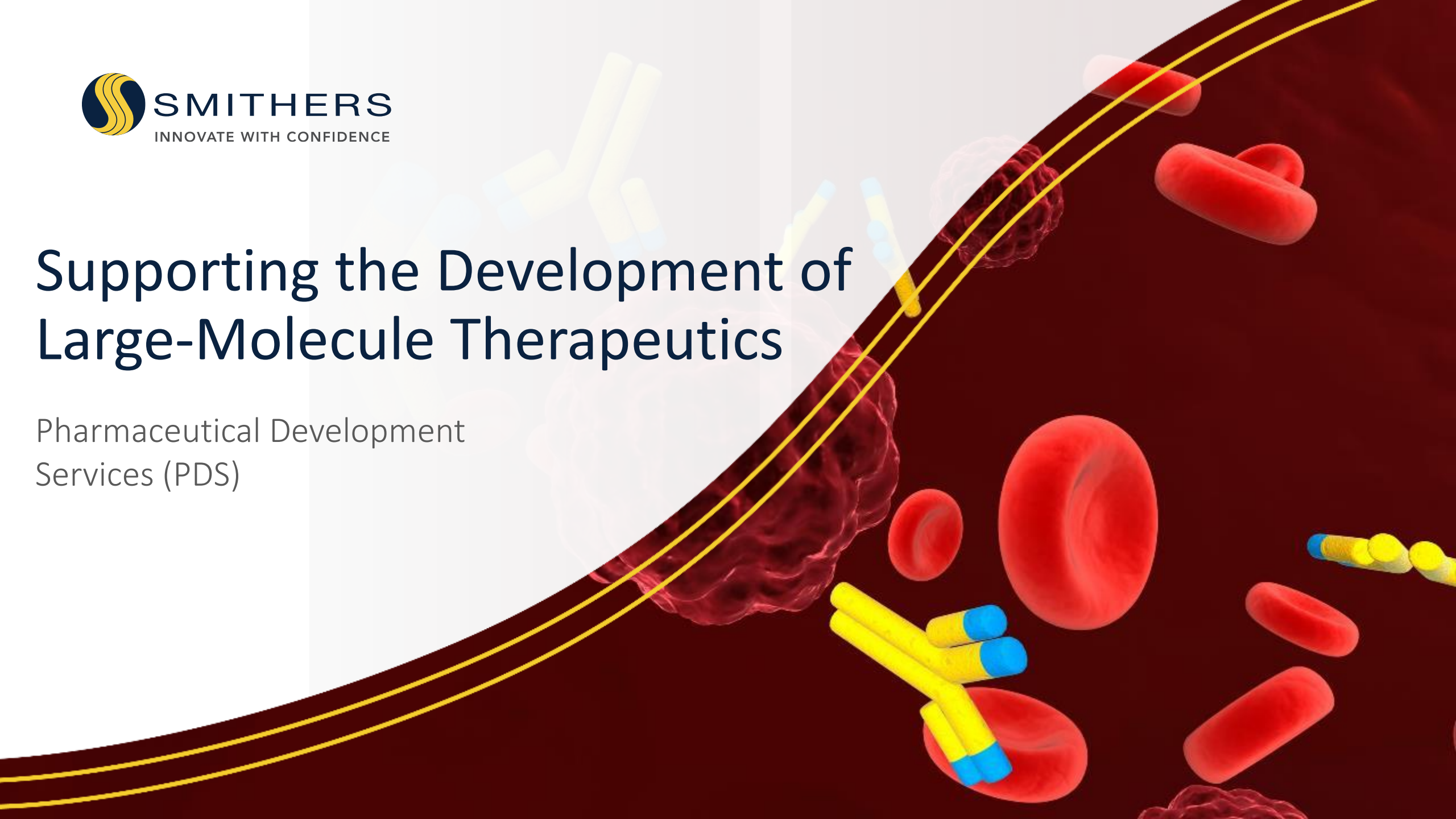




Supporting the Development of Large-Molecule Therapeutics

Pharmaceutical Development
Services (PDS)



Who We Are

A highly, specialized CRO – Smithers offers independent third-party, consultative laboratory testing customized to meet your most challenging drug development needs.



