CPC SCIENTIFIC INC.

PEPTIDE & OLIGO CRDMO

CGMP

ACCELERATING LARGE SCALE, LATE PHASE AND COMMERCIAL PRODUCTION

cpc scientific

Tides Partner. Concept to Commercial.

A SUBSIDIARY OF MEDTIDE INC. (HKEX: 3880.HK)

Table of Contents

Who We Are | What We Do

CPC Scientific Inc., a subsidiary of Medtide Inc. (HKEX: 3880.HK), is a pioneering CRDMO specializing in peptides. With a strong commitment to innovation, we provide comprehensive, full-life cycle services, supporting peptide-based therapeutics from early discovery and pre-clinical stages through clinical development and into commercial production.

We provide (i) CRO services, including peptide NCE discovery synthesis; (ii) CDMO services, including peptide chemistry, manufacturing, and controls development; and (iii) CMO services, including peptide NCE and generic drug commercial manufacturing. We have established global operations, with projects covering over 50 countries, including major markets in the United States, China, Japan, Europe, South Korea, and Australia. We also provide customers with peptide drug development, production, and CMC filing support services that meet regulatory requirements in major markets worldwide.*

*List of abbreviations on page 22

Seeking expert support?
Contact our team at:

+1 (408) 734-3800

Toll-Free:

+1 (877) 272-7241

Why Choose CPC Scientific?

Global Leader in Peptide CRDMO Services

- Ranked the third-largest peptide-focused CRDMO globally by 2023 sales revenue (Frost & Sullivan).
- Full-cycle service provider from **discovery to commercial manufacturing**.
- **Trusted by clients in over 50 countries**, including major markets like the US, China, Japan, Europe, South Korea, and Australia.

End-to-End Peptide Drug Development Support

- Comprehensive **CRO** and **CDMO** services, including peptide **NCE synthesis**, **CMC development**, and **commercial API** manufacturing.
- Specialized in peptides, providing API services that align with global regulatory standards.
- Seamless handover between stages reduces inefficiency, communication gaps, and supply chain risks.

Proven Quality and Regulatory Excellence

- Close to **25 years** of experience with a **99.95% success rate** in new molecule synthesis.
- Passed client and regulatory audits, including 5 FDA GMP inspections and others from **EMA, MFDS, TGA,** and **NMPA.**
- **ISO9001** and **ISO13485** certified; no product recalls due to quality issues.

Operational Efficiency Across the Full Lifecycle

- **Integrated project management** with shared master production plans ensures smooth process transfer.
- **Timely delivery:** 4–12 weeks for clinical stage, 8–12 weeks for commercial scale.
- Transparent client communication and feedback collection.

Cost Effectiveness Without Compromising Quality

- USA and China-based operations reduce freight and raw material costs.
- Strong supplier partnerships and bargaining power.
- **Advanced synthesis capabilities** optimize scale-up and production efficiency.

Company Timeline & History

Founded in 2001, our group is a globally recognized CRDMO specializing in peptides and oligonucleotides. Our integrated service model is designed to support partners through the most critical phases of drug development, with a particular focus on late-phase development, large-scale manufacturing, and commercial production. From initial discovery to full commercialization, we provide the expertise and infrastructure to accelerate your peptide and oligonucleotide programs to success.

Our global production facilities adhere strictly to CGMP standards as mandated by the world's leading regulatory authorities. We comply fully with the requirements of the US FDA, NMPA, EMA, TGA, and MFDS.

In June 2025, CPC Scientific's parent company, Medtide Inc., was officially listed on the main board of the Hong Kong Stock Exchange, marking a major milestone that reflects our continued growth and global impact.

2001

Founded by Shawn Lee, PhD

2004

1st Building

2005

ISO 9001:2015 Certification

2006

NMPA GMP Inspection

2009

ISO 13485 Certification

NMPA GMP Inspection

2010

2nd Building

2011

1st FDA Inspection

2012

2nd FDA Inspection

2014

3rd FDA Inspection
3rd Building

2016

4th FDA Inspection
4th Building

"We work directly with leaders in the biotechnology and pharmaceutical industries to help bring life-changing therapeutics and diagnostics to market."

2017

Triptorelin
Exenatide
DMFs

2018

EMA GMP inspection

2019

Korean
MFDS
Inspection

NMPA GMP
Inspection

2020

Cetrorelix DMF
Terlipressin

2022

Terlipressin CEP
Cetrorelix cGMP

API TGA Clearance
Leuprolide Acetate DMF-TFDA

New GMP Facility Construction Plans Begin
- 2026: Anticipated Completion of Facility

2023

NMPA GMP
Inspection

2024

TGA GMP
Inspection

5th FDA GMP
Inspection

2025

Medtide Inc., our parent company, listed on HKEX (3880.HK)

ISO 22716
Certification

Global Presence

We are a globally recognized and leading CRDMO specializing in synthetic peptide production. We work directly with leaders in the biotechnology and pharmaceutical industries to help bring life-changing therapeutics and diagnostics to market.

Rocklin, CA

3880 Atherton Rd
Rocklin, CA 95765

(US FACILITY)

Hangzhou, China

No. 69, 12 Street, Hangzhou,
Qiantang District

(MANUFACTURING SITE)

Hangzhou, China

Hangzhou Biopharma Town

(MANUFACTURING SITE)

Milpitas, CA

1900 McCarthy Blvd, Suite 204
Milpitas, CA 95035

(BUSINESS OFFICE)

New US Manufacturing Site

Rocklin, CA

Expanding our manufacturing footprint in North America enables CPC Scientific to continue to produce innovative peptide products, while providing additional capacity to specialty peptide APIs more rapidly.

