

# DEVELOPMENT OF BIOMARKER ASSAYS

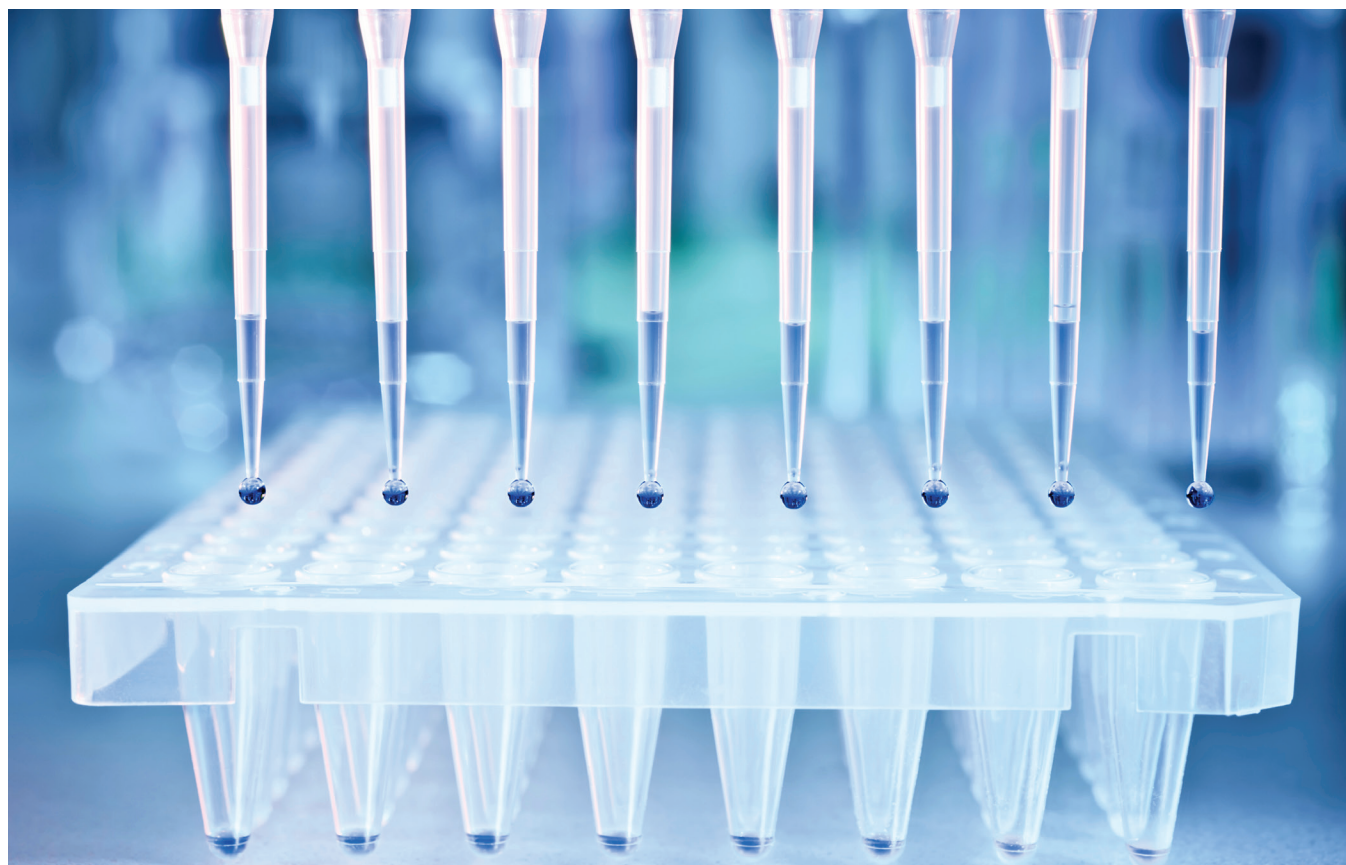
## IN LARGE MOLECULE BIOANALYSIS

### 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® and Singulex Erenna®. 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.



## '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.

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## OUR TECHNOLOGY PLATFORMS – APPLIED TO YOUR PROJECTS

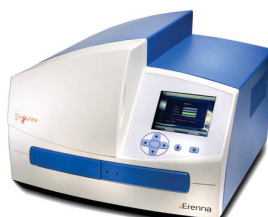
Eurofins Pharma Bioanalytical Services helps our clients make the optimal choice in this "fit for purpose" approach, leveraging a wide variety of different platforms including:



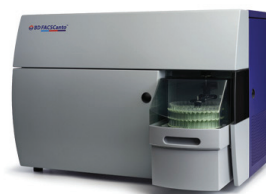
Gyrolab™ xP



MSD



Singlex Erenna®



FACSCanto™



Luminex®

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