



# Helping You Solve Your Most Challenging Drug Development Problems

Smithers, a bioanalytical contract research organization (CRO), supports the development of large molecule therapeutics from discovery through phase IV, with expertise in bioassays and ultra-sensitive ligand-binding assays.

Our services focus on development, validation and sample analysis for PK/TK, ADA, bioassays and fit-for purpose biomarker studies. Smithers supports biologics/monoclonal & polyclonal antibodies/bi-specific antibodies/CAR-T/TCR/ biosimilars and biobetters, among many other therapeutic technologies.

## Consultative Approach

### *Your Partner from Discovery through Post-Market*

Smithers supports your studies with the help of our world class scientists, who come from diverse backgrounds including CRO's, industry, and instrumentation providers.

Many of our scientific leaders, subject matter experts, and project managers have been involved in successful regulatory submission, approval, and commercialization of all types of biologics.

“*Smithers employs a consultative approach with industry leading experts who have years of experience in pharmacokinetic, immunogenicity, biomarker, and bioassay method development, validation, and sample analysis.*”

— IRA DUBEY, PHD  
President, Smithers Pharmaceutical  
Development Services

## GCP and GLP Compliant, CLIA-Certified

With two pharmaceutical development service locations in the United States, Smithers has over 41,000 square feet of GCP and GLP compliant, CLIA-certified available lab and support space with the capacity to support regulated studies of any size.

Studies supported cover a wide variety of indications including oncology, hematology, autoimmunity, cell- and gene-therapy, immunology, GI, cardiac, metabolic, infectious disease, and neurologic disorders.



## Technology-driven by Sponsors' Needs

### *Coupled with Expert Scientists & Dedicated Project Teams*

These platforms, coupled with our scientists, place Smithers at the forefront of the industry, developing and validating proprietary, fit-for-purpose assays.

- *Molecular Devices, Spectra Max M3 Plate Readers: Absorbance, Fluorescence & Luminescence*
- *MSD Sector® S600*
- *Gyrolab® XPlore*
- *Gyrolab® xP*
- *Singulex® Erenna, Fluorescence*
- *Quanterix® Simoa HD-X*
- *PerkinElmer® EnSpire Alpha Plate Reader*
- *PerkinElmer® Envision Multimode Reader*
- *Hamilton® STAR Liquid Handling System*
- *Biotek®, Elx405, Microplate Washers*
- *BD FACSLyric Flow Cytometer*
- *BC Vi-Cell Analyzer*
- *Thermo Stericult CO2 HEPA Class 1000 Tissue Culture Incubators*
- *Class 2 Biosafety Cabinets*
- *Clean Room Facility*
- *Siemens® BCS XP Coagulation Analyzer*



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