



Bushu Quality System

An internationally recognized, multi-dimensional standard which brings the highest level of product quality to our clients worldwide

CPhI Special Digest Version 2021

Quality Policy and Culture

Bushu Pharma's goal is to manufacture and package pharmaceutical products of the finest quality.

In order to fulfill this goal, we believe that it is important that every employee has a strong awareness that Bushu Pharma manufactures products which affect human lives and is committed to producing products with the highest quality attainable in our industry.

Bushu Pharma aims to cultivate a culture of Quality and ensure that all employees operate with a high sense of morality and ethics.

In addition to our on-going effort to cultivate a culture of Quality and ensure that all employees operate with a high sense of morality and ethics, we focus on ensuring quality in all elements of our business - from the processes we use for manufacturing to the way we approach delivery and supply chain management.

We combine these processes and know-how into the Bushu Quality Management System (QMS), which features:

1. The highest levels of Japan Quality, featuring an in-depth understanding of the quality requirements in Japan for the cosmetic quality of bulk drug and packaged products
2. Acceptance by regulatory authorities in multiple countries, including the US FDA
3. Strong capabilities for analysis of foreign materials
4. A business continuity plan which ensures stability of supply

'Japan Quality' takes Bushu Pharma to another level



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

We address the unique quality requirements expected by the Japanese market

- Cosmetic quality of bulk drug product
- Cosmetic quality of packaged products
- Foreign materials

Bushu Quality System Key Components

Robust GMP & QC System

Robust GMP system based on Japanese GMP, PIC/S GMP, and US cGMP. Have passed inspections by US FDA and other overseas authorities.

Quality Committee

Quality Committee holds meetings every month to review the effectiveness of individual GMP systems. The Committee reviews the efficiency and CAPA, the suitability of OOS, complaint management, and the status of the survey results of the contractor and public GMP.

Document Management System

Established individual procedures (SOPs) and other documents for each GMP activities and GMP documents are managed by Parma Document (Electronic QA Document System introduced recently).

Data Integrity

The data used for making decisions on developing, manufacturing, testing, delivering, and product monitoring at Bushu Pharma follows the principles of ALCOA+ (Attributable, Legible, Contemporary, Original, Accurate, Complete, Consistent, Enduring and Available).

Quality Control

Variety of tests can be performed by QC.

LIMS (Laboratory Information Management System) is used in the QC Lab.

Quality Statistics

<p>QA & QC dept</p> <p>More than 240 experienced staff</p>	<p>Regular & client inspection</p> <p>More than 40 times/year</p>	<p>GMP certification from:</p> <p>43 countries (USA, Euro, Southeast Asia, Middle East, Africa, Russia, Brazil etc.)</p>	<p>International business</p> <p>47%</p>
<p>Cold Chain Warehouse (at 2°~8°C)</p> <p>Kawagoe : 498 pallets Misato : 300 pallets</p>	<p>Clinical Samples Center</p> <p>Manufacturing and testing of clinical samples of solid dosages and injectables</p>	<p>GMP trained visual inspectors</p> <p>50 + Visual inspectors (Kawagoe) 20 + Visual inspectors (Misato)</p>	<p>Regulatory</p> <p>Access to Japanese market for international partners</p>
<p>Emergency Power</p> <p>100KL Oil Tank</p>	<p>EHS</p> <p>Environmental Committee, and Safety and Hygiene Committee in 2 sites</p>	<p>EHS International certifications</p> <p>Kawagoe: ISO14001 Misato: ISO14001 OHSAS18001</p>	<p>High containment</p> <p>OEL 0.1~1µg/m²</p>

Key Components of our Quality Policy

Bushu Pharma - High value contributor to human health

Establish a comprehensive quality assurance system and maintain high quality and reliability levels

Accurately grasp our clients' needs and always provide them with products of the highest quality

