eurofins | Bioanalytical Services

Large Molecule Bioanalysis Scientific Consulting

Delivering the scientific expertise and global resources you need to ensure successful execution of your deployment program through marketing approval.

Consulting Advantage

Eurofins Bioanalytical Services functions in tandem with our large molecule clients worldwide to provide the expertise and experience required in conducting and reporting new drug clinical study results to regulatory agencies. Our team offers a wide range of consulting services in support of proposed and ongoing large molecule bioanalysis.

We can provide on-site or remote scientific resources to meet in-house bioanalytical needs or to resolve issues. We can develop a comprehensive bioanalytical program for your drug candidate, provide method troubleshooting services as needed, and monitor and review method validation and sample analysis activities. Our aim is to verify that methods and data are scientifically sound and accurate, and that the necessary regulatory requirements have been met.

Eurofins consulting services can perform pre-qualification audits, monitor and troubleshoot ongoing projects, and audit final study data to ensure that bioanalytical methods, processes and data generated from the laboratory will be suitable for regulatory submission.

We serve to provide scientific and technical expertise, training to improve assay ruggedness and increase laboratory efficiencies, and our key strength is our dedication to meet the needs of customers with an emphasis on the design of large molecule bioanalytical programs, preparation of protocol synopses, and development of reports at various levels of detail summarizing findings.

With our scientific expertise, and global presence; Eurofins Bioanalytical Services Consulting team is uniquely qualified to provide clients with reliability you can trust.

SCIENTIFIC / TECHNICAL SERVICES

- Method transfers and partial validations
- Develop and implement method development strategies
- Provide remote or on-site bioanalytical expertise to US and International Clients
- Determine the root cause for assay issues observed during method development and validation and identify suitable solutions
- Evaluate, recommend and implement strategies for new technologies
- Review and critique assay methodology and validation data
- Develop and present targeted scientific seminars and training programs
- Immunogenicity Cut-Point Calculations

REGULATORY / DATA SERVICES

- Conduct pre-qualification / due diligence, GLP and OECD audits
- Monitor and track ongoing bioanalytical activities at a sponsor partner
- Perform post study data audits
- Perform critical review of method validation and sample analysis data and reports
- Develop, review and revise SOPs and laboratory processes
- Prepare and review study reports and manuscripts
- Develop and present regulatory training programs

SCIENTIFIC AND BUSINESS PROCESS SERVICES

- Aid start-up, small and virtual companies to assess or build bioanalytical expertise
- Review bioanalytical and site policies and procedures
- Review contracts, method development and sample analysis study plans and protocols
- Prepare method development strategies to streamline method development processes
- Prepare templates for proposals, work plans and reports

Seminars and training programs can be uniquely designed to meet your specific company needs. Additional services may also be available upon request, contact us for additional details.

The key to Eurofins Bioanalytical Services recognized success in meeting the needs of our clients in drug development is our unique combination of:

Proven Experience

- Extensive experience in large molecule bioanalytical industry drug development, clinical reporting and support services
- Proven expertise in navigating regulatory agency requirements
- Experience across all therapeutic areas

Trusted Partner

- Industry leading scientific experts and project management team throughout your drug development program

International Experts

- North America, Europe
- Scientific experts across all large molecule therapeutic areas

St Charles Site

Scientific Director
Jennifer Ohayon, PhD

Jennifer has 20+ years of experience in biomarker discovery and novel biomarker assay development. She received her doctoral studies at the Joslin Diabetes Center at Harvard Medical School. During her post-doctoral training Jennifer continued to study growth factor signaling using proteomics approaches. Her professional expertise incorporates the use of nanotechnology in ultra-sensitive assay development. She brings a depth of understanding in the development and validation of laboratory-developed tests and novel biomarker assay development in the clinical chemistry setting.

Scientific Director
Vimal Patel, MBA

Mr. Patel has over 15 years of experience consulting on development, validation, and application of assays to ensure compliance with scientific and technical goals and regulatory requirements. Prior to joining Eurofins, Vimal worked for Amgen as a Scientist specializing in assay development, automation, new technologies and the application of Design of Experimentation to improve method transfer and validation. Mr. Patel received his BSc from Cal State University and his MBA from California Lutheran University and has served in leadership positions in various industry organizations, and as an invited speaker at multiple industry events.

