HLB PEP

# *No.1 Peptide Company in Korea*

September. 2026

Since 2000

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# 1. History

Since 2000

# Company Information

## 2000 ~2010

00 **Founded ANYGEN CO., LTD.**

Venture Business Certification / Small and Medium Business Administration

05 Technology Innovation (INNO-BIZ) Selection of SMEs

06 Obtained ISO 9001 and ISO 14001 Certifications

10 **Peptide GMP Plant 1 (Jangseong, Jeollanam-do)**

## 2011 ~2015

11 **Korea's First GMP Certification for Peptide Active Pharmaceutical Ingredients**
Leuprorelin Approval

12 Approval for Desmopressin

**Leuprorelin DMF Submission / U.S. Food and Drug Administration (FDA)**

13 Approval for Exenatide
Approval for Ziconotide

## 2016 ~2025

16 **Listed on the KOSDAQ Market**

India DCGI Approval for Leuprorelin

18 **Completed Construction of Osong Plant No. 2 (Peptide Pharm Osong)**

20 **GMP Certification for Peptide Active Pharmaceutical Ingredients at Osong Plant No. 2**

24 **Ganirelix DMF (FDA, MFDS)**

25 **Acquisition by HLB Group (Company Name Changed to HLB PEP)**

26 **Vasopressin DMF (FDA, MFDS)**

1 Headquarter/R&D Center

2 JangSeong 1st GMP Plant

3 Osong Peptide Bio Pharm 2nd GMP Plant



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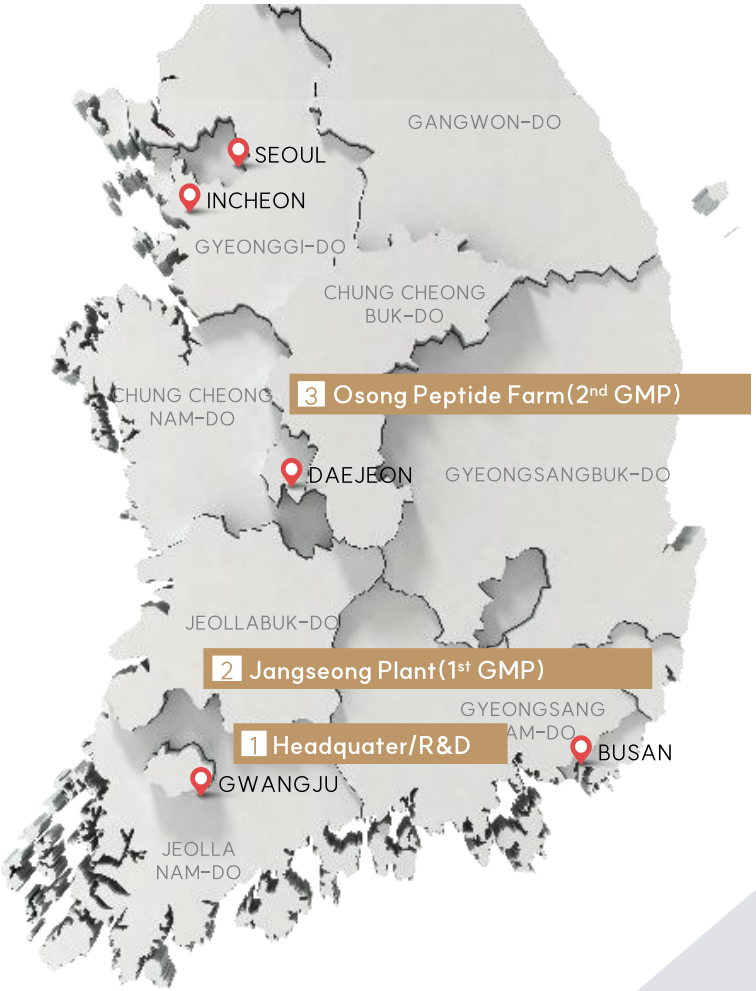
# Site Information