Located at 3880 Atherton Rd, Rocklin, CA 95765, our new 41,000 sq ft facility will be utilized to manufacture clinical-grade to commercial-grade peptide products for increased manufacturing capacity, diversifying CPC Scientific's supply chain.

Peptide-based therapeutic candidates have been the fastest-growing sector among all the chemically-synthesized NCE for new drug development in recent years. For over two decades, CPC Scientific has been a reliable partner for our clients all over the world, including multinational pharmaceutical companies, biotech companies, and academic institutions, by providing value-added one-stop-shop development and manufacturing services to support their clinical trials. CPC Scientific has successfully supplied commercialized APIs to clients in the U.S., Europe, Australia, Japan, and China for their peptide-based drugs and medical devices. By expanding our GMP manufacturing footprint, CPC Scientific will enable our clients and partners to have multiple geographic options, ensuring a secure API supply chain.

GMP Manufacturing Overview

Fully Customizable PRE-QUALIFIED Workspaces

~25
Years of Global Business Operation

50+
Countries with Active or Completed Projects

300+
Preclinical, Phase 1 to 3, Generic, and Cosmetic Projects

13
Commercial GMP Projects

GMP Facility Overview

Our operations in China are conducted in our facility located at No. 69, Street 12 of Qiantang District, Hangzhou ("**Qiantang Site**"), situated on our CGMP campus of approximately 26,000 square meters. Our CGMP-compliant production facility in Hangzhou has a gross floor area (GFA) of over 15,000 square meters, with an annual peptide API production capacity of 1,000 kg and a per-batch peptide production capacity of 20 to 25 kg. Our production facilities adhere rigorously to CGMP as mandated by major regulatory authorities globally, including the US FDA, NMPA, EMA, TGA, and MFDS.

Our Qiantang Site contains 19 peptide synthetic production suites with reactor volumes ranging from 20 to 3000 liters*, and 16 purification suites with HPLC column sizes of up to 30 inches. More recently, the Qiantang Site has been adapted to enable the manufacturing of 1 to 17 kg of oligonucleotides per year.

Equipment Overview

Synthesis Equipment

- Large solid- and solution-phase peptide synthesis reactors (50L, 100L, 200L, 500L, 1000L, and 3000L*)
- Hybrid synthesis reactor

Purification Equipment

- Preparative HPLC systems with multiple flow rates
- Chromatography columns with various diameters (8", 12", 20", 30", 50"*)
- Fast Protein Liquid Chromatography (FPLC) systems
- Ultra Performance Liquid Chromatography (UPLC)
- Charged Aerosol Detector (CAD)
- Refractive Index (RI)
- Multi Angle Light Scattering (MALS) detection

Isolation Equipment

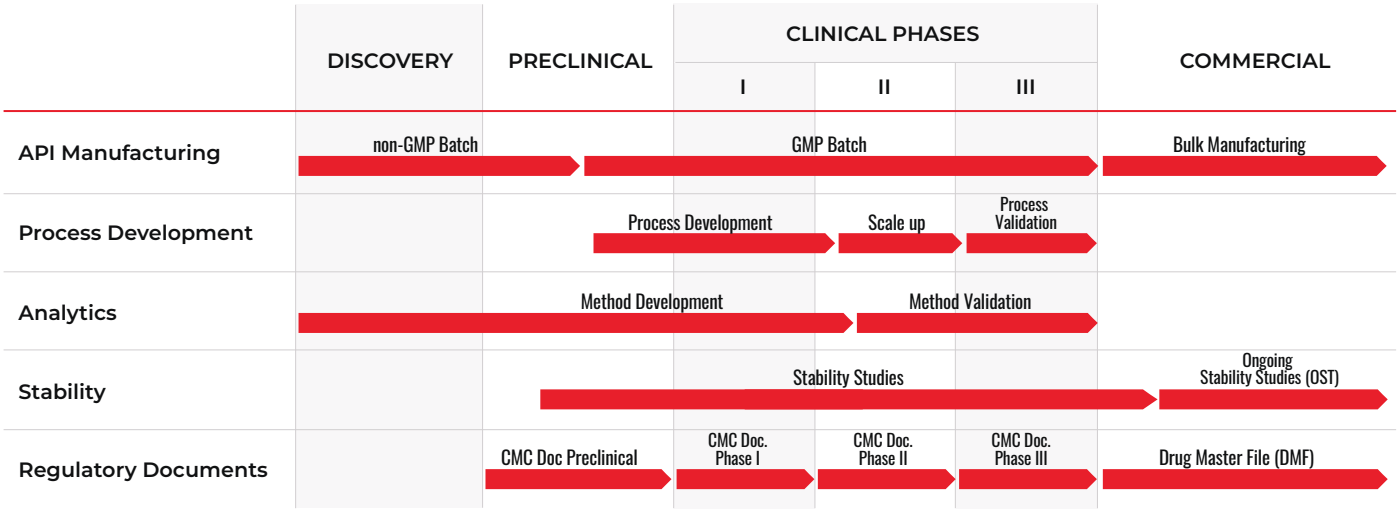
- Blenders and evaporators
- Manifold lyophilizers
- Tray lyophilizers (150L, 500L, and 1000L)

