Vimta

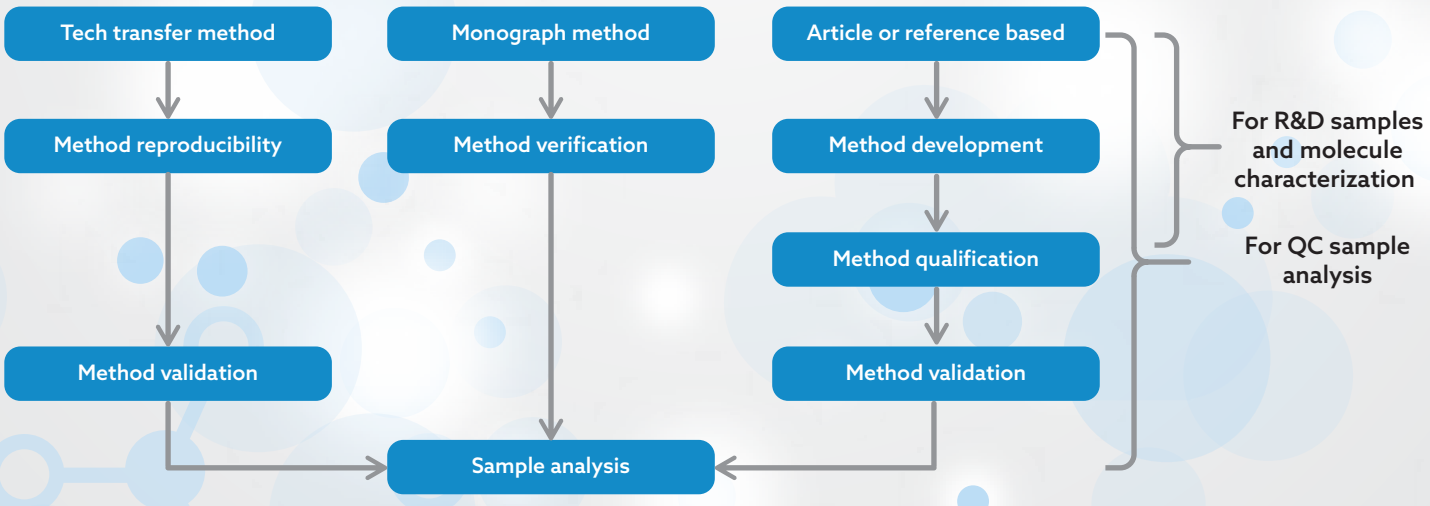
Driven by Quality. Inspired by Science.

BIOASSAYS

Bioassays are critical in evaluating potency of various biomolecules and peptides at each stage of drug discovery, development and manufacturing. The ability of bioassays should be reliable and reproducible to reflect the relevant biologic activities of the biomolecules; however, developing such assays is increasingly challenging as biologic drugs are recombinant produced with high end complexity and/or multiple mechanisms of action. Companies are continuously challenged with developing assays that are both functionally relevant, and which reflect these complex mechanisms of action. Bioassays that support lot release, stability, comparability and extended characterization, have the additional requirements to be robust, precise and, in the case of potency assays, suitable for use in a GMP-compliant environment.

Vimta develops and validates bioassays in accordance to applicable guidelines:ICH Q6B, USP Chapter 1032, 1033 and statistical analysis of biological assays by USP 1034 and E.P.5.3.

Work flow at Vimta



Areas of expertise

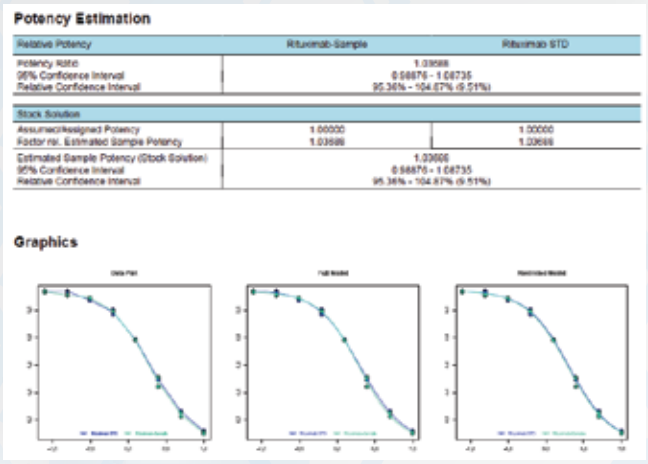
- **Secondary messenger assays:** Relative potency estimation by drug induced intracellular cAMP
- **Cytokine release assay:** *In vitro* drug induced cytokine release assay, based on Specific Recognition of Glatiramer Acetate by Mouse T Cells
- **Proliferation assay:** *In vitro* potency assay for various growth factors
- **CDC and ADCC assays:** *In vitro* potency assay for monoclonal antibody
- **Clotting factor assays:** Potency assay for anti-factor IIa and Xa assays for Low Molecular Weight Heparin and Heparin
- **CPER assays:** Relative potency estimation for anti-viral products by CPER assays
- **Neutralization assays:** Anti-drug antibody confirmation test by drug efficacy neutralization
- **Immunoassays:** ELISA based immunorecognition assays for different biosimilars