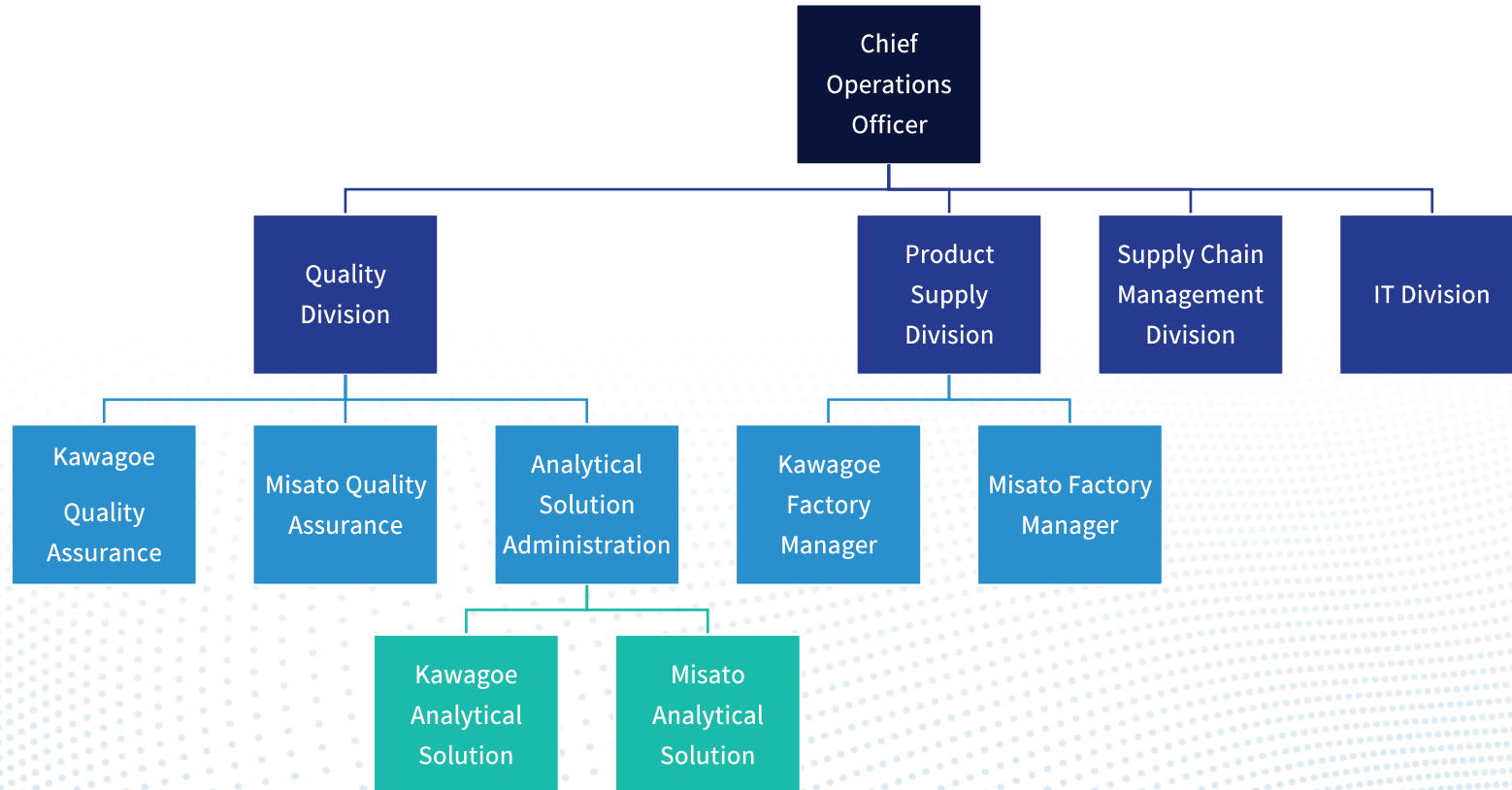
Seek out sophisticated technology and aim for even higher quality levels

Establish and ensure procedures for our quality system which apply internationally