WORLDWIDE

Part of the Smithers Group, which has been in operation for over 90 years, and now has 14 facilities globally with 700+ employees.



INVESTED

We continuously invest in our scientific talent, as well as our world-class facilities.



KNOWLEDGABLE

Our scientists are experts in their field and have a deep knowledge of the topics important to our clients.



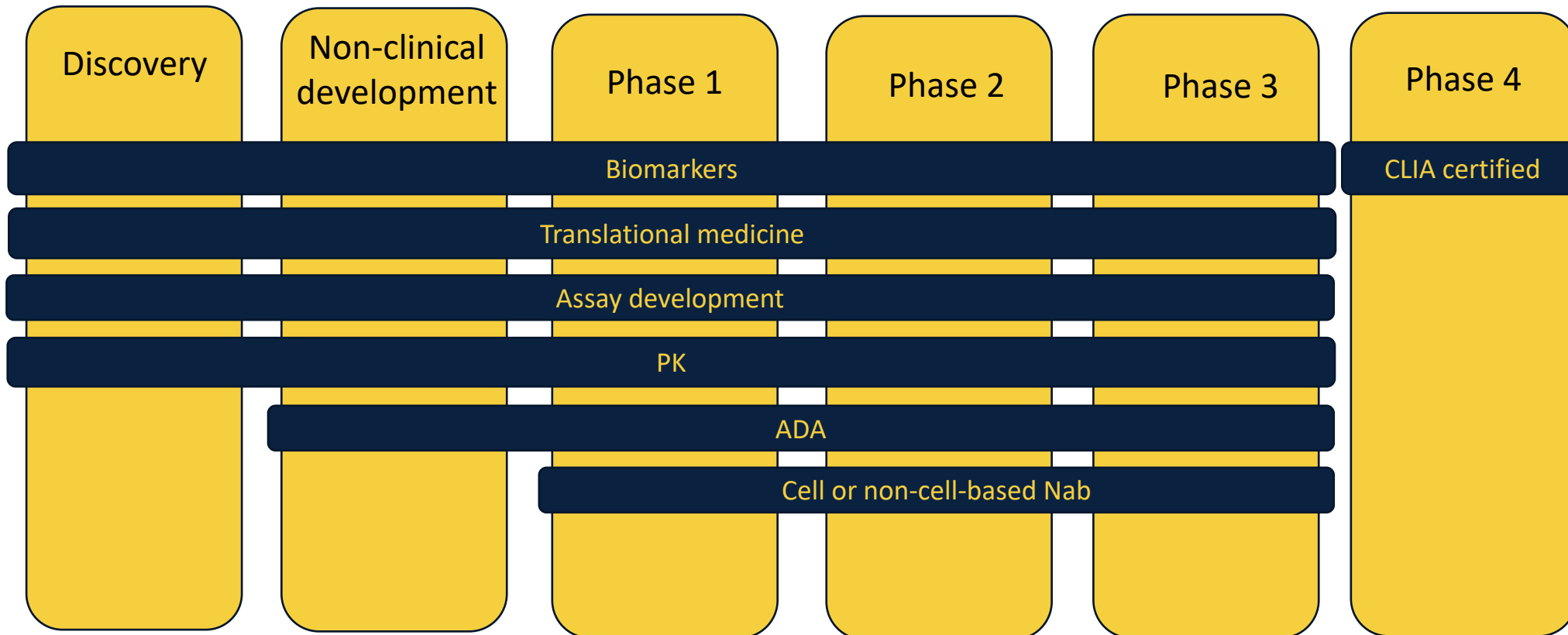
Bioanalytical Assay Services

- Large Molecule (Biologics)
 - Assay Development, Transfer, Validation, Sample Testing to Support the Development of Biologics, Biosimilars and Vaccines
- Quantitative Ligand Binding Assays (PK/TK) and ADA
- Comprehensive Biomarker Services
 - Single and Multi-Plexed Assays
 - Kits, fit-for-purpose and proprietary
- BioAssay: Cell Based and Non-Cell Based
 - Neutralizing Antibody Assays
 - Cell Bank creation and maintenance
- Flow Cytometry (FACS)
- Coagulation