Additional Bioanalytical services

- *In vivo* Bioassay
- Preclinical Toxicokinetic studies and Immunogenicity studies
- Residual Host Cell Impurities (Protein and DNA)
- Cytokine profiling by Luminex platform
- Immuno-diffusion
- Data analysis using Statistical tool PLA3.0 (CFR 21, Part 11 compliant)

Representative Data Generated In-house

Rituximab CDC assay



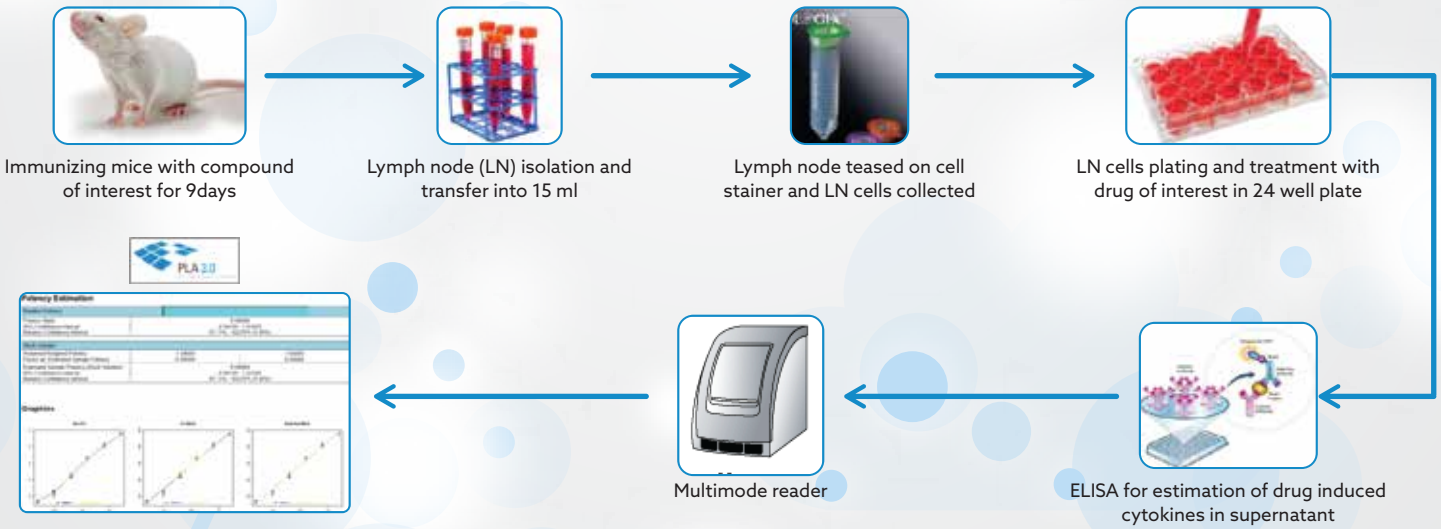
Potency estimation using Statistical tool
(PLA 3.0).

S/N ratio >10

Good assay reproducibility

Reference: *USP summary validation report*

In vitro drug induced cytokine release assay, based on Specific Recognition of Glatiramer Acetate by Mouse T Cells



Method verification data for rhPTH (Recombinant Human Parathyroid Hormone)

Parameter	Acceptance Criteria	Results
Specificity	Should be specific to analyte	Specific to analyte
Precision (Repeatability)	<20%	4.6 %
Precision (Intermediate)	<20%	5.4 %
Accuracy	85-115%	98.6-102%
Robustness	<20%	15%