AmbioPharm, Inc.

ACCELERATING YOUR PEPTIDE TO MARKET

Peptide Contract Manufacturing & Development Services

Company Profile

ACCELERATING YOUR PEPTIDE TO MARKET

AmbioPharm (APi) is a global, full-service, contract development & manufacturing organization (CDMO), with a focus on large scale production of peptide new chemical entities. Our facilities include our headquarters and USA campus located in North Augusta, South Carolina, as well as our China campus located in Shanghai. Our services include process development and optimization, and custom peptide active pharmaceutical ingredient (API) synthesis. We are capable of manufacturing scales from grams to hundreds of kilograms to produce bulk peptides to custom specifications, using a wide range of skill-sets in both solid-phase, solution-phase, and hybrid chemistry approaches. We also perform organic conjugations to small molecules, proteins, toxoids, antifungals, KLH, and PEG. With a leadership team of peptide experts consisting of over 200 years of cumulative experience running pilot to commercial scale production, AmbioPharm is ready to support all of your peptide needs.

FDA Inspected Facilities

South Carolina, US Campus (Headquarters)

More than 200 employees staff the USA campus where a huge expansion project was completed in 2020, adding 55,000 square feet of space to the existing campus, totaling 82,000 square feet. The new buildings include suites to increase our capacity for purification, lyophilization, analytical QC testing, and stability and warehouse storage.

Shanghai, China Campus

In Shanghai, China, more than 300 employees on this campus are supporting our peptide manufacturing and testing operations. An impressive 300,000 square foot state-of-the-art manufacturing building in Shanghai has been constructed, growing our total campus footprint to 380,550 square feet. This expansion allows us to more than double our synthetic chemistry capacity, and support the growth from current and new customers in both small and large scale peptide production.

Our Offerings

GMP Peptides

AmbioPharm has multiple manufacturing suites capable of producing peptide APIs (Active Pharmaceutical Ingredients) at varying scales from gram to multi-kilogram (> 100 kg) scale. We use solid phase synthesis, solution phase synthesis, hybrid solid and solution phase synthesis, and native chemical ligation to produce peptide APIs. Through a partnership with CEM Inc., we can also perform GMP production using their patented, large-scale Liberty Pro™ microwave peptide synthesizers in our in North Augusta, SC facility.

Non-GMP Peptides

In addition to producing peptide products under GMP standards and requirements, we also provide process development and analytical services for non-GMP grade peptides. We have added automated peptide synthesizers to help speed our delivery of these non-GMP research peptides. These services are available for a broad range of customers, including universities, research organizations, biotechnology, pharmaceutical, cosmetic, agricultural, veterinary companies, and beyond.

Cosmetic Peptides

As an experienced USA-based peptide API CDMO, AmbioPharm has the scale and quality systems in place to meet the stringent needs of the cosmetic formulation industry. Both manufacturing sites have completed successful US FDA inspections. With experience in all types of peptide synthesis from solid phase to liquid phase or a hybrid of strategies, we are a high quality cosmetic peptide manufacturer and can synthesize the simplest to most complex cosmetic peptide ingredients.

Analytical Development & Validation

As your clinical or commercial programs require, AmbioPharm has established analytical teams with specific peptide expertise to support the development and phase appropriate validation of methods. These methods allow us to monitor the process for side reactions, meet required purity standards, and limit any residual impurities in the product. Controlling the final API to ensure the required quality attributes are achieved, while minimizing process and degradation impurities, affords formulators the maximum labeled drug shelf-life under proper storage conditions.

Sustainability & Green Chemistry

Sustainability and green peptide chemistry efforts are an important part of the AmbioPharm philosophy of corporate responsibility. As a part of this effort, AmbioPharm has undertaken several steps to reduce our environmental impact through green chemistry and sustainability practices. Through EcoVadis, we are determining where we currently stand and identifying how we can improve in the journey towards sustainability.