Associate Scientific Director
Theodore Baginski, MS

Mr. Baginski has over 25 years combined experience in the Pharmaceutical and CRO industries. He has extensive experience in the design, qualification, and validation of a wide variety of regulated and non-regulated immunoassays. His knowledge extends to technologies and methods related to RIA, Gyros, MSD, ELISA, and Flow Cytometry platforms. His specialties include a unique ability to communicate and work with partnering groups on a technical level.

Associate Scientific Director
Mark A. Abrams, MS

Mr. Abrams has over 30 years of experience in the Pharmaceutical and CRO industries working in biomarker discovery and biomarker assay development. He has served as Principal Investigator and Lead Scientist for multiple novel drug development projects, assay development and qualification to support multiple disease platforms. Mark is currently leading the evaluation and implementation of Emerging Technologies.

Chief Scientific Officer

Jim Hulse, PhD

Jim brings over thirty years of experience in the Life Science and Bioanalytical Laboratory services industries where he served in global senior level positions. Jim develops strong relationships and consultation with clients in the industry as well as with regulatory agencies while overseeing and developing strategies for growth and new technologies. As General Manager and Chief Scientific Officer, Jim is responsible for scientific development and global oversight of Eurofins bioanalytical service labs in USA and UK.

Oxford Site

Scientific Director

David Shaw, PhD

David has over 15 years experience managing bioanalytical studies with the past 10 years devoted to the CRO industry. His particular focus is development and validation of large molecule therapeutics PK and ADA methods for regulated bioanalysis of both clinical and non-clinical samples using a range of different analytical platforms, including ECL, Gyros and SPR.

Scientific Director

David Lanham, BSc (Hons), MSc

David has over 25 years of experience in the pharmaceutical CRO industry, managing both research and regulated bioanalytical projects in the pre-clinical and clinical arenas. His wide range of experience includes cell-based assay modelling, pre-clinical toxicology assessment and clinical trial bioanalysis, with a particular interest and expertise in biomarker bioanalysis and immune function assessment using ligand binding technology and flow cytometry. He has a specific interest and expertise in the applications of flow cytometry and is a member of the AAPS Flow Cytometry Action Program Committee.

Scientific Director

Matthew Bentley, BSc. (Hons)

Matthew has over 24 years of experience in the Pharma industry, the past 11 years of which have been in the bioanalytical CRO industry, managing study types from non-regulated method development to regulated validation and sample analysis in the clinical and non-clinical areas. His diverse areas of experience includes PK and ADA method development, validation, and analysis and also an interest in the biosimiar arena with a particular focus on product characterization using cell based and ligand binding techniques such as SPR using the Biacore platform.

Director Quality Assurance & Regulatory Affairs

Eric Paddock

Eric has over 18 years of experience in Quality Assurance Regulatory field. He has extensive experience in GMP for medical devices, and has expanded his knowledge of GLP, GCP regulations and ICH guidelines with regard to analytical testing, batch testing and quality assurance while at Eurofins. Eric is responsible for managing the Archives, regulated study data and reports, validation IQ/OQ/PQ protocols, tests and reports, deviations, investigations and CAPAs, performing phase, process, and facility audits. Eric has a BS degree in Business Management and 40+ continued education credits in the quality field.

Immunogenicity

- Assay development, method transfer, validation. Cut-point calculation
- Screen, Confirm, Titer. Advanced methodologies to address drug tolerance and soluble target interference
- Advanced cell based laboratory dedicated to GLP NAb assay development and sample analysis
- Experience and capacity for large volume sample analysis

Biosimilars

- Pre-developed assays for Trastuzumab, Bevacizumab, Cetuximab, Adalimumab, and more
- PK, Immunogenicity evaluation
- FcRN, FcγRI, II, III and C1q binding
- Cell based assays
  - Receptor binding, proliferation, ADCC

Biomarkers

- GLP/GCP/CLIA assay development, method transfer, validation
- Exploratory sample analysis using kits from any vendor across a wide variety of platforms
- Luminex, ELISA, RIA, MSD, GyroLab, Flow Cytometry, Singulex
- Full flow cytometry capabilities to support GxP studies
- Immunophenotyping, pharmacodynamics
- Cytokine release assays

Pharmacokinetics

- Large molecule specialists, capacity for large volume sample analysis
- Clinical and Pre-clinical PK studies
  - Exploratory / GxP
- Latest platforms including GyroLab and Singulex

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For more information about Eurofins Bioanalytical Services team please contact

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