Drug Development

Smithers is with you throughout the drug development journey

CLINICAL TRIALS





Regulatory Experience

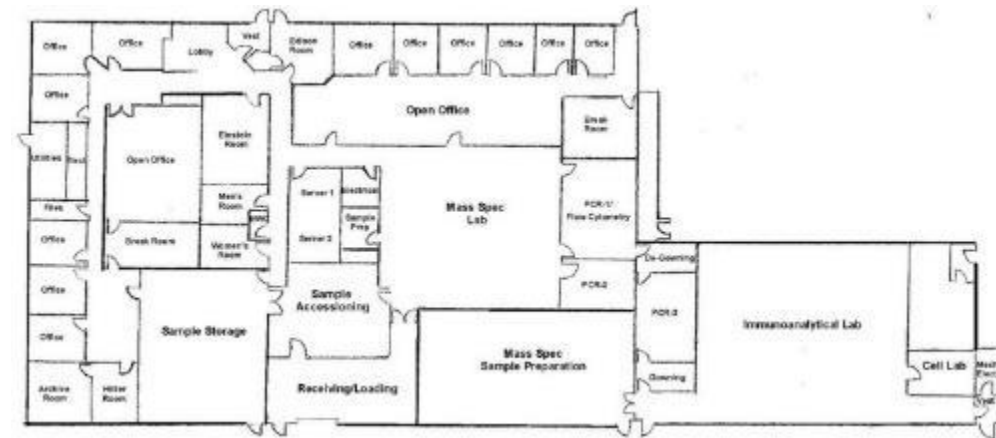
- FDA: Surveillance Audit (Last: 3/22/2019)
 - No findings, No 483's
- CLIA
 - Gaithersburg: (Last: 3/25/2019)
 - Ewing (Certification received)
- State, Federal; no findings
- Client QA Audits (onsite & virtual)

Facilities

- Over 41,000 sq. ft. of bioanalytical lab & support space.
 - 15,000 sq. ft in Gaithersburg, MD
 - 7,500 sq. ft. support space Gaithersburg
 - 19,000 sq. ft in Ewing, NJ
- Environmental controls
 - 24/7 automated Rees
 - Environmental monitoring
 - Temp, CO2, Humidity for incubators and storage units
 - Redundant systems / Backup generators



GAITHERSBURG, MD



EWING, NJ

Technology Driven by Sponsors' Needs

Our clients often need specialized technology. Smithers is proud to invest in our clients' projects.

- 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 Instrument

Biomarker / High Sensitivity

- Gyrolab xPlore™ and xP™
 - Small required sample volume - 4 μ L minimum
 - Biomarker – low pg/mL range
 - Multiple analyte measurements from as little as 12 μ L
- Applications include:
 - Cardiovascular and metabolic diseases
 - Central nervous system diseases
 - Oncology
 - Cytokines and Chemokines