Equipment	Size	Quantity
Lyophilizer	20-1000L	12
Columns	8-30" 50"*	14 +1*
Reaction Vessels	50-1000L 3000L*	14 +1*

* New equipment scheduled for November 2025

Complete Life Cycle Support

NCE Development Process



Late Phase Experience Track Record

CGMP Projects by Region

Location	Stage
USA	Approved
Japan	Approved
European Union	Approved
UK	Approved
Switzerland	Approved
China	Approved
Australia	Approved
Russia & CIS	Approved

CPC Scientific's CGMP program strictly adheres to all CGMP guidelines including:

- Code of Federal Regulations Part 210/211 (21 CFR 210/211)
- ICH Q7 (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH Harmonized Tripartite Guideline Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7)

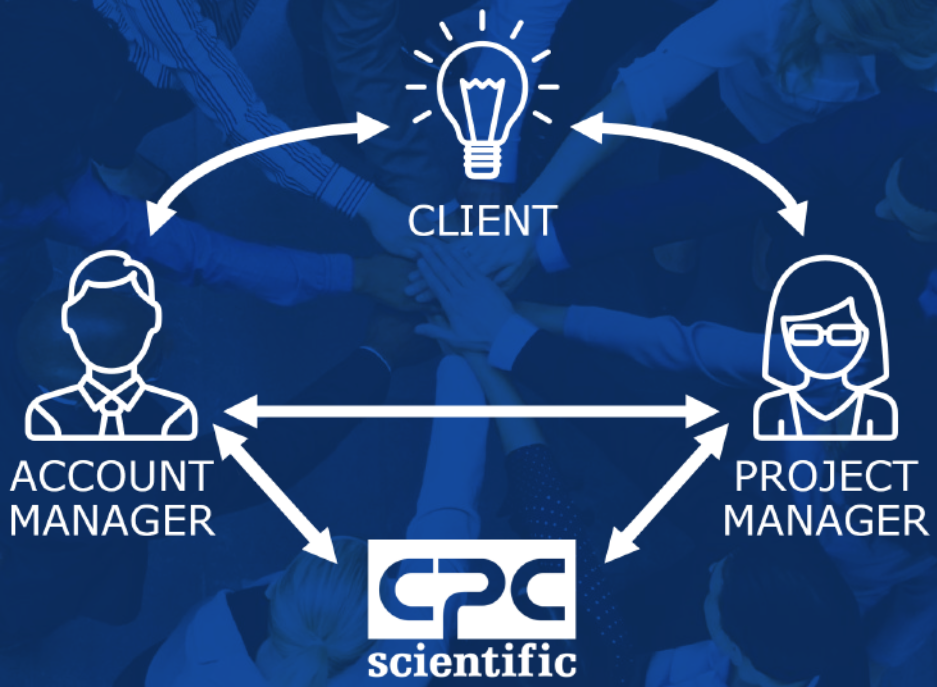
Comprehensive service in one, state-of-the-art, ISO 9001 Certified, and CGMP-compliant facility:

- GMP Manufacturing
- Stability Studies
- Analytical Services
- Scale up and Process Development
- Purification Services
- Peptide Vialing
- Regulatory Support

We adhere to **CGMP** standards and have successfully undergone **FDA inspections** 5 times

YOUR SUCCESS IS OUR SUCCESS.

Your dedicated contacts will know your project as well as you do, and they'll keep you in the loop.



Research & Development • Production
Regulatory Affairs • Quality Control • Quality Assurance
• Logistics & Environmental Health Services

Quality Program

Our CGMP specifications and testing procedures can include the following:

- Appearance: White to off-white solid
- Solubility: Clear solution at a predefined concentration
- Purity (HPLC, UPLC): 95-99% specific to phase of development
- Molecular Weight (MS)
- AAA (Amino Acid Analysis): ±10% of theoretical
- Peptide Content: ≥70%
- Counter-ion Content
- Moisture Content (Karl Fisher): ≤10%
- Residual Solvent Content: GC-MS
- Residual Trifluoroacetic Acid: ≤0.1%
- Bioburden: Report Aerobic and Spore Count, USP guidelines
- Endotoxin: Report LAL (Gel Clot), USP guidelines
- Elemental Analysis (ICP-MS): Report results for the following metals: Sb, As, Bi, Cd, Cu, Pb, Hg, Mo, Ag, Sn

Regulatory Support

- Phase-appropriate control systems consulting
- CMC compilation
- DMF compilation and submission
- Annual product reviews

Quality Assurance

- Batch record review
- Document management & control
- Deviations/Investigations
- CAPA follow up and tracking
- Complaint management
- Product release

Inspection & Certification History

2005
- ISO 9001 Certified

2006
- NMPA GMP Certification

2009
- ISO 13485 Certified
- NMPA GMP Certification

2011
- 1st FDA Inspection (on-site)

2012
- 2nd FDA Inspection (on-site)

2014
- 3rd FDA Inspection (on-site)

2016
- 4th FDA Inspection (on-site)

2018
- EMA GMP Inspection

2019
- NMPA GMP Certification
- MFDS GMP Inspection

2022
- NMPA Registration Inspection GMP Inspection

2023
- NMPA Registration Inspection GMP Inspection

2024
- TGA GMP Inspection
- 5th FDA Inspection (on-site)

2025
- ISO 22716 Certified

A dedicated, in-house Quality Department verifies full GMP compliance throughout production, testing, and documentation in accordance with even the most stringent FDA standards.

