Skills and Services

● Analytical Development

HPLC

Cation and Anion Exchange Chromatography

Size Exclusion Chromatography

Surfactant Analysis with Fluorescence Detection

Capillary Electrophoresis

SDS-CGE

cIEF

Enzyme Assays

Free drug in human serum

Drug activity assays

Biological Assays

Drug Potency

Neutralizing Antibody

● Method/Instrument Validation

Prepared method qualification/validation protocols and reports

Prepared instrument qualification protocols and reports

Reviewed method and instrument validation packages for compliance

Prepared gap analyses with remediation plans

● Formulation Development (liquid dosage form for biologics)

Excipient Selection

pH and Solubility Optimum

Design of Experiments

● Process Validation

Sampling plans

Analytical methods validation/compliance

Acceptance criteria review and justifications

● Interim Management

Quality Control Manager

Analytical Development Director

Formulation Development Manager

● CRO Management

PK, Anti-Drug Antibodies, and Neutralizing Antibody Assays

Manage interface for three clients

Manage interface at three CROs

cGMP and GLP operations

● Regulatory Submissions

CMC sections for several INDs

CTD formatted CMC sections for BLA