



# Bushu Pharmaceuticals Ltd.

## General Information

Supporting the global healthcare industry to create a healthier tomorrow

# Agenda

1. Basic Information of Bushu
2. History
3. Site Location
4. Proven Track Record
5. Inspection History by Foreign Authorities
6. Production Features including Sterile Products
7. High Potency Tablet Suite
8. Clinical Trial Support
9. Technical Transfer
10. BCP (Business Continuity Plan)
11. EHS





## Contributions to human health and global healthcare

- Contract manufacturing
- Formulation of Packaging and Testing/Inspection



## HQ and 2 factories in Saitama Prefecture

- Kawagoe HQ/Factory and Misato Factory
  - Established on August 3, 1998
  - Shareholder: Baring Private Equity Asia
- 
- Capital: 1.0 Billion Yen (USD: 90 mil., EUR: 82 mil.)
  - Revenue: 25.9 Billion Yen (USD: 230 mil., EUR: 210 mil.) (fiscal 2018)
  - Employees: 1,042 (Kawagoe: 670, Misato: 372)



## History of Bushu Pharmaceuticals

Bushu has established our strong company culture with combining many good culture.



1981

Kawagoe Factory was built by Sandoz as a flagship factory  
Commencement of packaging operation



1997

Factory name changed to Novartis Pharma Saitama



1998

Bushu Pharmaceuticals Ltd. founded by Shionogi



2006

Employees (Approx. 100) joined from Wyeth due to shut down of Shiki Factory



2014

Misato Factory transferred from Eisai Co., Ltd.



2020

Built a new Cold Chain Center at Misato Factory



# Location of Office/Sites



Kawagoe Site



Misato Site

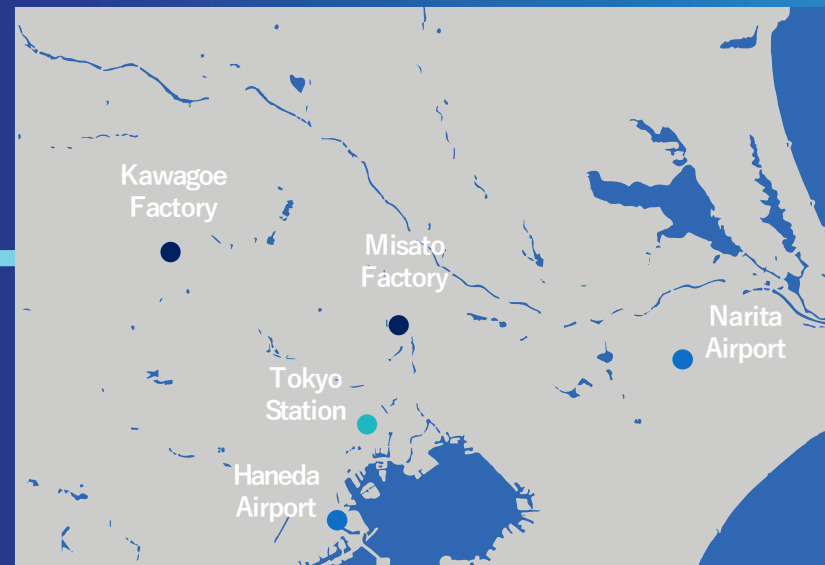


Head office/ Kawagoe:

Approx. 1.5 hour from  
Tokyo Station by Train  
& Taxi

Misato:

Approx. 1 hour from  
Tokyo Station by  
bullet train & Taxi



## Proven Tracking Record + Capabilities

### Experiences as a pure CMO



**21**  
years

CMO  
Business  
Experience

### Partnerships with Customers



**67**  
companies

Accumulated number  
of Commercial  
Customers

### Capabilities for Globalization



**47**  
%

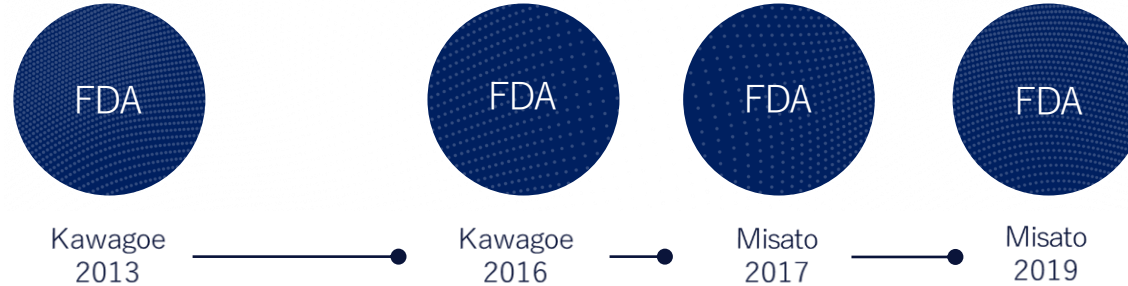
% of sales for  
Multi-national  
Customer