- In-process, release, and environmental control testing
- Standard release testing performed in-house
- Audited contract laboratories available for additional testing
- Method development and validation, formal method transfer
- Stability studies (ICH) and forced degradation

Generic API Development

CPC Scientific, a subsidiary of Medtide Inc. (3880.HK), offers generic peptides as APIs for diseases such as cancer, diabetes, and obesity. Our GMP manufacturing facilities ensure compliance with global regulatory standards through rigorous quality and EHS systems. We provide regulatory support, including DMF preparation, and serve as a one-stop solution for the drug development lifecycle, from discovery to commercial manufacturing. Our expertise in Generic (ANDA) and New Chemical Entity (NCE) development, including NDA submissions, offers efficient and reliable pathways for API regulatory approval, enabling seamless transitions from concept to commercialization.

DMF SCHEDULE

API NAME	INDICATION	EARLY R&D	LATE R&D	PROCESS VALIDATION	DMF AVAILABLE	REGULATORY FILING*
Semaglutide	▪ Diabetes (type II) ▪ Obesity					**FDA:** 039104 **NMPA:** TBD **CANADA:** TBD
Leuprorelin Acetate	▪ Prostate and Breast Cancer ▪ Endometriosis ▪ Central Precocious Puberty					**NMPA:** Y20190007496(A) (2009) **MFDS:** 20200625-210-J-661 (2020) **TFDA:** 110DMF050097
Triptorelin Acetate	▪ Prostate and Breast Cancer ▪ Endometriosis ▪ Uterine Fibroids ▪ Assisted Reproduction					**NMPA:** Y20170001090(A) (2019)
Terlipressin Acetate	▪ Bleeding Esophageal Varices ▪ Hepatorenal Syndrome					**NMPA:** Y20200000281(A) **EDQM:** R0-CEP 2020-111
Cetrorelix Acetate	▪ In Vitro Fertilization (IVF)					**NMPA:** Y20190001147 (A) **FDA:** 034884
Goserelin Acetate	▪ Prostate and Breast Cancer ▪ Endometriosis ▪ Uterine Fibroids ▪ ART					**NMPA:** Y20230000413 (A)
Linaclotide	▪ Irritable Bowel Syndrome with Constipation (IBS-C) ▪ Chronic Idiopathic Constipation (CIC)					**NMPA:** Y20210000906
Triptorelin Pamoate	▪ Endometriosis ▪ Uterine Fibroids ▪ Premature Puberty ▪ Prostate Cancer ▪ ART					**NMPA:** Q4 2025
Tirzepatide	▪ Diabetes (type II) ▪ Obesity					**FDA:** Q1 2026
Teduglutide	▪ Short Bowel Syndrome					**FDA:** Q2 2026
Difelikefalin	▪ Chronic Kidney Disease-associated Pruritus (CKD-aP)					**NMPA:** Q1 2026
Etelcalcetide	▪ Secondary hyperparathyroidism (sHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy					**NMPA:** Q4 2026
Plecanatide	▪ Chronic Idiopathic Constipation (CIC) ▪ Irritable Bowel Syndrome with Constipation (IBS-C)					Pilot Testing Completed

*Subject to change.

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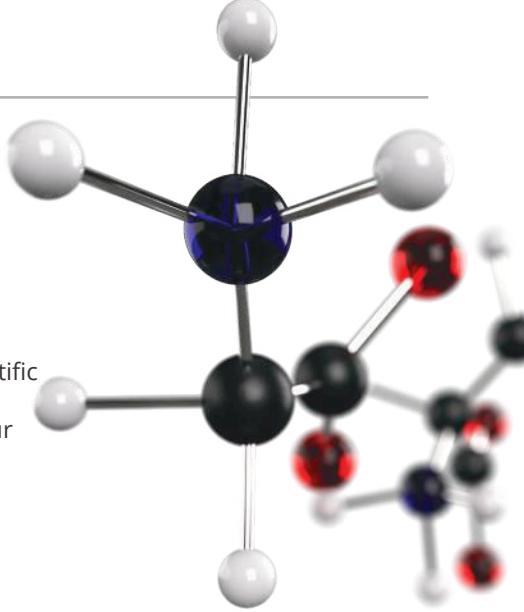
Custom Peptide Synthesis



We have the expertise to design and manufacture peptides from 2 to >200 AAs in length at purities from 80% up to 99%, and can perform almost every available peptide modification. By focusing stringently on quality and cutting-edge innovation, CPC Scientific is the preferred vendor for top pharmaceutical companies, biotechnology companies, respected universities, and research institutions throughout the world. We measure our success by the success of the researchers and clinicians we serve.