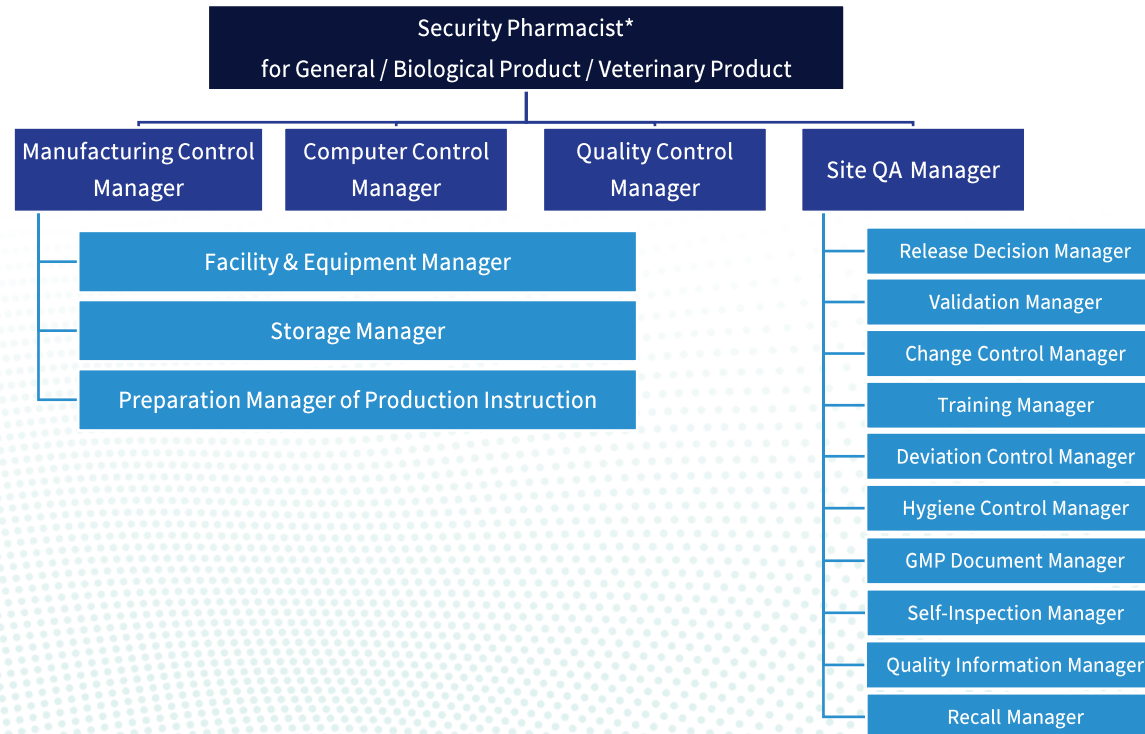
Apply the basic principles of data integrity required in manufacturing and quality control

Emphasize education and training to increase awareness of quality among all employees of Bushu Pharma