1 Headquarter/R&D Center

2 JangSeong 1st GMP Plant

3 Osong Peptide Bio Pharm 2nd GMP Plant

- ✓ Korea's No.1 Research Peptide Leader
- ✓ Over 5,000 Peptides Produced and Studied Each Year
- ✓ Driving the Latest Market Trends

- ✓ Korea's First Dedicated Peptide GMP Facility
- ✓ European Medicines Agency QP Certification

**Korea's First GMP-Certified Smart Factory**

- ✓ KGMP Certification
- ✓ EU-GMP, cGMP, PMDA Approval in Progress
- ✓ European Medicines Agency QP Certification
- ✓ USFDA Preliminary Inspection Completed
- ✓ LIMS Implementation in Progress

# 2. Core Competitiveness

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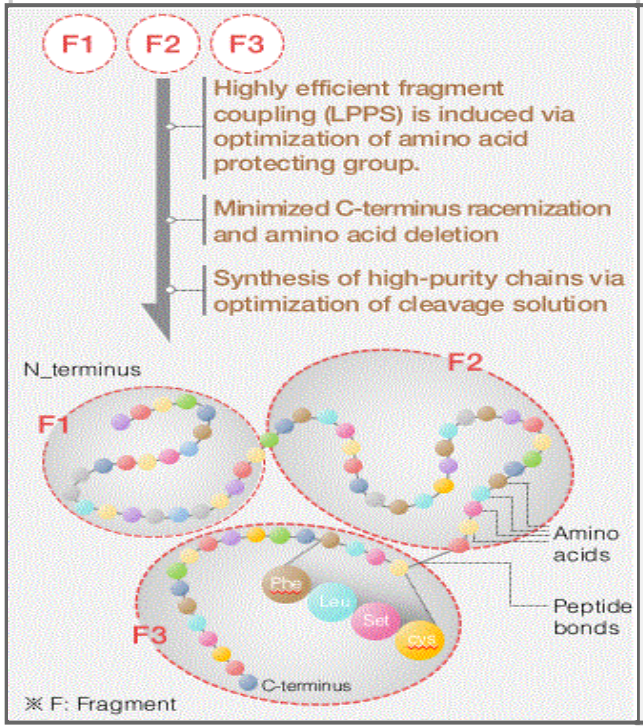
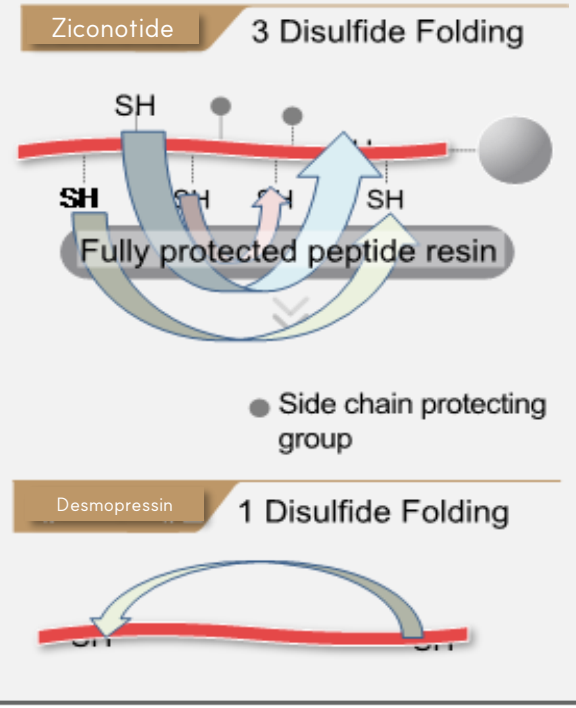
# Strengthening Core Business