Modifications Available

- Lactam Cyclizations
- Thioether Cyclizations
- FRET Substrates
- TR-FRET Substrates
- Isotope-labeled Peptides
- Peptide Stapling
- Peptide Macrocycles
- Click Peptides
- Dye and Fluorescent Labels
- PEGylation (mono- and polydispersed)
- Metal Chelating Conjugates
- Multiple Disulfide Bonds
- Glycosylation
- Phosphorylation
- Sulfation and Sulfonation
- Incorporation of Unnatural Amino Acids
- Lipidation
- N-Terminal Modifications
- C-Terminal Modifications
- Hydrophobic Sequences
- Peptoids
- Rhodamine 110 Labeled
- Cell-Penetrating Peptides
- Long Sequences
- Native Chemical Ligation
- Epitope Mapping
- Peptide Libraries
- Neoantigen-based Libraries
- Protein Conjugation
- Selenocysteine
- Depsipeptides
- Peptidomimetics
- Multiple Antigenic Peptides (MAPs)
- Maleimide Group Installation

Suggested Purity Levels

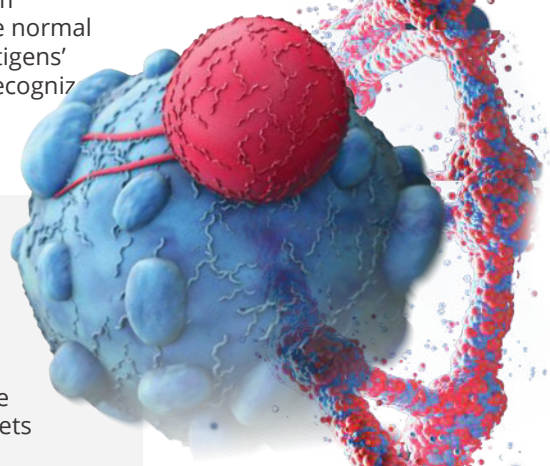
Immuno-grade > 70% purity	80% purity	95% purity	98% purity
Antigen for antibody production	Non-quantitative enzyme-substrate studies	Standards for quantitative ELISA and RIA protocols	SAR Studies
ELISA standard for measuring titers of antibodies in antisera	Phosphorylation assays	Quantitative receptor-ligand interaction studies	Clinical trials
Competitive elution chromatography	Non-quantitative peptide blocking studies	In vitro bioassays	API (Active Pharmaceutical Ingredients)
Peptide array production	Coupling to resins for affinity purification	In vivo studies	Commercial products
	Coating of tissue culture plates for cell attachment	Quantitative enzyme studies	X-Ray crystallography studies
	Protein electrophoresis applications	NMR studies	
		Mass spectrometry	
		Quantitative assays	

Neoantigen Peptides:

PERSONALIZED IMMUNOTHERAPY

Vaccines that activate the immune system play a key role in the prevention and treatment of human diseases. The development of cancer vaccines, however, has only been effective in virus-caused cancers such as human papillomavirus-induced cervical cancers. It has long been known that T-cells play important roles in the recognition and control of tumor cells. Harnessing T-cells to target and kill specific cancer cell types (i.e., immunotherapy) has emerged at the forefront of novel cancer therapeutics. Traditional immunotherapy, which targets existing tumor epitopes, has had limited success outside viral-induced cancer types, mainly due to the low T-cell avidity from thymic selection and central tolerance.

In order to increase the quality and T-cell binding affinity of the tumor epitopes, researches began targeting 'neoepitopes' that result from non-synonymous mutations. During progression and carcinogenesis, tumors acquire random mutations [i.e., tumor-specific antigens (TSAs)] that are not encoded by the normal tumor genome. The mutations result in proteins that may serve as 'neoantigens' which are not subject thymic selection and central tolerance. T-cells that recogniz tumor neoantigens are therefore likely to have high avidity.



Neoantigen Manufacturing Platform

The individualized nature of neoantigen immunotherapy typically requires 10-30 GMP-grade peptides to be manufactured for each patient. Peptide neoantigen therapy constitutes a significant paradigm-shift in GMP peptide manufacturing due to the need for multiple unique peptide sequence targets within a short, sensitive timeframe.

With this in mind, CPC Scientific has launched its personalized neoantigen manufacturing platform:

- Dedicated Neoantigen GMP Suites
- Accelerated Manufacturing, QC, and Release
- Fast & reliable project execution
- Cost-effective solutions for small-scale GMP projects
- Combination of Automated and Manual Synthesis capabilities
- Flexible & adaptable synthetic approaches to enhance success rates

A neoantigen peptide manufacturer must excel in optimizing success rates and ensuring timely delivery—and CPC Scientific is committed to achieving both.

Oligonucleotide Services

Competitive Advantage

CPC Scientific Inc Has ~25 Years of Solid-Phase Manufacturing Experience.

We provide our clients with research-grade and clinical-grade oligonucleotide manufacturing services spanning from discovery to clinical phases. Using solid-phase manufacturing protocol, we offer contract development and manufacturing of custom oligos, including scale-up development and analytical testing. CPC Scientific has the manufacturing capacity to support your GMP projects from early discovery (mg quantities) through commercialization (kgs). We stand with you at every stage of development, including life-cycle support at discovery phase, preclinical development, clinical trials, and commercial manufacturing.

In addition to peptides, we have developed a diverse project pipeline focusing on various types of complex peptide- and oligonucleotide-based NCE. Our peptide conjugation services seamlessly integrate our peptide and oligonucleotide platforms to produce a wide range peptide conjugates products.