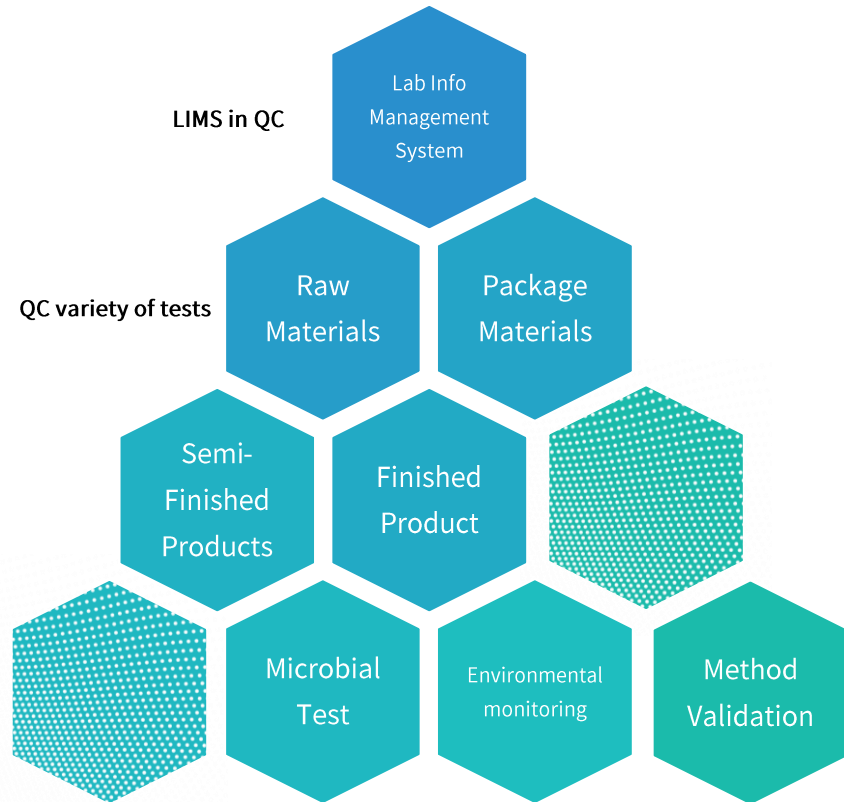
Scope of COO Jurisdiction



GMP Organization



* A 'Qualified Person' in the manufacturing plant



- LIMS
- QC can perform a variety of tests:
 - Raw Materials
 - Packaging Materials
 - Semi-Finished Products
 - Finished Products
 - Microbial Testing
 - Stability Testing
 - Environmental monitoring
 - Method Validation

- If there is a consumer complaint or an issue in the manufacturing process, a timely response is required.
- Both non-destructive and destructive analysis is available.
- Knowledge and experience of manufacturing for foreign materials based on the results of analysis.

Bushu Pharma fulfills all requests

* Confirmation of internal state by X-ray CT is also available



Methodology

1. Microscopic observation

2. Element analysis by X-ray Microscope

3. Identification by Raman

4. Identification by FT-IR

Japan Quality

Details of our QMS System

Cosmetic Appearance Protocol



Solid Dosage

The cosmetic quality of bulk drug product can be inspected by automated inspection machine or well-trained operators, with removal of defects (ex. foreign materials, dirty spots, chipped tablets, pigment agglomeration etc.) to meet Japan market requirements.



Injectable

Foreign materials in filled vials and syringes manufactured overseas can be inspected to remove the defects (ex. small glass fragments, fibers) to meet Japan market requirements by well-trained operators.



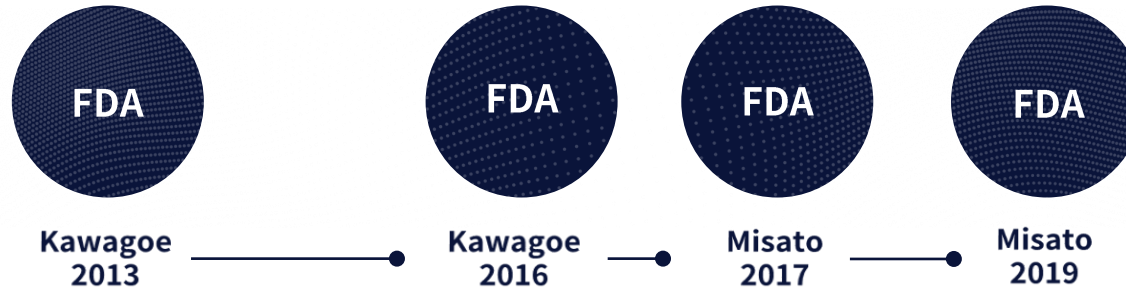
Finished Products

Cosmetic Quality of finished drug products can be inspected by well-trained operators and remove the defects (ex. dent, scratched carton boxes) to meet the Japan market requirements.



Globally Qualified

Inspection History by Foreign Authorities: Bushu Pharma has a high-quality management system and provides performance track-record as Asia Hub.



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



Thank You

www.bushu-pharma.com

Head Office / Kawagoe Plant

1 Takeno, Kawagoe-shi, Saitama, Japan

TEL : +81-49-233-4651

Misato Plant

950 Hiroki, Misato-machi, Kodama-gun, Saitama, Japan

TEL : +81-495-76-3111