## Advancing Peptide Development Technology

| 1. Long Chain Technology | 2. Cys rich disulfide folding Technology | 3. Modified Peptide Synthesis Technology |
|---|---|---|
| **Securing Unique Convergent Manufacturing Technology**<br>Overcoming increased synthetic complexity associated with longer peptide chains | **Cysteine disulfide bond technology with impurity minimization.** | **All modifications possible (e.g., FITC, Cyclic, pNA, etc.)** |




| N-terminal | Side Chain | C-terminal |
|---|---|---|
| Acetylation / Biotinylation | | Amidation |
| Fluorescence Dye (FITC/Cy3/Cy5 and its derivative) | | Esterification |
| DNP (2,3-D-Niroanilide) | | pNA (p-Niroanilide) |
| Dabcyl/Dabsyl/ Dancyl | Phosphorylation (Ser,Thr, Tyr) | AMC (Aminomethylcoumarin) |
| Fatty acid | Disulfide Bonds | MAP (Multiple Antigen peptide) |
| PEG | Cyclization | EDANS |
| KLH/BSA Conjugation to Antibody Production | | |



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# 3. CDMO Service

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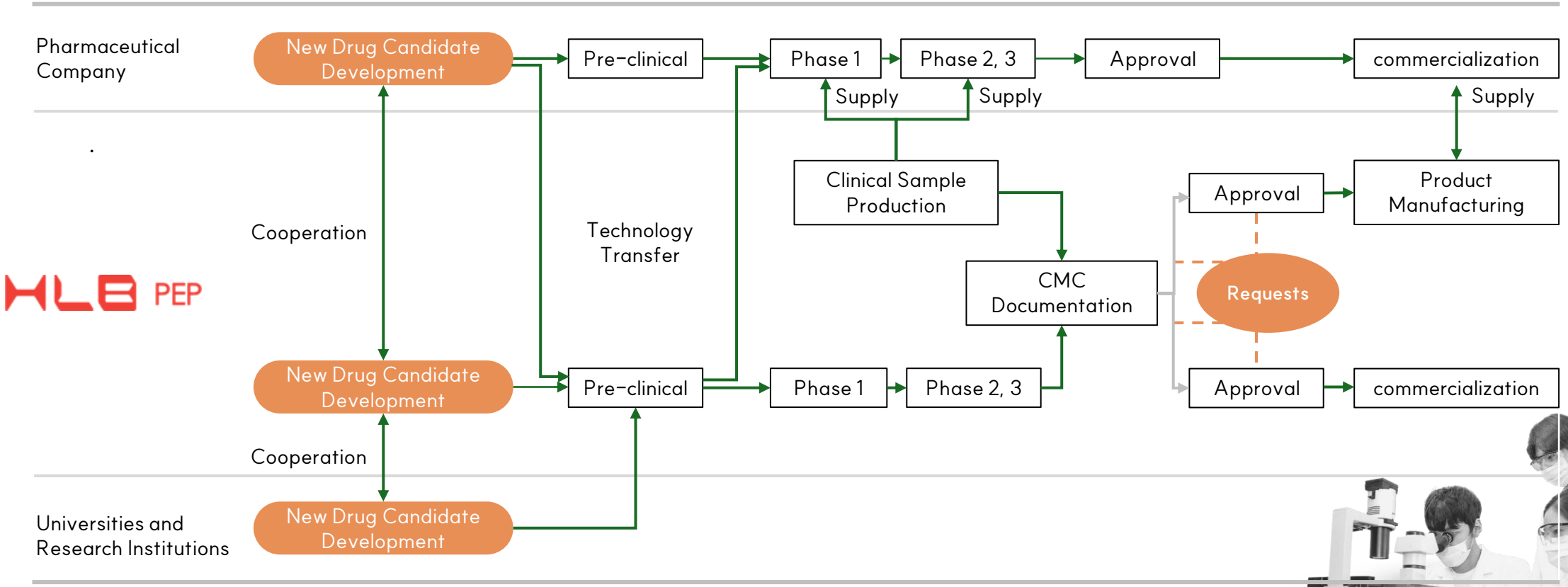
# CDMO Capabilities with GMP-Certified Facility

HLB PEP provides One-Stop Services from new drug candidate development to addressing regulatory requests from health authorities in each country.



