

## I. Corporate Overview

**Foundation** September 2017

**Business** Contract Development and Manufacturing of Peptides

**Location** Osaka, Japan

**Features**

- 1) Established by collection of partners and top talents in various fields of peptide production
- 2) Advanced and unique technologies / expertise / capabilities brought by various partners
- 3) State-of-the-art R&D and production facilities on all scales



HQ Office / R&D Building

## II. Facilities

### 1. Production Equipment

	Reactor	Purification Column	Freeze Drier
R&D	Auto-synthesizer, 1L and 10 L (Microwave)	φ10mm, 30mm, 50mm, 100mm and 150mm	Manifold, 1L & 30L
Bldg. 1 (GMP)	30L (Microwave)	φ200mm - 400mm	50L
Bldg. 2 (GMP)	30L and 300L	φ300mm - 450mm	500L

- Non-GMP and cGMP for various scales of production and enables scale-up in a straightforward manner
- SPPS, LPPS and **Microwave technologies** are available on a wide range of scales.



Synthetic Area

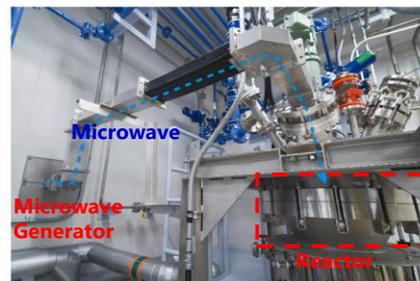
## 2. Analytical Equipment

- Various Analytical Equipment to test all the typical items for peptide APIs.
- Various MS enable to conduct various analytical study  
Triple Q : Impurity Quantification, TOF-MS : Impurity Profiling
- SFC (Supercritical Fluid Chromatography)
- Low Humidity Sampling Room

## III. Competitive Advantage

### 1. Various Patented Synthetic Methodologies

- Microwave Technology:**
  - ✓ Under GMP, at the largest scale in the world (~sub kg/ batch)
- STag-PST™ (Tag-assisted LPPS):**
  - ✓ Continuous coupling reaction in ONE reactor
  - ✓ Work-up only by extraction
- Novel LPPS:**
  - ✓ Patent filed, to be published in late 2020.



Micro-wave Filter Reactor (30L, Manufacturing Bldg.1)

### 2. Downstream Capacity & Capability

- A wide range of column and freeze drier (500L, the world's largest capacity)
- Shorten lyophilization time by various concentration technology
- Various technologies in purification, concentration & lyophilization.**

### 3. Know-how, Expertise, Experience by Collection of Partners

- Japanese leading chemists, analytical chemists, GMP/CMC experts
- Accumulated expertise through over 10,000 peptides synthesis/y.
- Experienced QA team with a track record of 41 audits by FDA, EMA, PMDA, ROW
- Experienced R&D team with a track record of 10 NDA/MAA + 10 IND/INPD documentation