



Avecia Pharma is a **CGMP contract development and manufacturing organization** offering parenteral manufacturing services from pre-clinical to commercial. With a **state-of-the-art facility, experienced staff, and robust quality infrastructure**, Avecia Pharma delivers **client-centric solutions** in a timely manner.

## COMPLETE PACKAGE OF SERVICES

- Toxicology, clinical trial and commercial manufacturing
- CGMP fill/finish
- Aseptic filling/lyo (0.3-100mL vials)
- Custom hand fills
- Process assessment and validation
- Lyophilization
- Terminal sterilization
- Tangential flow filtration
- Microfluidization
- Inert gas purge/overlay
- Documentation preparation (including CMC submission)
- Formulation/product development
- Analytical and Biopharmaceutical development
- CMC analytical testing
- Stability
- Visual inspection, labeling and packaging

## LEADING-EDGE FACILITY

- Three manufacturing suites
- Single use components
- Passive RABS filling line
- Dedicated air-handling in each suite
- No seasonal uncertainties
- Formulation lab and pilot suite
- Flexible and scalable

## EXPERTISE IN MULTIPLE DOSAGE FORMS

- Liquid
- Lyophilized
- Emulsions/Suspensions
- Liposome

## STATE-OF-THE-ART EQUIPMENT

- Filling Machine with 100% vial weight check capability
- Water for Injection (WFI) generation and storage
- Steam sterilizer
- Pure Steam generation and distribution
- Vial washer
- Lyophilizer/Freeze dryer
- Depyrogenation oven

## PARTNER WITH NITTO AVECIA PHARMA SERVICES' PARENTERAL MANUFACTURING TEAM

Nitto Avecia Pharma Services has a state-of-the-art facility capable of handling an array of unique products. The facility is complemented by a well-trained and knowledgeable staff with a proven track record of developing processes for some of the most sensitive and complex products. Nitto Avecia Pharma Services' manufacturing department produces batches at the highest quality as the team works hand-in-hand with the Formulation and Quality teams as well as other resources to develop the documentation, process flow, material list and equipment recipes needed in the successful transfer from a lab environment into manufacturing.

Nitto Avecia Pharma Services has received licenses for Pharmaceutical Drug and Device Manufacturing by the California Food and Drug Branch in addition to receiving an ISO 13485 certificate for contract manufacturing and formulation of pharmaceutical, biopharmaceutical, and medical device products.

## 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

### 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]