

# EXPERTS *in*

## High Potency Substance Manufacture



Hamari Chemicals, Ltd.

## High Potency Peptides

Looking for someone to manufacture high potency peptides at commercial scale?

- ✓ Our Hokkaido commercial manufacture site, **HAMARI PFST, LTD. Chitose Site**, has a dedicated, isolated manufacture area to produce *your* high potency peptides (OEL 1 - 10  $\mu\text{g}/\text{m}^3$ ) from dipeptides to long peptides (30 a.a.).



Construction Outline	
Manufacture Equipment	Solid-phase reactor (10 L), liquid-phase reactor (20 L), automated HPLC purification system, lyophilizer (flask manifold / tray), shunt-flow precision humidity generator
Cleanliness Class	Class C (ISO7)
Temp./Humidity	22 $\pm$ 3 $^{\circ}\text{C}$ 、30 $\pm$ 15%RH
Primary Contain.	Balance enclosure, safety cabinet
Secondary Contain.	Pressure controlled room, HEPA, emergency decontamination mist shower
Exposure Mgmt.	OEL 1 to 10 $\mu\text{g}/\text{m}^3$ , Category 4 (Pharma Solutions Co., Ltd.'s Classification)
Batch Size	grams to 1 kg
Production Line	1 line



MADE IN JAPAN

# High Potency APIs

Looking for someone to manufacture high potency substances (such as anti-cancer agents) at commercial scale?

- ✓ Our US-FDA inspected commercial manufacture site, **HAMARI PFST, LTD. Yonezawa Site**, has a dedicated, isolated manufacture plant to produce *your* high potency substances, such as anti-cancer agents (OEL 1 - 10  $\mu\text{g}/\text{m}^3$ ).



Construction Outline	
Manufacture Equipment	GL reaction, press filter, centrifugal separator, filter dryer, milling machine
Cleanliness Class	ISO7 / ISO8
Primary Contain.	Hard isolator and flexible enclosure
Secondary Contain.	Pressure controlled room, clothes entry/exit separation, decontamination shower, HEPA-2, BIBO
Exposure Mgmt.	OEL 1 to 10 $\mu\text{g}/\text{m}^3$ , Category 4 (Pharma Solutions Co., Ltd.'s Classification)
Batch Size	10 to 20 kg
Production Line	1 line



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