**43**  
years

Number of  
GMP  
Certification

# Inspection History by Foreign Authorities



Authorities	Site	On-site / Doc	Objectives	Date
FDA	Kawagoe	On-site	Regular	Oct. 2013
Turkish MOH	Kawagoe	On-site	PAI	Jun. 2014
Veterinary Medicines Directorate (EU)	Kawagoe	On-site	Regular	Apr. 2015
ANVISA (Brazil)	Kawagoe	On-site	PAI	Jul. 2015
Kenyan	Misato	On-site	Regular	Apr. 2015
FDA	Kawagoe	On-site	Regular	Sep. 2016
FDA	Misato	On-site	Regular	Jan. 2017
ANVISA (Brazil)	Misato	On-site	PAI	Jun. 2017
Veterinary Medicines Directorate (EU)	Kawagoe	On-site	Regular	Jan. 2018
Russia	Misato	On-site	Regular	July 2018
FDA	Misato	On-site	Regular	Aug. 2019

## Production Features including to Sterile Products

### Solid Form

#### Drug products

- Granules
- Tablets
- Capsules
- Dry Syrup

#### Primary/Secondary Packaging

- Blister
- Strip package
- Stick package
- Bottle



6.8 bil./year  
Possible for high activity

### Injectable Form

#### Drug products

- Liquid
- Lyophilization

#### Inspection Assembling

- Pre-filled Syringe

#### Secondary packaging

- Vial
- Ampule
- Pre-filled Syringe
- Auto Injector



6 mil./ year  
Possible for refrigerated items

### Medical Device

#### Drug products with no description

#### Assembling Inspection & Secondary packaging

- Drug & Device/Machine (ex. IVD machine)
- Device only (ex. catheter) possible





## Production Features including to Sterile Products

### Visual Inspection

- Skill qualification system for VI
- Over 50 visual inspectors
- Expand the line-up

### Cold Chain Warehouse

- 500 pallets in the Cold storage at 2-8°C
- Backup electrical power source
- Planning to build up more capacity

### Packaging Line

- Automatic line: 660,000 packs/annual
- Process for cold chain dosage form
- In line visual inspection cameras
- Stable production available by adequate production technology

## High Potency Tablet Suite

OEL	0.1 - 1( $\mu\text{g}/\text{m}^3$ ) in principle
OEB Level	OEB4, OEB5 level and hormone product
Production Scale	From 5 to 15kg
Dosage Form	Granules, plain tablets, and coated tablets
Main Equipment	<ol style="list-style-type: none"><li>1. High speed agitation granulator</li><li>2. Fluidized bed granulator</li><li>3. Granulator</li><li>4. Tableting machine</li><li>5. Mixing machine</li><li>6. Coating machine</li><li>7. Packing machine</li></ol>

We manufacture at our buildings for formulation of high potency products from clinical samples to pharmaceuticals.

Products for overseas are also available.

We establish a manufacturing environment based on hazard assessment and exposure assessment and we implement strict residue management.