Oligonucleotide Synthetic Capabilities

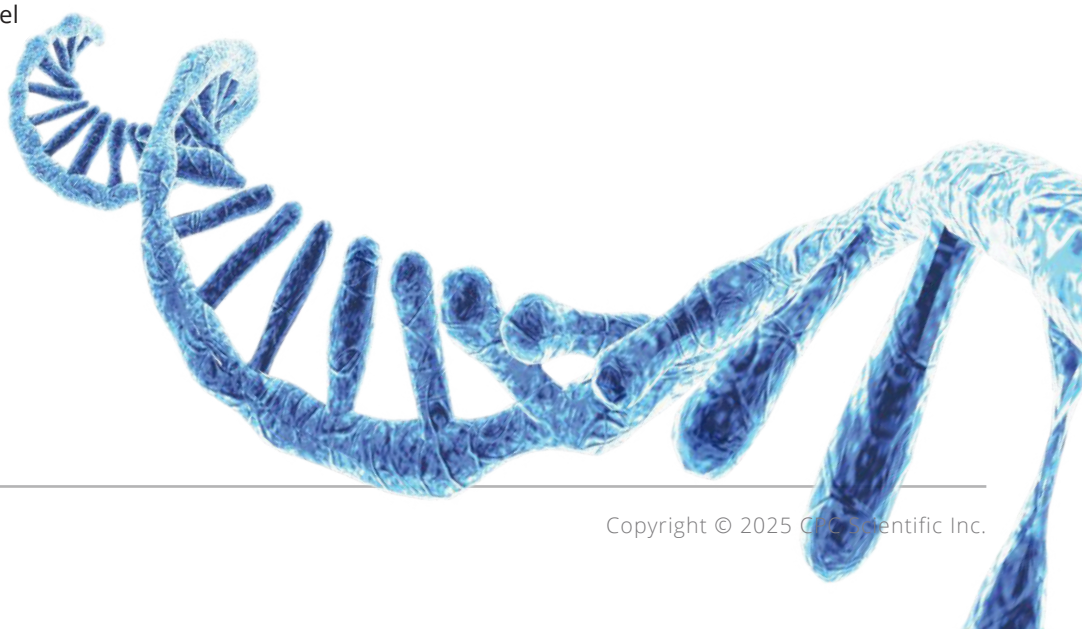
Our strong expertise in the synthesis of custom oligonucleotides with **a wide range of modifications** enables us to best meet the needs of our clients.

Synthetic Capabilities

- Quantities from milligrams to multi-kilograms scales
- Purity meets customer's requirement (80% – 95%)
- Length up to 40+ nt
- Most types:
  - ASO, siRNA, CpG, miRNA, aptamer
- Most modifications:
  - Backbone: PO, PS, PN
  - Base: 2'-OMe, 2'-MOE, 2'-F, LNA, cEt
  - Conjugate: GalNAc, PEG, Cholesterol
- Customized manufacturing model
- Peptide–oligo conjugates (POCs)
- PMO (morpholinos), PPMO

Suggested Purity Levels

> 80%	> 85%	> 90%
Single strand RNA	Conjugate modified sequence	Generic siRNA duplex
	Generic LNA (Locked nucleic acid)	Generic DNA
	Batches for toxicology studies	2'- Modified RNA (OMe, MOE, F)



Quality Control and Stability

CPC Scientific's Quality Control group performs **CGMP testing of raw materials**, **intermediates**, and **crude API** including duplexes and conjugates. We also process micro risk assessment as well as in-process micro studies to support your project.

Our experts can help you design a comprehensive stability study in order to meet regulatory guidelines for your product.

QC and Stability Testing to Meet Your CMC Needs

Our Quality Control group has the expertise and resources you need to keep your project on track.

In-process and Release Testing

Our QC performs all the necessary testing to generate a comprehensive certificate of analysis. We can also test drug products manufactured by a third party.

Microbiology Support

We perform environmental sampling and monitoring of the in-house purified water system and the manufacturing areas.

Comprehensive Stability Study Service

We have qualified on-site and off-site ICH sample storage to meet a range of temperature and humidity requirements.

Reference Standard Testing

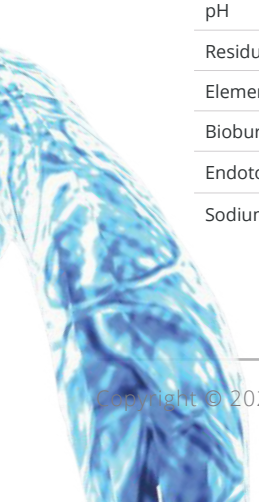
CPC provides complete solutions for your reference standard's needs.

OLIGOS

Production Specifications

We provide all in-house release testing for typical GMP product specifications.

Test Category	Specifications
Appearance	White to off-white solid
Molecular Weight	Consistent with calculated molecular weight
Sequence	Consistent with sequence
Purity	≥ 90%, according to customer's requirement
Related Substances	Report result
Melting Temperature (siRNA)	Report result
Water Content	Not more than 15%
pH	Report result
Residual Solvents	Report results for the following solvents: pyridine, acetonitrile, toluene, dichloromethane, ethanol
Elemental Analysis (ICP-MS)	Report results for the following metals: Sb, As, Bi, Cd, Cu, Pb, Hg, Mo, Ag, Sn
Bioburden	Report Aerobic and Spore Count, USP guidelines
Endotoxin	Report result, KTA (Kinetic Turbidimetric LAL Assay)
Sodium(Na+) content	Report result



SCAN TO SUBMIT A QUOTATION REQUEST:

CPC Scientific is a CRDMO specializing in synthetic **peptide** and **oligonucleotide** manufacturing for NCE development and commercial production. Complete the quotation request on our website to receive pricing and delivery time for your custom project.

