Pace
LIFE SCIENCES

BIOLOGICS DEVELOPMENT

ANALYTICAL SUPPORT FROM R&D THROUGH MANUFACTURING

PEOPLE ADVANCING SCIENCE

Pace® Life Sciences offers a full suite of integrated research, development and testing services for the biopharmaceutical industry. We provide chemistry and microbiology expertise for the development of novel therapies, including therapeutic proteins, peptides, enzymes, conjugates, oligonucleotides and gene therapies ensuring the quality of your marketed product. Utilizing state-of-the-art equipment, our team of experts will be an integral component in driving success of your biopharmaceutical development, commercialization and product release.

Technology transfer from our early-phase development laboratory in Boston, MA, to our Oakdale, MN state-of-the art GMP testing facilities enables our clients to seamlessly and confidently advance their programs through pre-clinical and clinical studies onto commercialization in a manner compliant with regulations and industry standards.

CHROMATOGRAPHY

- **UPLC/HPLC Separation:**
  - Reversed Phase, IP-RP, HIC, HILIC
  - Ion exchange (IEX)
  - Size-Exclusion Chromatography (SEC)
  - Field Flow Fractionation
- **UPLC/HPLC Detection:**
  - UV/FLR/ELSD
  - RI/MALS
  - MS (Triple Quad and High Res)
- **Applications:**
  - Disulfide Bonding
  - Glycosylation
  - Deamidation, Glycation, Oxidation
  - Payload-linkers, DAR, Free Drug for ADCs
  - Sequence Variants
  - Peptide Mapping
  - Amino Acid Composition Analysis
  - Carbohydrate Analysis (Released Glycans, Monosaccharides, Sialic Acid)
  - Soluble Aggregates/Oligomeric State
  - Surfactants (PS20, PS80, Poloxamer)
  - Raw Material Protein Characterization

ELECTROPHORESIS

- **Capillary Electrophoresis:**
  - PA800 (CE-SDS/CZE/cIEF)
  - Maurice (icIEF, iCGE)
- **Lab Chip**
- **Fragment Analyzer**
- **Agarose / SDS-PAGE**

MASS SPECTROMETRY (MS)

- **UPLC /HPLC/with Triple Quad and Q-TOF**
  - Intact, Reduced, Deglycosylated Mass Determination
  - Sequencing (Peptide Mapping, Oligonucleotides)
  - Disulfide Bonding/Structural Elucidation
  - Glycosylation (N- and O-linked)
  - Carbohydrate Analysis (Released Glycans, Monosaccharides, Sialic Acid)
  - Chemical & Post-Translational Modifications
  - Identification of Process Impurities/Related Substances
  - Extractables & Leachables
  - HCP Identification
- **GC-MS with Headspace & FID for Residual Solvents & Impurities**

EXTENDED CHARACTERIZATION

- **Differential Scanning Calorimetry (DSC)**
- **Light Scattering (MALS, DLS)**
- **Circular Dichroism (CD)**
- **Differential Scanning Fluorimetry (DSF)**
- **Intrinsic Fluorescence**
- **FTIR**

LAB SCALE PROCESSING

- **Tangential Flow Filtration (TFF)**
- **Lyophilization**
- **Spray Drying**
- **Fast Protein Liquid Chromatography**

MOLECULAR BIOLOGY

- **PCR/qPCR**
- **RNA/DNA ID & Integrity Testing**

COMPATIBILITY TESTING

- **UP Processing Conditions/Equipment**
- **Filtration**
- **Container/Closure**
- **Silicone Oil, Stainless Steel, PTFE**
- **Infusion/Injection Delivery Devices**

CLEANING VERIFICATION – VALIDATION

- **API and Excipient Residuals**
- **Surfactants**
- **Flocculation/Antifoam Reagents**
- **Processing Reagents /Impurities**

PHYSICAL & COMPENDIAL TESTING (USP, EP, JP)

