

# Analytical Testing Services for Biopharmaceutical Product Development

Trust our analytical development and testing experts to rapidly advance your biologic for the greatest chance of success. Led by our broad experience and collaborative approach, we are committed to finding the shortest, most efficient path to success for our customers. Cambrex has extensive experience in Drug Metabolism and Pharmacokinetic (DMPK), Bioanalytical and Biopharmaceutical Analyses.

The Biopharmaceutical Analyses scope supports GMP and non-GMP method development, validation, and routine analysis for Drug Substance, Drug Product and Intermediates.

- Method development, Optimization, Verification, Validation and Transfers
- Release and Stability testing and Storage
- Material characterization
- Structural chemistry-impurity isolation and characterization

## Characterization

- Protein Structure
- PTMs/Degradants
- Glycosylation
- Peptide mapping and Mass spectrometry: NMR, Q-TOF, LC-MS/MS, QQQ, UPLC-MS, GC-MS, LC-UV, FLD, CAD, ELSD, RID, NGS

## Biopharmaceutical APIs

- Bacteriophage and mammalian viral titer assays; Infectious titer
- Antibodies
- Enzymes; Peptides; Lipids; Carbohydrates
- Routine sample analysis-tissues, microsomes/exosomes, proteins, blood, plasma

## Identification

- Purity (SDS-PAGE, UV-VIS, RP-HPLC, UPLC, SEC-HPLC, CE-PDA/FLD, GPC-MALS/RI/UV)
- Assay (Western Blot, ELISA)
- Potency/Binding
- NGS

Jake Dam  
Sr. Associate Scientist



## Biopharmaceutical Growth

- Facility expansion at Durham, NC site completed in 2021
- Range of new instruments, including particle analysis, imaging, qPCR, fluorescent/absorbance plate reader, immunoblotting, mass spectrometry, capillary electrophoresis (CE-PDA and FLD), GPC-MALS/SEC/RI and other compendial testing apparatus.
- New capabilities are applicable to a broad variety of biopharmaceuticals, including bacteriophage and mammalian virus infectious titer assays for intermediates, drug substances, and final drug products.

## About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

## Quality

- Residual Host cell DNA
- Residual Host cell protein
  - Partner with Cygnus for coverage analysis
  - Antibody Affinity Extraction (AAE)
- Particulate analysis USP <787>, <788> (HIAC)
- Osmolality, pH, Conductivity
- Ion analysis
- Process impurities (qNMR; LC-QQQ; LC-qTOF; LC-MS; LC-UV, FLD, CAD, ELSD, RID; GC-FID/MSD (residual solvents and volatiles))
- Impurities analysis by ELISA or Plate based methods: Gentamycin, FBS, Glycerol, Endotoxin A, Exotoxin, Benzonase, DNase, and RNase

## Sample Types

Viruses (Deactivated and Live)

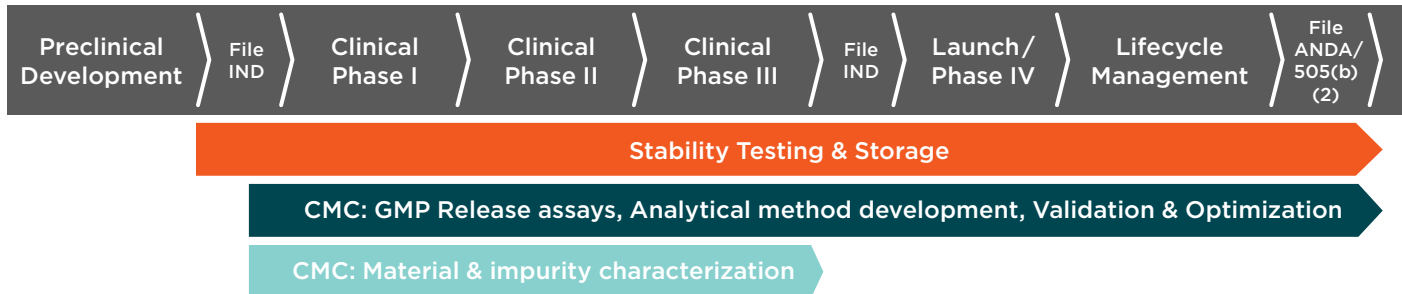
- Bacteriophage
- Mammalian

Large Molecules

- RNA and DNA
- Proteins
  - Antibodies
  - Enzymes
  - Peptides
- Lipids
- Carbohydrates

## Safety

- Microbiology
- Endotoxin (LAL)
- Bioburden
- Extractable & Leachables



## Instrumentation

### qPCR

- Residual DNA
- DNA copy number
- Quant studio 5 hardware and software

### Next Generation Sequencing

- Illumina MiSeq NGS

### Other Instrumentation/Capabilities

- Automated DNA/RNA purification (Kingfisher Flex)
- HIAC particle counter (PharmSpec)
- Particle Size Distribution and Enumeration (Malvern NS300)
- Viral titer assays (PFU/mL)
- ICH stability storage and photostability

- UPLC-qTOF, UPLC-QQQ, UPLC-UV/FLD, SEC-RID, CE-PDA/FLD, GPC-MALS/RI/UV
- NMR spectroscopy
- Ion Chromatography (ICS-5000+)

### Imaging Systems

- BioRad ChemiDoc MP (Epi-fluorescent capable)
  - Image and count plaques and colonies
  - SDS-Page
  - Western blots
  - Titer assays (bacterial and mammalian cell based)
  - Cell based expression assays

### Plate Readers (UV and FLD)

- SpectraMax M2 with Pro 7 software
  - Total DNA, RNA, Protein (CBQCA, BCA, Banford assay and more)
  - Enzyme kinetic assays
  - Endotoxin (chromogenic and turbidimetric)
  - ELISAs
  - Cell based biological assays

### Capability Highlights

- Extensive experience
- Custom development programs
- Expanded end-to-end service offerings