

# BIOPHARMACEUTICALS

Analytical Chemistry | Analytical Development | Biopharma | Drug Delivery | Formulation | Manufacturing | Microbiology | Stability | Structural Chemistry

*Supporting start-ups to globally recognized biotech companies, Nitto Avecia Pharma Services has the track record and knowledge to provide comprehensive support for biomolecules at all phases.*

## FULL RANGE TESTING OF BIOMOLECULES

- Nucleic acids
- Oligonucleotides
- Peptides
- Natural and recombinant proteins
- Vaccines
- Monoclonal antibodies
- Carbohydrates

### COMPREHENSIVE BIOPHARMACEUTICAL SUPPORT

- Cell-based bioassays
- Western blot analysis
- Residual host cell protein
- Residual chemical analyses
- Residual DNA analysis ELISA
- Ninhydrin-positive substances

### PRODUCT CHARACTERIZATION EXPERTISE

- Identity by Amino Acid Analysis
- Protein content
- Peptide mapping by LC-MS
- Immunoassays
- Residual DNA analysis

### STATE-OF-THE-ART INSTRUMENTATION

- Fast Real-Time PCR: Applied Biosystems 7500 (QPCR)
- iCE3 Capillary: Protein Simple
- Fast Resolution Chromatography: Agilent 1290
- UPLC
- UHPLC
- LC/MS/MS
- LC/QTOF
- Agarose and cellulose acetate (flatbed chambers)

- Gel electrophoresis
- Capillary electrophoresis: CGE, CZE, cIEF, iCE
- Isoelectric focusing (IEF)
- Peptide mapping
- Protein content (strength)

- Purity/Potency
- Glycosylation analysis
- Functional analysis
- Process and product related impurity analysis

- HPLC: Waters, Agilent, Dionex (UV/Vis, PDA, RI, FL, CAD, ELSD, ES)
- Ion Chromatograph: Dionex
- Capillary electrophoresis: Beckman Proteomelab™ PA 8000
- SDS-Page (multiple formats)
- Immunoblot (multiple formats)
- Solo VPE

- Amino acid analysis
- HPLC (RP, SEC, HIC, IEX and mixed mode)
- Surfactant analysis
- Sugar analysis
- Glycan analysis

- Disulfide bonds: Thannhauser method
- Determination of extinction coefficients
- Stability studies

- Biotek Synergy
- HT Microplate Reader
- Biotek ELx405 Microplate Washer
- Ultra-centrifuge: Beckman
- UV transilluminator: BIO-RAD
- Gel DOC (UV/VIS): BIO-RAD
- Post column amino acid derivatization system: Pickering
- UV/VIS Spectrophotometer Agilent

**We invite you to visit us, audit our facilities, discover our insight, and learn more about our commitment to excellence. Visit [www.aveciapharma.com](http://www.aveciapharma.com) or call 877-445-6554.**

WWW.AVECIAPHARMA.COM

## PARTNER WITH NITTO AVECIA PHARMA SERVICES' BIOPHARMACEUTICAL DEVELOPMENT TEAM

From proof-of-concept to commercialization, depend on the scientific strength of Nitto Avecia Pharma Services. We offer reliable technical expertise, rigorous quality systems, state-of-the-art instrumentation, and thorough experience working with a range of biomolecules. What's more, we maintain focus on the leading edge of science, service, and seamless collaboration.

Nitto Avecia Pharma Services provides a broad range of services including but not limited to method transfer, method development and validation, drug substance/drug product release, stability, process and product related impurity analysis, leachable and contaminants, and investigational support for large molecules programs. Our customer service oriented project management team can help leverage your supply chain capabilities and improve project efficiencies to reduce time to market.

At Nitto Avecia Pharma Services our mission is to provide our clients with outsourcing solutions that make their drug development and commercialization priorities possible.

## OUR PROJECT MANAGEMENT TEAM SERVES YOU BETTER

Our signature service assigns you a single, dependable point of contact who guarantees all of the benefits of valued partnership such as strategic planning meetings, weekly reports, high quality data, and detailed post-project follow-up.

We invite you to visit us, audit our facilities, discover our insight, and learn more about our commitment to excellence. Visit [www.aveciapharma.com](http://www.aveciapharma.com) or call 877-445-6554.

### AVECIA PHARMA'S COMPLETE PACKAGE OF SERVICES INCLUDE

#### PARENTERAL MANUFACTURING

- Process Validation
- Lyophilization
- Scale-Up Studies

#### FORMULATION DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

#### ANALYTICAL CHEMISTRY

- USP/NF, EP, BP, JP, ACS, AOAC, and Client Methods

#### ANALYTICAL DEVELOPMENT

- Method Development and Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

#### BIOPHARMACEUTICALS

- Method Development and Validation
- Product Characterization and Quality Control Testing

#### DRUG DELIVERY TECHNOLOGIES

- Inhalation/Nasal Product Testing
- Transdermal Product Testing
- Device Evaluation

#### MICROBIOLOGY

- Quality Control Testing
- Research and Development

#### STABILITY STORAGE

- Standard ICH and Custom Storage Conditions

#### STRUCTURAL CHEMISTRY

- Extractable/Leachables
- Reference Standard Characterization
- Structural Elucidation of Unknowns
- Investigational Studies

#### API OLIGO MANUFACTURING (VIA NITTO DENKO AVECIA)

- Pre-Clinical, Clinical and Commercial Supply
- Small Scale [mg] to Large Scale [multi kg]

[WWW.AVECIAPHARMA.COM](http://WWW.AVECIAPHARMA.COM)