# GMP Service Package for CDMO

## GMP Service Package

- Process Development for Toxicity
- Reference Standard
- Analytical Development and Characterization
- Method Validation
- Full stability testing according to KFDA/ICH guidelines over 48 months
- Process Validation
- All batch documentation and any required supporting documents, including a CTD package and a US or European DMF when needed

## GMP Standard Specifications

- Appearance
- Solubility
- Identity by Mass Spectral Analysis (LC-MS)
- Amino acid Analysis
- Peptide Purity, Related Substances by HPLC
- Assay by Peptide Content
- Bacterial Endotoxins
- Counter-ion Content (TFA, AcOH, HCl)
- Water Content / Mass Balance
- Specific Rotation
- Residual Organic Solvents by GC
- Inorganic Fluoride
- Bioburden
- UV
- FT-IR

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# Project Track Records

| Applicant | Stage | Contents |
|---|---|---|
| Company "N" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "C" | Phase 2 | Process development, Manufacturing, CMC, Stability |
| Company "O | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "C" | Phase 1, 2 | Manufacturing, Stability |
| Company "G" | Phase 1, 2, 3 | Product manufacturing, CMC |
| Various Customers | Investigator-initiated clinical studies with GMP small batches API and multiple variants | |

| Applicant | Stage | Contents |
|---|---|---|
| Company "Y" | Phase 1, 2 | Product manufacturing, CMC |
| Company "E" | Phase 1 | Process development, Manufacturing , CMC, Stability |
| Company "H" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "N" | Phase 1,2 PV, MV | Process development, Manufacturing, CMC, Stability |
| Company "A" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "A" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "G" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "K" | Phase 1 | Process development, Manufacturing, CMC, Stability |
| Company "H" | Phase 1 | Process development, Manufacturing, CMC, Stability |

Achieved a 100% completion rate with
Zero failures and no critical major corrective actions across all clinical peptide projects.

# 4. APIs

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# Expanding API Indications & Market Pipeline

| APIs | Indications | Process Development & Process Validation | Drug Master File | Commercialized |
|---|---|---|---|---|
| **Leuprorelin**<br>DMF, Ph Eur, USP,<br>US FDA #25878, ANDA | Prostate cancer, Precocious precocious puberty for IVF | → | → | → |
| **Desmopressin**<br>DMF, Ph Eur, USP | Nocturnal enuresis | → | → | → |
| **Ganirelix**<br>DMF, Ph Eur, USP<br>US FDA #040573, ANDA | Fertility treatment | → | → | → |
| **Vasopressin**<br>DMF, Ph Eur, USP<br>US FDA #044390, ANDA | Antidiuretic hormone<br>anti-diuretic, vasoconstriction | → | → | → |
| **Taltirelin**<br>DMF scheduled for PMDA submission in 4Q 2026 | Spinocerebellar Degeneration | → | DMF (2027, PMDA) | |
| **Triptorelin**<br>DMF scheduled for US FDA submission in 2Q 2027 | Prostate cancer, Early puberty,<br>Prevent premature ovulation of IVF | → | DMF (2027, USFDA) | |

# Development of Product (Peptide APIs) with High Market Value

Takeda
Approximately
USD 823 million

Prostate cancer, Early puberty

Leuprorelin

Bed wetting

Desmopressin

Pfizer Inc.
Approximately
USD 2 billion

Organon & Ferring
Approximately
USD 1,022 million

IVF by blocking a hormone that triggers egg release

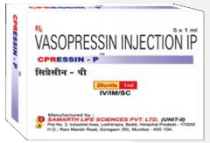
Ganirelix

Prostate cancer, Early puberty

Triptorelin

Ipsen
Approximately
USD 1.4 billion

Par/Endo
Approximately
USD 2.8 billion




Diabetes insipidus, Septic shock (increase blood pressure)

Vasopressin

Spinocerebellar Degeneration

Taltirelin

Mitsubishi Tanabe Pharma.
Approximately
USD 4.5 billion

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# 감사합니다.

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