

Development of Biomarker Assays in Large Molecule Bioanalysis

Experience and the Application of Technology

The growing use of biomarker data to support and streamline the drug development process has become an integral part of the path to bringing new and effective therapeutics to market.

Eurofins Pharma Bioanalytical Services has extensive experience in performing large molecule bioanalysis, which includes routinely performing quantitative assessment of soluble biomarkers, using a variety of platforms including RIA, Gyrolab™, Luminex®, MSD, Singulex Erenna® and Quanterix SR-X™. We utilize the different platforms based on knowledge of the specific strengths and weaknesses of platform and the associated methods.

Eurofins Pharma Bioanalytical Services provides the technical expertise, quality assurance and peace of mind essential when considering an outsourcing partner for pre-clinical through clinical sample analysis, and has unsurpassed experience and a deep understanding of regulatory guidance.

Our Technology Platforms – Applied To Your Projects

Eurofins Pharma Bioanalytical Services helps our clients make the optimal choice in this “fit for purpose” approach, leveraging a wide variety of different platforms including:



Quanterix SR-X™



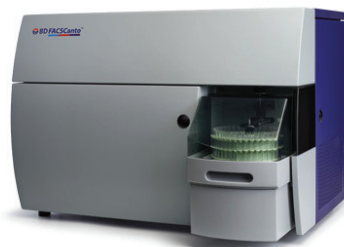
Gyrolab™ xP



MSD



Singulex Erenna®



FACSCanto™



Luminex®

'Fit-for-Purpose' Biomarker Analysis

- Consultation and services for biomarker assay validation
- Implements scientific and industry best practices including fit-for-purpose qualification and validation
- Full GxP compliance
- Breadth of experience contributing to industry guidelines.
- Single-plex and multiplex assays

Exploratory Biomarker Services

- Developing novel biomarker assays requires a great deal of time, a high level of expertise, and often comes at an incredibly high expense
- Commercially available kits
- Lower price point
- Benefits of portability, expedited analytical solutions and ease of operation

Validated Biomarker Services

- Validation of analytical methods is crucial in generating data to be used in support of regulatory submissions
- Fully consultative and comprehensive assay validation or cross-validation service
- Validate our bioanalytical assays following the 'fit-for-purpose' strategy, guided by our in-house expertise and latest industry white paper recommendations

Flow Cytometry Services

- Over 20 years of experience in flow cytometry custom assay development, assay validation, and sample processing
- Design customized solutions to overcome logistics issues for multi-site trials
- Sophisticated consultation and service solution for a wide variety of applications
- Multi-colour surface phenotyping and intracellular analysis, through target engagement and receptor occupancy assessments to the analysis functional endpoints such as ADCC cytotoxicity

Biologics Done Right



About Eurofins Bioanalytical Services

Over 15 years of industry-leading global **Scientific Expertise** supporting the widest breadth of Biologics' clinical trials with PK/TK, ADA, Nab and Biomarker assays and sample analyses.

Versatile Performance and Project Management Excellence to adapt to a client's specific needs. Clinical or preclinical, regulated or non-regulated, assay development, qualification or validation; we custom design our support to match the client's program.

State-of-the art laboratory facilities in St. Louis, USA providing **Global Reach and Capacity** to address clients' needs while simultaneously offering regionally-based solutions.

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