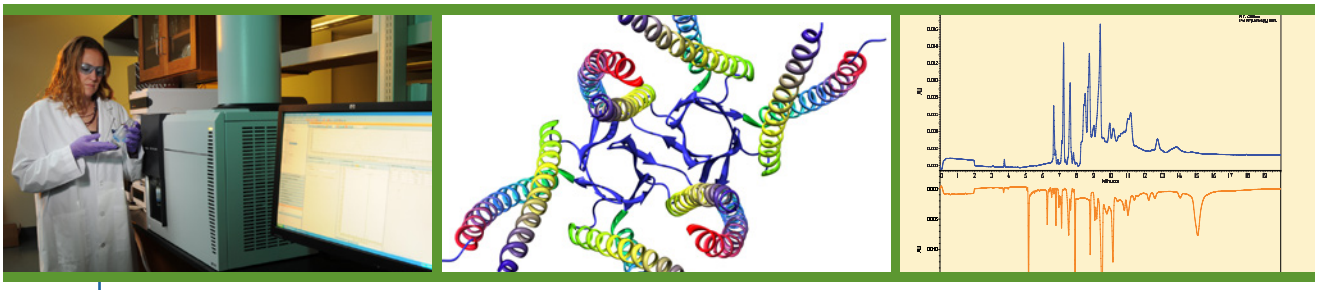
Biotherapeutics and Biologics Services



RTI International has nearly three decades of experience in pharmaceutical analysis and characterization in support of Investigational New Drug submissions and clinical trials. Clients include a number of institutes within the National Institutes of Health and commercial sponsors. Staff are skilled at troubleshooting complex problems and working with difficult test articles and products such as vaccines and other biologics.

Drug Discovery and Development Services

- Physicochemical and biophysical characterization
- Impurity identification
- Method development and validation
- Lot release and stability testing
- CMC support for drug substance and drug product
- Toxicology
- ADME
- Bioanalytical support
- QC and distribution for clinical supplies
- Clinical trials management

Biotherapeutic Capabilities

- Separation and identification of peptides, proteins, oligonucleotides, and adjuvants using HPLC, UPLC, LC-MS
- Analysis of peptides, proteins, and oligonucleotides by charge or pI (isoelectric point) using cIEF and IEX
- Analysis of peptides, proteins, and oligonucleotides by size using SEC, CGE, SDS-CGE
- Qualitative and quantitative analysis of toxic metals by ICP-MS, OES
- Amino acid analysis by GC-MS or GC-MS/MS
- Primary structure analysis by bottom-up or top-down MS/MS methods
- Detailed sequence characterization, including sites of PTM and PEGylation
- Glycan analysis by HILIC-FLR and LC-MS
- Peptide mapping by CE and HPLC/UPLC with UV, MS, fluorescence
- Secondary/tertiary structural analysis by FTIR, CD, fluorescence
- Aggregation/stability studies by SEC with MALS/RI/UV
- Higher-order structure analysis by ion-mobility MS
- Structural analysis of protein or lipid components by NMR
- Stability studies using controlled, FDA/ICH–compliant stability chambers to accommodate long-term, intermediate, and accelerated storage along with special conditions

Instrumentation

LC/MS systems (MS/MS, high-resolution, ion mobility, ETD)

- Waters Synapt G2 HDMS Q-TOF with ion mobility
- Thermo Scientific LTQ Orbitrap Velos with ETD
- Agilent 6410 triple quadrupole LC/MS/MS
- Thermo Scientific LTQ, LTQ ETD, and LTQ Velos LC/MSn
- Jeol AccuTOF DART-TOF
- AB Sciex 4700 MALDI-TOF/TOF
- *Agilent 6230 high-resolution MS-TOF with 1290 UHPLC
- *AB Sciex API 4000 and 5000 triple quadrupole LC/MS/MS
- *AB Sciex API 4000 Q-TRAP hybrid triple quadrupole/linear ion trap UPLC/MS/MS

Chromatography Systems

- *Waters Acquity UPLC with PDA and FLR
- *Waters HPLC with PDA, Wyatt miniDAWN TREOS, and Wyatt Optilab T-rEX
- *Additional UPLC and HPLC with PDA, UV, ELSD
- *Dionex ion chromatography with conductivity and UV
- *Beckman Coulter CE with PDA and variable λ UV (CZE, cIEF, CGE, CE-SDS)
- *Capillary GC with headspace, FID, NPD, TCD, ECD, MS, and triple quadrupole MS/MS

Spectroscopy

- Beckman Coulter DU800 UV/vis spectrophotometer
- *Jasco J-815 CD/fluorescence spectrophotometer
- *ThermoFisher Nicolet 6700 FT-IR with Proteus protein analysis software

*ICP spectrometers: emission, MS, high-resolution MS

*Karl Fischer titration	*NMR (multi-nuclear, 2D)
*Particle size (laser, sieve)	*Environmental chambers
Microscopy (SEM, TEM, AFM)	X-ray diffraction (XRD)

*GLP/cGMP validated systems

Facilities

RTI's secure, access-controlled laboratory facilities are located on our 180-acre campus in Research Triangle Park, NC. These facilities contain a 1,200-square foot drug storage vault for controlled and cGMP materials, a biorepository (–80 °C, liquid N_2, and –180 °C storage), NMR facility and proteomics facility, DMPK and pharmacology laboratories, and cGMP stability study facilities.

Quality Systems at RTI

RTI has an independent Quality Assurance Unit (QAU), which is part of the Office of Regulatory and Quality Assurance. The QAU supports projects that are subject to quality regulations and guidelines (e.g., cGMP, GLP nonclinical studies, and U.S. Environmental Protection Agency Quality System Regulations). RTI QAU activities include releasing drug products, reviewing batch production records, and hosting sponsor and regulatory site visits.

More Information

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