Our Capacity

Synthesis Capacity

Solid Phase Reactors
(standard or microwave*)
30mL*, 1 , 3, 5, 8*, 10, 15*, 30, 50, 80, 200, 500, 1000, & 3000L
(up to 100kg crude/batch)

Solution Phase Reactors
10, 20, 30, 50, 80, 100, 200, 300, 500, 1000, 1500, 2000, 3000, & 5000L
(up to 500kg crude/batch)

Hybrid Synthesis
(up to 500kg crude/batch)

Hydrogenation Reactors
500L, 1000L

Lyophilization Scale

Multiple Manifold Lyophilizers
(up to 1kg/batch and 50kg/year)

100, 200L Tray Lyophilizers
(up to 6kg/batch and 250kg/year)

400, 500L Tray Lyophilizers
(up to 8kg/batch and 400kg/year)

800, 1000L Tray Lyophilizers
(up to 15kg/batch and 800kg/year)

Purification Scale

Automated State-of-the-Art HPLC Large Scale Purification

Preparative HPLC columns:

ID: 5, 8, 15, 20 & 30cm HPLC Columns
(up to 7kg/batch and 100kg/year)

ID: 45cm HPLC Columns
(up to 15kg/batch and 120kg/year)

ID: 60cm HPLC Columns
(up to 28kg/batch and 200kg/year)

ID: 100cm HPLC Column
(up to 40kg/batch)

Quality & Compliance

AmbioPharm maintains the highest level of quality and compliance in its manufacturing plants in North Augusta, SC, and Shanghai, China. As one of the leading suppliers of peptide APIs worldwide, we provide rigid quality control, SOPs, training, and rigorous testing.

Key analytical testing which we offer includes: HPLC, UPLC, GC, LC-MS, IC, SEC, KF, Nitrogen Content, AAA, N-terminus Sequencer, Endotoxin, Bioburden, and more.

Process Development

- Initial synthesis usually in Fmoc-tBu format for SPPS
- Hybrid methods if scale or length warrant this approach
- Solution phase approach for large volumes projects
- Scouting synthesis run in a fully automated approach using conventional and microwave techniques
  - LC-MS analysis of crude product to determine efficiency of synthesis and where any failures appear
  - Resynthesis with special resins (e.g. TentaGel, Chem-matrix, CTC, etc.) with substitutional variation
  - Resynthesis also with special building blocks such as Psuedopro to minimize resin aggregation and eliminate tough deletion peptides (Gly, Ser, Pro, Thr)
  - Compile data and determine optimal choice of resin, substitution, building blocks and protecting groups
  - Initiate secondary steps such as cleavage, oxidation/folding, purification optimization
- Perform SPPS with the above selections and analyze crude product (automated)
- Begin scale-up with optimized synthesis protocol (usually manual)
- Finalize process optimization for cleavage & oxidation, cyclization etc.
- Develop preparative HPLC conditions for purification and analysis
- Scale-up HPLC purification
- Establish analytical RP-HPLC method for purity
- Establish salt-exchange and lyophilization conditions
- QC specifications: determine & report
- Technical document preparation

Non-GMP & Development Services

SUPPORTING LARGE SCALE & COMMERCIAL NEEDS

Key R&D Equipment & Capacity

- CEM Liberty Blue HT-12 Automated Microwave Peptide Synthesizers

  (up to 12 sequential peptides; rapid HTP work)
- Manual Glass Reactors (100, 150, 250, 500mL, & 1L)
- Multiple Large Scale 2, 5, 10, & 20L SPPS Reactors

Key R&D Analytical & Purification Equipment

- Shimadzu and Aglient Analytical HPLC Systems
- Small & Large Scale Purification Systems

  (multiple HPLC self-pack axial pressure columns: 5, 8, 15, & 20cm)
- SG100 Protein Purification Systems
- HPLC automated Semi-Prep HPLC Systems
- Production & Analytical MS & HPLC Systems

Why Us

Capability

Wide range of technologies, equipment, & scale.

Experience

Extensive peptide & GMP management expertise.

Capacity

Industry leading manufacturing capacity & continued expansion.

Globalization

Multiple manufacturing sites & global customer support.

Quality

Systems & infrastructure to support commercialization of peptides.

Speed

Resources & infrastructure to ensure shortened delivery times.

AmbioPharm, Inc.

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