CGMP Product Citations

A RANDOMIZED DOUBLE-BLIND PHASE 2 CLINICAL TRIAL TREATING CERVICAL INTRAEPITHELIAL NEOPLASIA 2/3 WITH PEPCAN OR CANDIDA

"The vaccine consisted of four current good manufacturing production-grade synthetic peptides covering the HPV 16 E6 protein [amino acid (aa)1-45, 46-80, 81-115, and 116-158] (CPC Scientific, San Jose, CA [..]"

Nakagawa, Mayumi, Teresa Evans, Milan Bimali, Hannah Coleman, Jasmine Crane, Nadia Darwish, Jennifer L. Faulkner et al. *MedRxiv* (**2025**): 2025-01.

CHEMOKINE RECEPTOR 2 IS A THERANOSTIC BIOMARKER FOR ABDOMINAL AORTIC ANEURYSMS.

"The CCR2 binding peptide ECL1i (LGTFLKC) was customized using D-form amino acids by CPC Scientific (Sunnyvale, CA). DOTA-ECL1i conjugate was synthesized following our established protocols (37). Copper-64 (64 Cu, t1/2 =12.7 hour) was produced by the Washington University Cyclotron Facility. The DOTA-ECL1i conjugate was radiolabeled with 64 CuCl 2 (64 Cu-DOTA-ECL1) following established protocols, and the radiochemical purity (>95%) was determined by radio-HPLC. For human CCR2 imaging, 64 Cu-DOTA-ECL1 was produced under exploratory investigational new drug application (IND 137620) approved by the US FDA following batch production record in ISO class 7 manufacturing suites under current good manufacturing practices (cGMP) conditions within the biological therapy core facility of Siteman Cancer Center at Washington University."

Liu, Yongjian, Santiago Benedetto Elizondo, Sergio Sastriques-Dunlop, Lisa Detering, Batool Arif, Gyu Seong Heo, Deborah Sultan et al. *MedRxiv* (**2023**): 2023-11.

AN OPTIMIZED RADIOSYNTHESIS OF [18F]DK222, A PET RADIOTRACER FOR IMAGING PD-L1.

"to current Good Manufacturing Practice (cGMP) requirements. In addition, the production is ... -NODA; Figure 1) was custom synthesized from CPC Scientific (San Jose, CA). The authentic ..."

Holt, Daniel P., Dhiraj Kumar, Sridhar Nimmagadda, and Robert F. Dannals. *Journal of Labelled Compounds and Radiopharmaceuticals* 66, no. 2 (**2023**): 47-54.

CETRORELIX DMF SUBMISSION ANNOUNCEMENT

"We are very excited about the addition of the cetrorelix DMF to our growing generic peptide portfolio. Our multi-kg scale cGMP manufacturing facility for cetrorelix will provide more opportunities for IVF treatments in the medical communities and pathways to new treatments for hormone-sensitive breast and prostate cancers."

CPC Scientific Inc. June 25, **2020**.

ASSESSMENT OF THE PHARMACOKINETICS, DISPOSITION, AND DURATION OF ACTION OF THE TUMOUR-TARGETING PEPTIDE CEND-1.

"The cyclic iRGD/CEND-1 peptide [sequence: CRGDKGPDC] and RGD control peptide (CRGDDGPKC) for pre-clinical use was sourced either from GenScript (Piscataway, NJ, USA) or CPC Scientific (Hangzhou, China)."

Järveläinen, Harri A., Christian Schmithals, Maike von Harten, Bianca Kakoschky, Thomas J. Vogl, Stephen Harris, Claire Henson, Gemma Bullen-Clerkson, and Albrecht Piiper. *International Journal of Molecular Sciences* 24, no. 6 (**2023**): 5700.

PHARMACOKINETICS AND SAFETY OF TCMCB07, A MELANOCORTIN-4 ANTAGONIST PEPTIDE IN DOGS.

"TCMCB07 [a cyclic substituted melanocortin antagonist with the structure Ac- Nle- cyclo[Asp- Pro- DNal(2')- Arg- Trp- Lys]- DVal- DPro- NH2] was manufactured by CPC Scientific Inc. under CGMP conditions. Active pharmaceutical ingredient was dissolved in milliQ water at 10 mg ml−1, sterile filtered [..]"

Axiak-Bechtel, Sandra M., Stacey B. Leach, David G. Scholten, Jessica R. Newton-Northup, Brendan J. Johnson, H. E. Durham, Kenneth A. Gruber, and Michael F. Callahan. *Pharmacology Research & Perspectives 9*, no. 3 (**2021**): e00777.

RECALL ANTIGEN FOR PROMOTING T-HELPER TYPE 1 RESPONSE.

