Bushu Pharma

Bushu Pharmaceuticals Ltd.
Trusted Mafunfacturing

Supporting the global healthcare industry to create a healthier tomorrow.

CPhI Special Digest Version 2021

Proven Track Record + Capabilities

Supporting the global healthcare industry to create a healthier tomorrow.

Bushu Pharma is committed to producing and delivering quality healthcare products, including pharmaceuticals and medical devices, to patients around the world through its role as a healthcare Contract Development and Manufacturing Organization (CDMO).

By ensuring optimized QCD (Quality, Cost, Delivery) through our advanced technology and production capacity, we create strong partnerships with pharmaceutical manufacturers and other customers – making it possible to grow the global healthcare industry and in effect, to make better health a reality around the world.

Our success is focused on our customers – we strive to help them achieve their business goals and build lasting relationships through which we support the construction of global supply chains.

22 Years of CMO Business Experience

69 Accumulated number of Commercial Customers

43 Number of GMP Certifications

47 Percentage of sales generated from international customers

as of October 2020

Our Core Services

Bushu Pharma

Pharmaceutical Manufacture

The trusted, secure manufacturer for pharma businesses.
We empower the flawless manufacture of your most important products.

Quality Analysis and Management

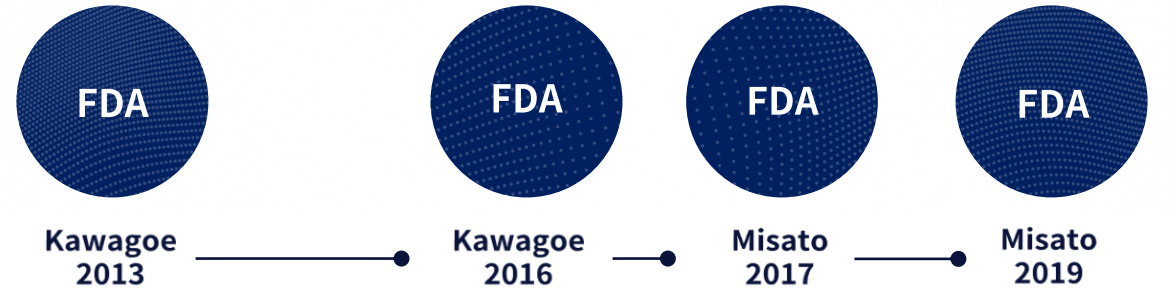
We provide Analysis and Technical Transfer services based on the highest Japanese quality standard and GMP certifications globally.

Supply Chain and Gateway to Asia

Reach new markets in Asia and beyond with our end-to-end supply chain expertise, backed by our 22 years of experience as Japan's leading CMO.

Globally Qualified

Bushu Pharma's Quality System is accepted by regulatory authorities in multiple countries, including the US FDA.



Key Features of our QMS

- GMP certification from 43 countries
- Established comprehensive quality assurance system employed to maintain high quality and reliability levels
- Ability to accurately grasp our customers' needs through close communication provided in English or Japanese
- Continuous acquisition of new technology in order to further increase production quality levels
- Established procedures for quality system management that meet international standards
- Voluntary data management system (LIMS)
- Responsive actions ensuring data integrity
- Continuous quality education and training

Production Features

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
- Ampoule
- Pre-filled Syringe
- Auto Injector

6 mil/ year
Possible for refrigerated items

Medical Devices

Assembling Inspection + Secondary packaging

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

Note: Out of scope - Penicillin / Cephalosporin / Insecticide / Agrichemicals

Production Features

Visual Inspection

- Skill qualification system for all Visual Inspector staff
- Over 50 Visual Inspectors
- Expand the line-up

Cold Chain Warehouse

- More than 800 pallet capacity in the Cold storage at 2-8°C
- Backup electrical power source
- Planning to expand facility for increased capacity

Packaging Line

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

High Potency Tablet Dosage Form

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.