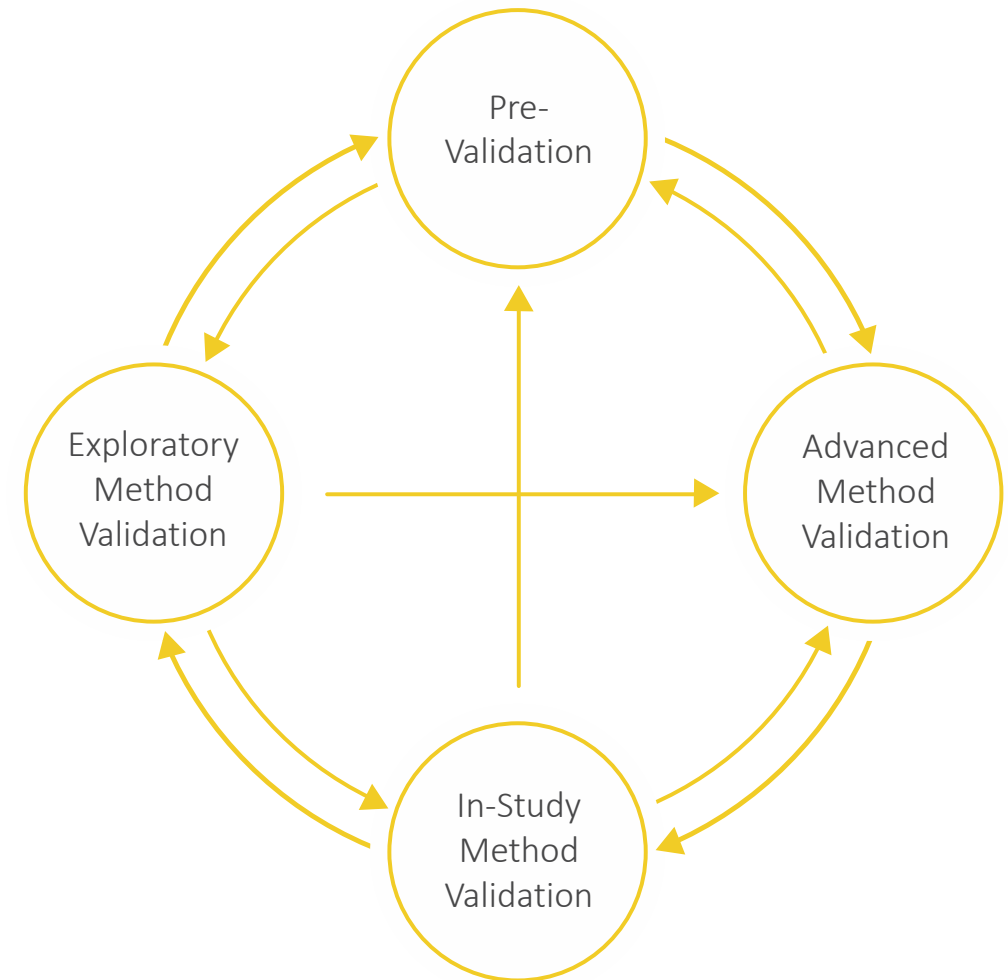
Biomarker / High Sensitivity

- Singulex Erenna[®] Immunoassay System
 - Single Molecule Counting (SMC) technology
 - Ultra-High Sensitivity – fg/mL
 - Interfaced to Validated Watson LIMS
 - Developed and validated both PK and biomarker assays
 - About 50% biomarker and 50% PK
- Quanterix Simoa HD-X Analyzer[™]
 - Ultra-High Sensitivity – fg/mL Range
 - Capable of multiplexing



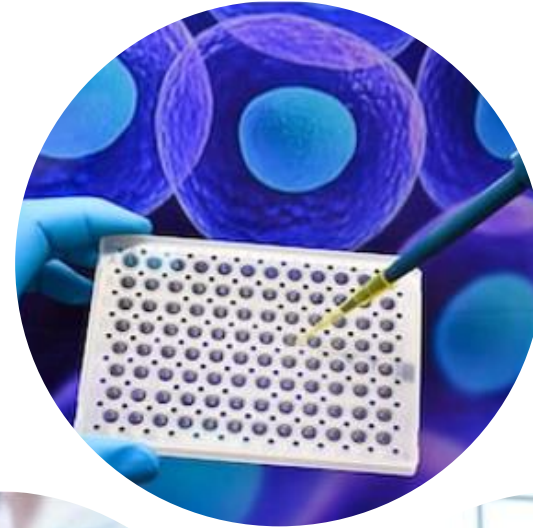
Fit-for-Purpose Biomarker Method Development and Validation

- Biomarker assay development and validation at Smithers Avanza follows the “Fit-for-Purpose” concept described by Lee et al. (2006)
- Biomarker assay capabilities include:
 - ELISA (single analyte)
 - Meso Scale Discovery (single and multiple analytes)
 - Singulex Erenna (Ultra Sensitive, single analyte)
 - Quanterix Simoa HDX (Ultra Sensitive)
 - GyroLab (Sample Volume)