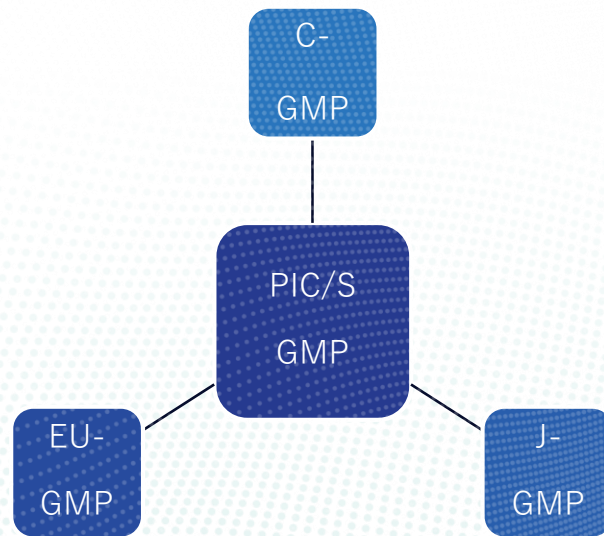
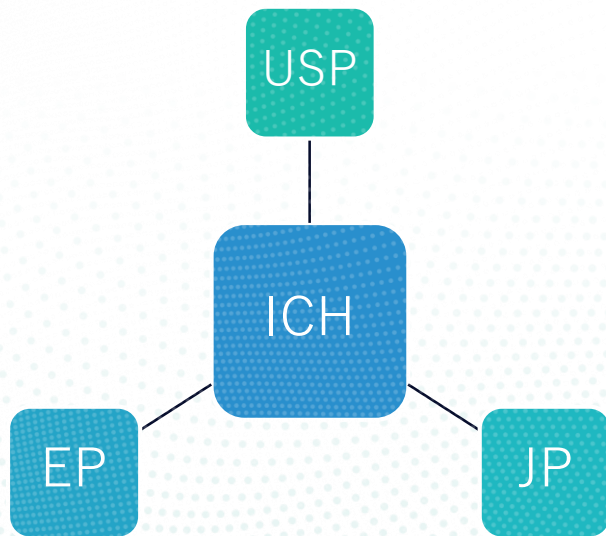
In addition, we will monitor the environment and verify the containment by measuring the exposure to workers.

Bushu “Clinical Trials Team” in Packaging Section provides the following services:

- Package Engineering
- Package Material Management
- QC Test
- GMP Release
- Product delivery

They are well trained for any Clinical Trials package and can provide the services within shorter lead time.

Over 20 years, Bushu has many experiences in development and technical & QC testing method transfer under USP, EP, JP and ICH.



**Backup power generator**

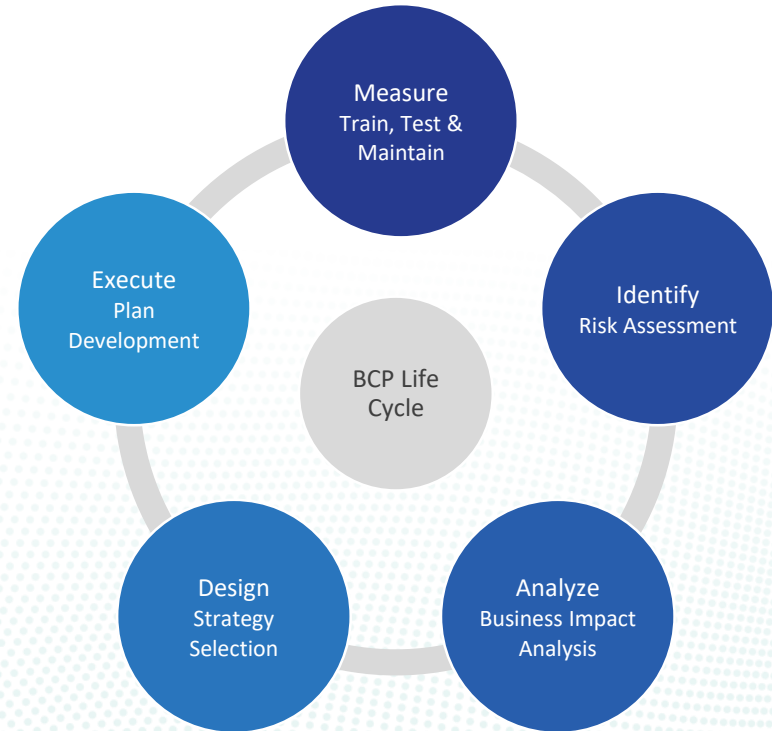
- Kawagoe: Established with 100kL A oil tank.
- Misato: Power generator is installed.  
Proceeding with augmenting the oil tank.

**Supply of heavy oil**

- Contracted with 3 companies on the supply of heavy oil in case of emergency.

**Risk assessment for natural disaster including earthquake**

- Earthquake risks within next 30 years : Less than 0.008% of Magnitude 8.0 in Saitama where Kawagoe and Misato plant locates. The risks are significant smaller than other area in Japan.





### 1. EHS Organization

- Environmental Committee, and Safety and Hygiene committee on 2 sites.

### 2. International Certificate

	ISO14001	OHSAS18001
Kawagoe	Since 2001	
Misato	Since 2000	Since 2004

### 3. Customer Audit

- Environmental Committee, and Safety and Hygiene committee on 2 sites.

### 4. Association

- Kawagoe Environmental Maintenance Liaison Council
- Environmental section in Saitama Pharmaceutical Manufacturers Association

