Nitto Avecia Pharma Services

biopharmaceuticals

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**.

COMPREHENSIVE BIOPHARMACEUTICAL SUPPORT

- Cell-based bioassays
- Western blot analysis
- Residual host cell protein
- Residual chemical analyses
- Residual DNA analysis
- Binding assay (ELISA, HTRF, AlphaLISA)
- Ninhydrin-positive substances
- Gel electrophoresis (SDS-Page)
- Capillary electrophoresis: CGE, CZE, cIEF, iCE
- Isoelectric focusing (IEF)
- Peptide mapping
- Protein content (strength)
- Amino acid analysis
- HPLC (RP, SEC, HIC, IEX and mixed mode)
- Surfactant analysis
- Sugar analysis
- Glycan analysis

PRODUCT CHARACTERIZATION EXPERTISE

- Identity by Amino Acid Analysis
- Protein content
- Peptide mapping
- Immunoassays
- Residual DNA analysis
- Purity/Potency
- Glycosylation analysis
- Functional analysis
- Process and product related impurity analysis
- Disulfide bonds: Thannhauser method
- Determination of extinction coefficients
- Stability studies

STATE-OF-THE-ART INSTRUMENTATION

- Fast Real-Time PCR: Applied Biosystems 7500 (QPCR)
- iCE3 Capillary: Protein Simple
- Fast Resolution Chromatography
- UPLC
- UHPLC
- LC/MS/MS
- LC/QTOF
- Agarose and cellulose acetate (flatbed chambers)
- HPLC (UV/Vis, PDA, RI, FL, CAD, ELSD, ES, DAD, MALS)
- IC
- CE
- SDS-Page (multiple formats)
- Immunoblot (multiple formats)
- Solo VPE
- Tecan M1000 Pro Plate Reader
- MD SpectraMax M5 and L Plate readers
- Biotek ELx405 Microplate Washers
- Ultra-centrifuge
- UV transilluminator
- Gel DOC (UV/VIS): BIO-RAD
- Post column amino acid derivatization system: Pickering
- UV/VIS Spectrophometer

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PARTNER WITH NITTO AVECIA PHARMA SERVICES' BIOPHARMACEUTICAL 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 including nucleic acids, natural and recombinant proteins, monoclonal antibodies, peptides, carbohydrates, vaccines, as well as oligonucleotides. 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 or call 877-445-6554.

AVECIA PHARMA'S COMPLETE PACKAGE OF SERVICES

PARENTERAL MANUFACTURING

- CGMP Fill/Finish
- Aseptic Filling/Lyo
- Pre-Clinical through Commercial

FORMULATION/PROCESS DEVELOPMENT

- Formulation Characterization
- Container/Closure Compatibility Studies

ANALYTICAL CHEMISTRY

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

ANALYTICAL DEVELOPMENT

- Phase Appropriate Validation
- Process Validation Support
- Cleaning Validation and Verification
- Comparator Studies and Reference Standard Qualification

BIOPHARMACEUTICALS

- Cell-Based Bioassays
- Phase Appropriate Validation
- Product Characterization and QC 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

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

OLIGO MANUFACTURING (API) VIA NITTO DENKO AVECIA

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