
partner with AVECIA PHARMA
Nitto
Avecia
Pharma Services
A CGMP CONTRACT DEVELOPMENT & MANUFACTURING ORGANIZATION

# contract development & MANUFACTURING ORGANIZATION

Nitto Avecia Pharma Services is a FDA audited, **contract development and manufacturing organization** (CDMO) supporting the pharmaceutical and biopharmaceutical industries with CGMP parenteral manufacturing and product development services from early phase through post-market life cycle management.

## Avecia Pharma's comprehensive package of CGMP services include:

- Formulation/Process Development
- Parenteral Manufacturing
- Lyophilization
- Regulatory Filing Support

CMC Analytical Services:

- Analytical Chemistry and Development
- Biopharmaceutical Development
- Structural Chemistry
- Microbiology
- Stability
- Process and Analytical Development, Preclinical and Oligo Manufacturing via parent company, Nitto Avecia

# product/process
## DEVELOPMENT

Avecia Pharma's in-depth scientific expertise covers a diverse range of products, as well as a wide variety of dosage forms and routes of delivery. Avecia Pharma's pre-formulation studies are designed with an anticipated formulation strategy, route of administration, and ultimate formulation configuration in mind. Our formulation experts unite a thorough understanding of your needs along with the data on the physicochemical properties of the compounds to ensure the delivery of a stable and robust product.

## Pre-Formulation Expertise

- Solubility/Solubilization
- LogD/LogP
- Polymorph Screening by DSC
- Excipient Compatibility
- Stability Evaluation
- Effect of pH
- Arrhenius Kinetics

## Disciplined Technology Transfer

- Batch Record Development
- Method Transfer, Development and Validation
- Critical Process Parameters Evaluations
- Scale Up from Lab to Manufacturing

## Comprehensive Formulation of Sterile Injectable Products

- Parenteral Dosage Forms (Liquid/Lyo)
- Emulsions/Suspensions, Semi-Solids
- Ophthalmics
- Liposome and Microsphere Encapsulation
- Lyo Cycle Development
- Admixture and Container/ Closure Compatibility Studies
- Toxicology Supply Dosing Solutions
- Pilot Batch Production and Stability Analysis
- Development Report in Support of CMC

# CGMP manufacturing

Avecia Pharma's experienced staff is committed to first-time-right and on-time-in-full manufacturing support services customized to client needs. Avecia Pharma's manufacturing department works hand-in-hand with the formulation, analytical and quality staff, to ensure an optimal transfer from a laboratory environment into a GMP manufacturing setting. Avecia Pharma's state-of-the-art facility has been inspected by the FDA and is ISO 13485 certified.

Additionally, Avecia Pharma's parent company, Nitto Avecia, maintains a world-class reputation as a leader in oligonucleotide development and API production with over 20 years industry experience.

## Supporting a Broad Range of Dosage Forms

- Liquid
- Lyophilized
- Emulsions
- Suspensions
- Liposome

## Single-Source Comprehensive Package of Services

- Process Assessment and Validation
- Toxicology, Clinical Trial and Commercial Manufacturing
- Full Analytical and Biological Testing
- CMC Section Preparation
- Full Range of Documentation Preparation

## State-of-the-Art Equipment

- Filling Machine with 100% Vial Weight Check Capability
- Lyophilizer/Freeze Dryer
- Water for Injection (WFI) Generation and Storage
- Depyrogenation Oven
- Pure Steam Generation and Distribution

With nearly 30 years of providing CGMP CMC analytical services to the pharmaceutical, biotechnology and medical device industries, Avecia Pharma has a proven track record of providing testing and phase-appropriate validation services for nearly all dosage forms from pre-clinical through post-mark life cycle management (including potent and controlled substances).

Avecia Pharma's expertise in servicing small to large molecule programs is complemented by our parent company Nitto Avecia's world renowned oligonucleotide API manufacturing and analytical service offering.

# CGMP support services

## Analytical Chemistry and Microbiology

- Testing of Final Product, In-Process, or Raw Materials
- USP/NF, EP, BP, JP, and CP Compendial Methods
- FCC, ACS, and AOAC Methods
- Client-Provided Methods

## Stability Storage and Testing

- Stability Studies
- Conditions in Accordance with ICH Guidelines
- Customized Storage Conditions

## Structural Chemistry

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

## Analytical Development (Small/Large Molecules/Oligonucleotides)

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

# contact us

Visit us, audit our facilities, discover our insight, and learn more about Avecia Pharma's commitment to excellence.

**Visit www.aveciapharma.com or call +1 949-951-4425.**


4

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