Battelle Life Sciences Research

ASSAY DEVELOPMENT AND VALIDATION

The answers you need are all right here.

- Biomarker Sample Analysis
- Vaccine Efficacy and Maturation from Testing to FDA Approval
- *In vitro* and *In vivo* Services
- CDC Select Agent/USDA Approved BSL-3+ Containment Laboratories
- Chemical Warfare Agent Containment and Highly Toxic Materials Laboratories
- Good Laboratory Practices (GLP) Compliant

BATTELLE

Comprehensive service with unmatched expertise

When it comes to *in vitro* assays, all the expertise you need is right here. Battelle offers comprehensive assay development and validation services for GLP drug development, pre-clinical and clinical research, diagnostics, vaccine efficacy, disease surveillance and more.

We go beyond standardized methods to solve some of today's most difficult *in vitro* assay challenges. That's why clients like the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD) and many commercial customers trust Battelle to meet their assay development and validation needs.

We can:

- Develop and optimize novel assays that meet stringent FDA Bioanalytical Method Validation guidelines for a wide range of analytes and matrices
- Validate assays for Good Laboratory Practices (GLP) pre-clinical investigational new drug enabling studies and clinical trials
- Conduct technology transfer and validation studies for novel applications of commercially available assays
- Conduct commercial diagnostic platform testing and evaluation

Our Approach

At Battelle, everything we do is built around your needs and requirements. We are the world's largest nonprofit research organization, with access to an unmatched range of subject matter expertise to solve complex analytical challenges. At the same time, our *in vitro* team is dedicated to offering personalized, responsive service tailored for each individual client. We take the time to understand your requirements and develop a program that will meet your goals in the most effective, efficient and economical way possible.
We offer:

- A flexible, adaptable approach to meet challenges as they arise and ensure that your assay fully meets your requirements
- Deep experience with a wide range of assay types, analytes and biomarkers
- A GLP-compliant quality system and proven ability to meet FDA requirements for validation
- State-of-the-art facilities and equipment with biocontainment up to BSL-3 and chemical surety laboratories with the capacity for safe handling of highly toxic materials including chemical warfare nerve agents
- High-throughput capabilities for efficient sample analysis
- Integration of *in vitro* and *in vivo* capabilities for "one stop" pre-clinical study services

Our Capabilities

In Vitro Services

We develop and validate bioanalytical and anti-drug antibody assays for large and small biologics for use in sample analysis to support:

- PK/TK Analysis
- Vaccine Efficacy
- Immunogenicity
- ADME Analysis
- *In vivo* Services
- Immunotoxicity
- Dose Formulation and Analysis
- Immunophenotyping
- Stability Studies

Cell Culture Services

We develop and validate cell-based assays including primary and stem cell models to support cytotoxicity studies.

Quality Assurance

Battelle has been performing GLP studies since the inception of the regulations and recognizes the critical role of quality assurance in monitoring and maintaining a compliant GLP quality program.

- Independent Quality Assurance Unit
- GLP Compliance (21 CFR Part 58)
- Computer system and electronic records compliance (21 CFR Part 11)
- Organisation for Economic Cooperation and Development (OECD) and International Council for Harmonization (ICH) compliance
- Respected auditors with experience conducting and handling inspections by sponsors and federal agencies

Assessing Biodistribution of a Viral Therapeutic

Battelle developed and validated a quantitative, sensitive PCR assay to assess the biodistribution of a novel oncolytic viral therapeutic to treat glioblastoma, in support of an investigational new drug (IND) filing with the U.S. Food and Drug Administration (FDA). The assay was validated using a plasmid construct containing the target as reference and positive controls for target detection in numerous liquid and solid mouse tissues. The resulting data demonstrated the suitability of the assay to support *in-vivo* biodistribution studies. The assay was validated to detect as few as 5 target copies per microgram of DNA with 95% confidence and met other strict criteria for specificity, accuracy and precision. The validated assay ultimately determined that the therapeutic biodistribution was mainly located at the site of tumor injection in the brain.

Improving the Sensitivity of a Bioanalytical Assay for Nonclinical Testing

Getting products approved as INDs requires nonclinical testing using validated bioanalytical assays that are reliable, reproducible and suitable for the intended use. Battelle was contacted by a biotechnology company looking to find a better solution for a bioanalytical assay to quantify their drug product. The company had already validated a bioanalytical assay using a traditional plate-based enzyme-linked immunosorbent assay (ELISA), but it did not meet the sensitivity required for the nonclinical studies. Battelle customized an approach for improving the bioanalytical assay sensitivity by optimizing the drug-specific antibodies used in the assay and changing the platform from the traditional plate method to a bead-based platform known to improve sensitivity.

Our Facilities

One of Battelle's strengths is our ability to provide assay development and validation facilities, under our own scheduling control, for a wide variety of needs. Battelle can leverage facilities, skilled technical staff, and process/analytical development and validation experience. Our facilities are composed of biological and chemistry centers for GLP-compliant studies and CDC Select Agent/USDA-approved BSL-3+ containment laboratories. We have a comprehensive and flexible portfolio of technology platforms for a wide range of analytical needs.

Capabilities	Facilities	Specialty Facilities and Equipment
• Assay development and validation in accordance with FDA, OECD, and ICH guidelines • CDC/USDA select agent-registered facilities • Immunology and response characterization • Proteomics and genomics • Immunology for evaluation of vaccine-induced humoral and cell-mediated immune responses • Bioanalytical chemistry for comprehensive drug and biologics analysis, including assay development and validation	• >22,000 square feet of BSL-3 space • >70,000 square feet of BSL-2 space • 77,000 square feet of chemical research laboratories • 293,000 square feet of biological research laboratories	• qRT-PCR machines (ABI Quant Studio Dx and 7500 Dx) • Agilent Bioanalyzer • Multiplex platforms (Luminex 200, MAGPIX and Meso Scale Discovery Sector Imager) • Nanodrop spectrophotometer • Zeiss fluorescent and inverted microscopes • BSL-2 and BSL-3+ laboratories: Chemical surety laboratories for safe handling of highly toxic materials including chemical warfare agents • High-end immunology, biomarker and flow cytometry laboratories • Tissue and cell biology laboratories • Flow cytometry • LC-MS/MS (ABI Sciex 5500 and 6500 QTrap) • LC, GC and GC-MS (Agilent) • Microelectrode array analysis (Axion Maestro) • High content imaging (GE IN Cell)

What can we solve for you today?

solutions@battelle.org | www.battelle.org

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries.

800.201.2011 | solutions@battelle.org | www.battelle.org

BATTELLE
It can be done

ID 565 01/17