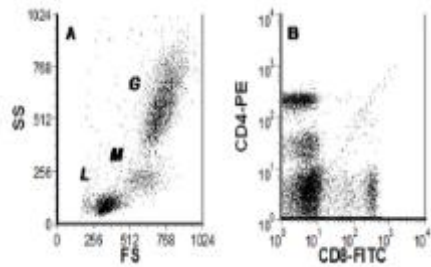
Bioassay: Cell and Non-Cell Based

- Dedicated team and facilities for cell-based assays
- Facilities in Gaithersburg and Ewing
- Cell Proliferation
- Reporter Gene
- Apoptosis
- Enzyme Activity

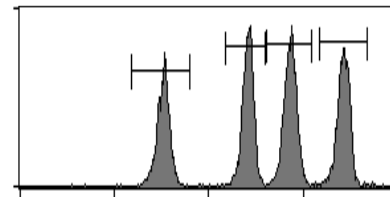


FACS Capabilities

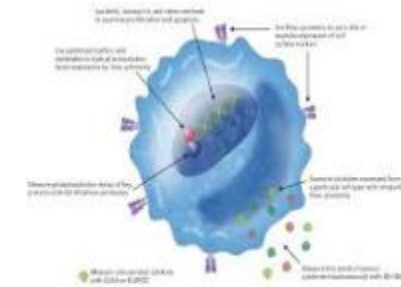
BD FACSLyric™: 3 lasers/ 12 colors | BD FACSuite™ Software



CELL PHENOTYPING



RECEPTOR
ENUMERATIONS



CELL SURFACE /
INTRACELLULAR
MARKERS

What to Expect from Smithers

Client Engagement Process



Intelligence Gathering

- Initiatives, Needs, & Goals
- Key Team Members
- What Matters Most
- Constraints & Timelines
- CDAs / MSAs
- Expectations / Deliverables

Crafting the Solution / Service

- Resources & Experts
- Protocols & Methods
- Value-Added Guidance
- Customized Services
- Alignment with Your Business Goals
- Generate Proposal

Study Awarded / Implementation Management

- Kick-Off & Update Meetings
- Delivery Milestones, Project Management
- Quality Assurance
- Reporting & Communication

Project Cycle

Client Engagement Process



A Smithers Project Manager is assigned to the study.

The project manager meets with the Sponsor's team and works through any areas of concern and understand and agree upon the basic requirements.



The Project Manager generates an analytical plan based on your project.

The plan will then be sent to the Client for comments. Plans will be exchanged until both parties agree and include timelines and endpoints of the proposed work.



Smithers will communicate throughout the entirety of the study.

Communication is critical; we suggest weekly teleconferences to review the project status, timelines and deliverables, as well as quarterly face-to-face meetings to discuss progress and future partnerships.



Smithers provides the agreed upon services and follow-up support.

Studies are conducted according to approved plans. Data is collected in Watson LIMS and reviewed in compliance with Smithers' SOPs. QA is included if appropriate once assays are initiated.

Emerging & Supporting Services

- Emerging Services
 - Quantitative Real-Time PCR (qPCR)
 - ddPCR
 - Hybridization assays (oligonucleotide)
 - Expanded Bioassay Capabilities
- Supporting Services
 - Gene Therapy
 - Translational Medicine





Dedicated to Helping You Solve the Most Challenging Drug Development Problems through:



Understanding Your Needs



Commit the Resources & Expertise



Flexibility & Responsiveness



High Level Communication

Build Relationships

Smithers Pharmaceutical Development Locations

11 Firstfield Road, Suite C
Gaithersburg, MD 20878
+1 240 364 6360

111 Silva Street
Ewing, NJ 08628
+1 609 882 2050



Thank you!



smithers.com | infoPDS@smithers.com | Gaithersburg, MD | Ewing, NJ