OEL	0.1 – 1 (μg/㎡) in principle
OEB Level	OEB4, OEB5 level and hormone product
Production Scale	From 5 to 15kg
Dosage Form	Granules, Plain Tablets + Coated Tablets
Main Equipment	1. High speed agitation granulator 2. Fluidized bed granulator 3. Particle Sizing Equipment 4. Tableting machine 5. Mixing machine 6. Coating machine 7. Packaging machine

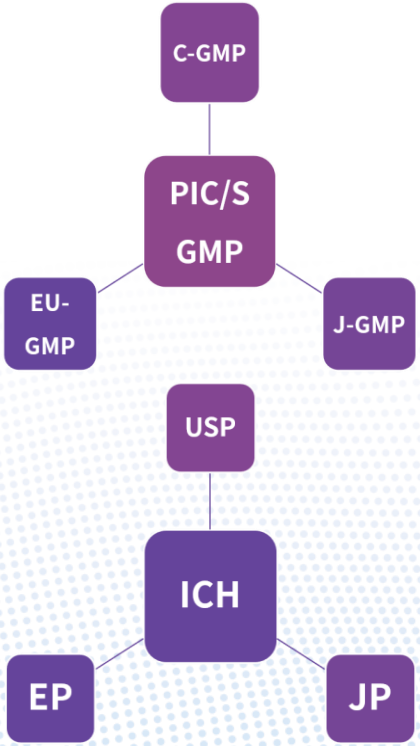
Bushu Pharma

Bushu Pharma's Packaging Section "Clinical Trials Team" can provide the following services:

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

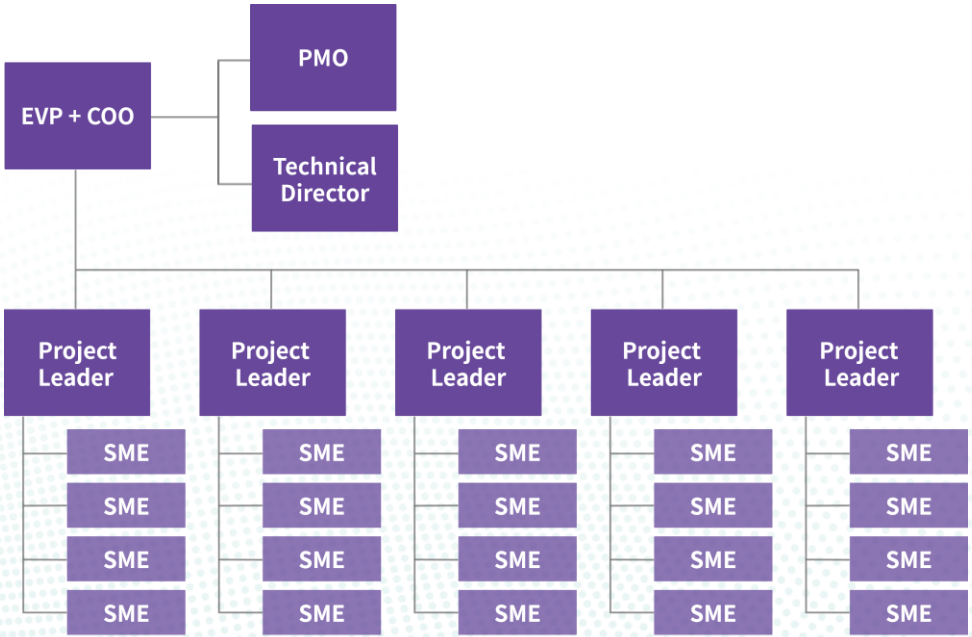
We are well trained for any clinical trial packaging request and can provide service within shorter lead times.

Technical Transfer into Bushu Pharma



Over 22 years, Bushu Pharma has gained a wealth of experience in development, technical & QC testing method transfer under “c-GMP, EU-GMP, J-GMP and PIC/S GMP” and “USP, EP, JP and ICH” .

Fully supportable from early to late stage by SME team



- Management for each project and/or client by dedicated team consisting of SMEs
- Assign SME, e.g. Bioassay, Biological, etc. for QC method transfer
- Bilingual approach in both English and Japanese available
- Technical Services, PMO and Technical Operation Strategy are under COO for direct management

Development services for packaging & artwork

1. Artwork Coordination

- Receive product brand strategy and/or draft of artwork design from client.
- Create/revise artwork with printing vender.
- Ask the client to review and finalize the artwork.
- Order the packaging material with the finalized artwork version.
- Receive the packaging material and conduct incoming test according to the artwork version.

2. Package & Artwork development

For unique Japanese market, possible to support package configuration and artwork design development

Thank You

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