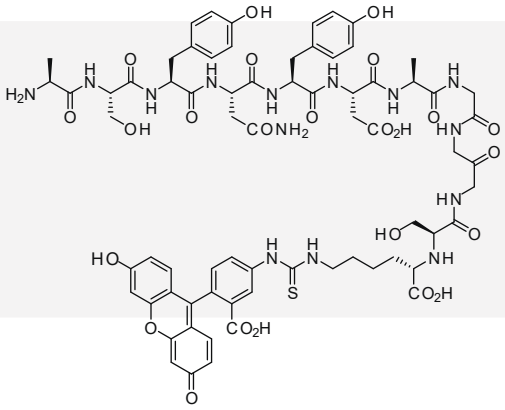
"The PepCan peptide mixture will contain four HPV 16 E6 peptides: E6 1-45 (Ac-MHQKRTAMFQDPQER PRKLPQLCTELQTTIHDIILECVYCKQQLL-NH2..), E6 46-80 (Ac-RREVYDFAFRDLCIV YRDGN PYA VCDKCLKFYSKI-NH2..), E6 81-115 (Ac-SEYRHYCYSLYGTTLEQQYNK PLCDLLIRCINCQK-NH2..), and E6 116-158 (Ac-PLCPEEKQRHLDKKQRFHNIRGRWT GRCMSCCRSSRTRRETQL-NH2..) (U.S. Pat. No. 8,652,482). Commercially produced CGMP-grade peptides (CPC Scientific, San Jose, Calif.) will be examined.."

Nakagawa, Mayumi. *U.S. Patent Application* 15/552,285, filed February 15, **2018**.

MULTIMODAL ENDOSCOPE CAN QUANTIFY WIDE-FIELD FLUORESCENCE DETECTION OF BARRETT'S NEOPLASIA.

"ASY*-FITC was synthesized using good manufacturing practice (GMP) methods (CPC Scientific, Inc.). Stability was evaluated on high-performance liquid chromatography (HPLC) and mass spectrometry. Aliquots of peptide (0.8 mg) were stored at −20 °C as lyophilized powder in single-use amber vials for protection from light."

Joshi, Bishnu P., et al. "Multimodal endoscope can quantify wide-field fluorescence detection of Barrett's neoplasia." *Endoscopy* 48.02 (**2016**): A1-A13.



HPV E6 PROTEIN T CELL EPITOPES AND USES THEREOF.

"To define the minimal and optimal amino acids sequences of the CD8 T-cell epitope, 8-mer, 10-mer, 11-mer, and homologous peptides were synthesized (CPC Scientific, Inc, San Jose, Calif.). [..] Commercially produced CGMP-grade peptides (90% purity; CPC Scientific, San Jose, Calif.) is examined. Their safety for human use is ensured, in accordance with FDA requirements, by testing 14-day sterility (USP), testing pyrogens, describing appearance and identity, analyzing amino acids, determining impurities by HPLC, assessing H2O content and net active peptide, and describing any organic solvents (each peptide to be assessed individually as per the FDA)."

Nakagawa, Mayumi. "Hpv e6 protein t cell epitopes and uses thereof." U.S. Patent Application No. 14/566,604. (**2015**)

CANDIDA SKIN TEST REAGENT AS A NOVEL ADJUVANT FOR A HUMAN PAPILLOMAVIRUS PEPTIDE-BASED THERAPEUTIC VACCINE.

"...four current good manufacturing practice-grade HPV16 E6 peptides [E6 1-45, E6 46-80, E6 81-115, and E6 116-158 (referred to as "peptides" hereafter); 10 μg/ml/peptide; made by CPC Scientific, Sunnyvale, CA...."

Wang, Xuelian, et al. "Candida skin test reagent as a novel adjuvant for a human papillomavirus peptide-based therapeutic vaccine." *Vaccine* 31.49 (**2013**): 5806-5813.

TLR4-DEPENDENT ACTIVATION OF DENDRITIC CELLS BY AN HMGB1-DERIVED PEPTIDE ADJUVANT.

"The peptides, including Hp91 (DPNAPKRPPSAFFLFCSE), Hp121 (SIGDVAKKLGEMWNNTAA), scrambled Hp91 (ASLAPPFPNCFDPKSREF), and OVA-I (SIINFEKL) were all synthesized at GMP facilities by GenScript Corp (Piscataway, NJ, USA) and CPC Scientific (San Jose, CA, USA). Peptides were synthesized with an N-terminal biotin, acetyl, or fluorescent tag (Cp488) as indicated in the figure legends. Peptides were routinely synthesized with greater than 95% purity."

Saenz, Rebecca, et al. "TLR4-dependent activation of dendritic cells by an HMGB1-derived peptide adjuvant." *J Transl Med* 12 (**2014**): 211.

TARGETED IMAGING OF ESOPHAGEAL NEOPLASIA WITH A FLUORESCENTLY LABELED PEPTIDE: FIRST-IN-HUMAN RESULTS.

"For the clinical and pharmacology/toxicology studies, ASY*-FITC was GMP synthesized (CPC Scientific). Stability was evaluated by appearance (color), HPLC, and mass spectrometry for 3 years. The pharmacology/toxicology study in rats was conducted in accordance with FDA CFR title 21, part 58...."

Sturm, Matthew B., et al. "Targeted imaging of esophageal neoplasia with a fluorescently labeled peptide: first-in-human results." *Science Translational Medicine* 5.184 (**2013**): 184ra61-184ra61.

List of Abbreviations

CRDMO:	Contract Research, Development, and Manufacturing Organization
CDMO:	Contract Development and Manufacturing Organization
CMO:	Contract Manufacturing Organization
CRO:	Contract Research Organization
CGMP:	Current Good Manufacturing Practice
CMC:	Chemistry, Manufacturing, and Controls
NCE:	New Chemical Entity
EMA:	European Medicines Agency
FDA:	Food and Drug Administration
MFDS:	Korean Ministry of Food and Drug Safety
NMPA:	National Medical Products Administration
TGA:	Therapeutic Goods Administration

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