- **Extinction Coefficient Determination**
- **Protein Concentration by SoloVPE UV/Vis**
- **Sub-visible Particle Analysis:**
  - Dynamic Light Scattering (DLS)
  - HIAC particle counter
  - MFI – Micro-Flow Imaging
  - Zeta potential
- **Osmolarity (Freezing Point, Vapor Pressure)**
- **Functional Testing (PFS, Autoinjector, Cartridge)**
- **Viscosity**
- **Refractive Index**
- **Opalescence**
- **Solubility**
- **Container Closure Integrity**
- **Water Content by KF**
- **Trace Metals:**
  - ICP-OES
  - ICP-MS
  - AA

MICROBIOLOGY

- Sterility Testing
- Bacterial Endotoxin Testing
- Microbial Limits & Enumeration Testing
- Microbial Bioburden
- Antimicrobial & Disinfection Efficacy Testing

BINDING ASSAYS

- ELISA (96 & 384-well formats)
  - Colorimetric
  - Fluorescent/Luminescent
  - kD-Determining

GLP CAPABILITIES

- Drug Metabolism:
  - PK/PD & Biomarkers
  - Bioanalytical
- Cell-Based Bioassays & ELISA
- Immunogenicity:
  - Anti-drug Antibodies (ADA)
  - Neutralizing Antibodies

IMPURITY ASSAYS

- Host Cell Residual DNA Content
- Host Cell Protein (Generic & Specific)
- Residual Protein A, L, G

STABILITY STORAGE CAPABILITIES

- ICH & Customizable Chambers for:
  - Long-term Stability
  - Thermal Cycling
  - Freeze-thaw
  - In-use Stability
- Over 32,750 ft3 of Mapped & Qualified Chambers
- Photo-Stability, ICH Qb1 (Option 2)
- -80°C, Reach-In
- -20°C, Reach-In
- 5°C, Walk-In (ICH Refrigerated)
- 15°C/Ambient Humidity
- 25°C/35% RH
- 25°C/40% RH
- 25°C/60% RH, Walk-In
- 30°C/65% RH, Walk-In
- 40°C/75% RH, Walk-In

BOSTON, MA - CRO
- 22,500 FT²
- BIOLOGICS / OLIGO CHARACTERIZATION
- SOLID STATE AND API CHARACTERIZATION
- FORMULATION DEVELOPMENT
- TOX STUDY SUPPORT
- TEST ARTICLE PREPARATION

SALEM, NH - CDMO
- 30,000 FT²
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY / SOLUBILITY ENHANCEMENT
- ANALYTICAL DEVELOPMENT
- STERILE FILL-FINISH GMP MANUFACTURING

SAN DIEGO, CA – CDMO
- 5,500 FT²
- BIOLOGICS/PROTEINS/PEPTIDES
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY/LONG-ACTING FORMULATIONS
- STERILE FILL-FINISH GMP MANUFACTURING

ANN ARBOR, MI - CDMO
- 11,000 FT² LABORATORY
- 4,500 FT² GMP MANUFACTURING
- FORMULATION DEVELOPMENT
- ANALYTICAL DEVELOPMENT
- CLINICAL TRIAL SUPPLY MANUFACTURING

OAKDALE, MN – CRO (HEADQUARTERS)
- 50,000 FT² OF LABORATORY SPACE
- FDA-REGISTERED, DEA-REGISTERED
- CHEMISTRY / MICROBIOLOGY
- ICH STABILITY PROGRAMS
- SPECIALTY SERVICES

SAN GERMAN, PR - CRO
- 22,000 FT² OF LABORATORY SPACE
- FDA-REGISTERED, DEA-REGISTERED
- CHEMISTRY / MICROBIOLOGY
- ICH STABILITY PROGRAMS
- NEAR SHORE PROGRAMS

PHILADELPHIA, PA - CDMO
- 33,000 FT²
- FORMULATION DEVELOPMENT
- BIOAVAILABILITY / SOLUBILITY ENHANCEMENT
- ANALYTICAL DEVELOPMENT
- TABLET/CAPSULE GMP MANUFACTURING

SOUTH NEW BERLIN, NY - CRO
- 12,500 FT²
- FDA-REGISTERED
- CHEMISTRY
- ICH STABILITY PROGRAMS
- SPECIALTY SERVICES

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