li> <li>Urinalysis</li> <li>Endocrinology</li> <li>Tumor markers; thyroid functions</li> </ul>
Hematology / coagulation	<ul> <li>Automated cell counting</li> <li>Leukocyte differential counting</li> <li>Conductivity and light scatter</li> <li>Chromatography</li> <li>Clotting time</li> </ul>	<ul> <li>CBC, WBC differential, Reticulocytes</li> <li>HbA1c</li> <li>Prothrombin time, aPTT, Fibrinogen</li> <li>D-dimer, proteins S and C</li> <li>Von Willebrand factor</li> </ul>
Flow cytometry	<ul> <li>Light scatter</li> <li>Cellular fluorescence</li> <li>Custom panel development</li> </ul>	<ul> <li>T cell subsets (Tregs, Th17, exhaustion, CM/EM/E)</li> <li>Minimal residual disease</li> <li>Phosphomarkers</li> <li>Activated T and B cells</li> <li>NK cells</li> <li>Dendritic cells</li> <li>Monocytes</li> <li>Activated granulocytes</li> </ul>
Anatomic and molecular pathology	<ul> <li>Tissue processing (FFPE, cryo, TMAs)</li> <li>H&amp;E</li> <li>Digital pathology</li> <li>Assay and algorithm development</li> <li>IHC, ISH, FISH</li> <li>Mutation and expression analysis</li> <li>(PCR, RT-qPCR)</li> </ul>	<ul> <li>PI3K/EGFR/RTK pathways</li> <li>Apoptosis/cell-death markers</li> <li>MAPK pathway</li> <li>Tumor stroma and infiltrating lymphocytes</li> <li>Companion diagnostic (CDx) assays</li> </ul>
Microbiology	Direct inoculation     Molecular characterization	<ul> <li>Bacteria and yeast identification</li> <li>Antimicrobial susceptibility</li> <li>Ova and parasites</li> <li>TB testing, Latent TB infection</li> </ul>
Genomics	<ul> <li>PCR and variants</li> <li>SNP Analysis</li> <li>Universal array sorting</li> <li>FISH</li> <li>NextGen sequencing</li> </ul>	<ul> <li>Viral loads and genotyping</li> <li>ADME/PGx</li> <li>HLA typing</li> <li>GEP (array, RNAseq)</li> <li>Whole or targeted exome sequencing</li> </ul>
Mass spectrometry	• LC/MS/MS	<ul><li>Drugs of abuse</li><li>Hormones</li><li>Metabolics</li></ul>
Immunoassay	<ul> <li>Standard plate ELISA</li> <li>Multiplexing (bead-based detection, biochips)</li> <li>Immunoblotting (RIBA)</li> <li>Automated immunoassay platforms</li> </ul>	<ul> <li>Immunogenicity /ADAs/HAHA</li> <li>Cytokines</li> <li>Immunoglobulins</li> <li>Cardiac and bone markers</li> </ul>

# **Contact** us

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