

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