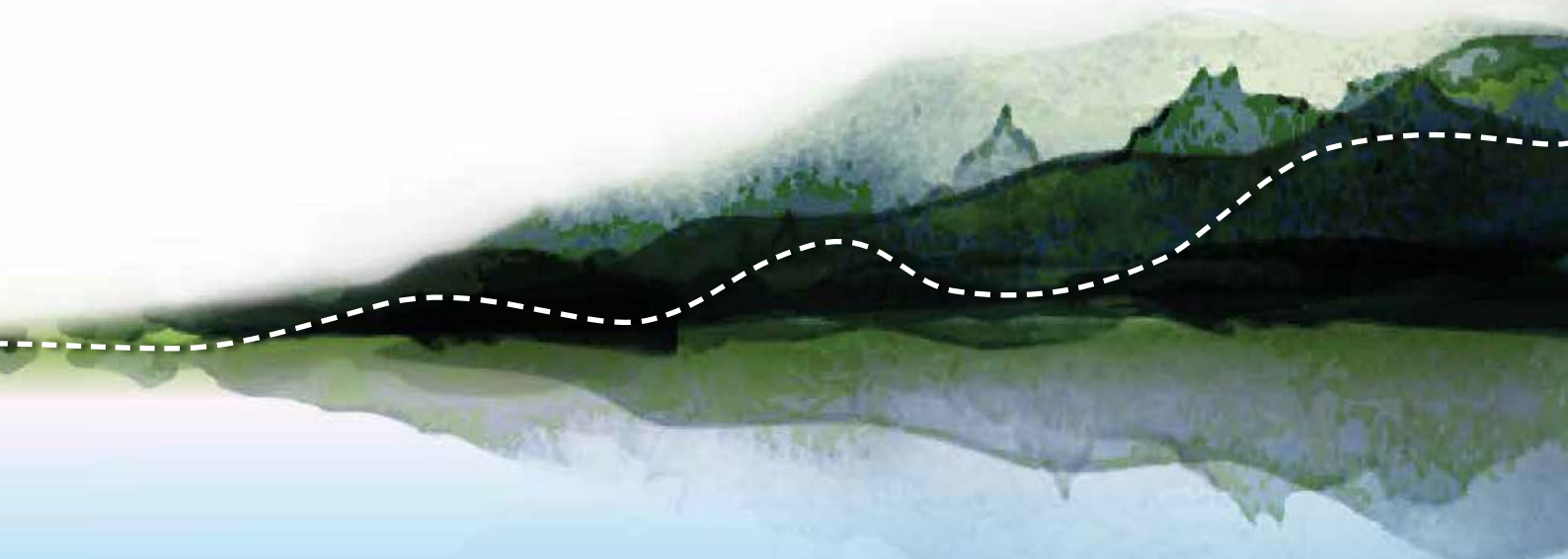
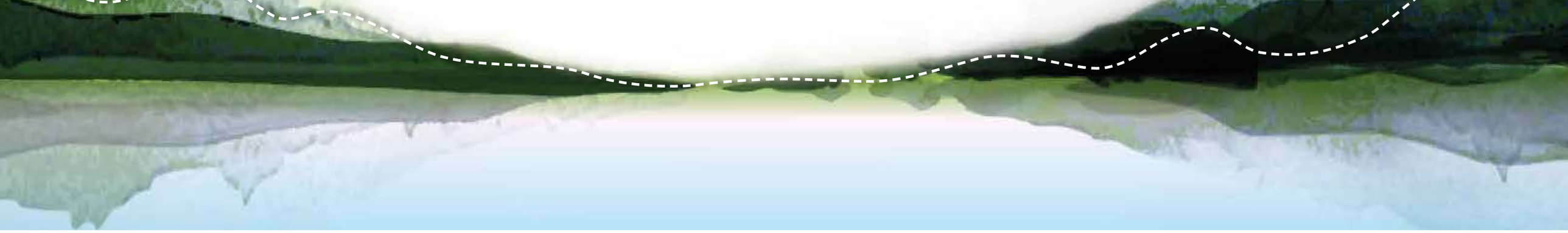
An eco-centric cdmo solution



Shionogi Pharma Co.,Ltd.　シオノギファーマ株式会社　SHIONOGI



Shionogi Pharma Co.,Ltd.

シオノギファーマ株式会社

SHIONOGI

Company Profile

Company Name: Shionogi Pharma Co., Ltd

Opening of Business: April 1st 2019
(Incorporated: October 1st 2018)

Paid-in Capital: 90 Million yen

Type of Business: Manufacturing and commercializing Pharmaceuticals and Investigational Medicine Product Analysis, Test and pharmaceutical engineering

Head Office and Settsu Plant: 5-1, Mishima 2-chome, Settsu, Osaka 566-0022, Japan
Tel : +81-6-6381-7322

Amagasaki Site: 1-3, KuiseTerajima2-chome, Amagasaki, Hyogo 660-0813, Japan
Tel: +81-6-6401-1221

Kanegasaki Plant: 7, Moriyama, Nishine, Kanegasaki-cho, Isawa-gun, Iwate 029-4503, Japan
Tel: +81-197-44-5121

Tokushima Plant: 224-20, Hiraishiebisuno, Kawauchi-cho, Tokushima, Tokushima, 771-0132, Japan
Tel: +81-88-665-2312

Shionogi Pharma Co., Ltd - an eco-centric cdmo solution

At Shionogi Pharma Co, Ltd we offer a high quality, comprehensive, CDMO (development & proposal CMO) service for investigational medicine & commercial production.

We are committed to production technology to develop Shionogi original manufacturing methods and products. We are an 'advanced technology development-type pharmaceutical company' that can compete globally. We will contribute to the development of the worldwide pharmaceutical industry to utilize not only pharmaceutical manufacturing contracting, but also our experience and advanced great technology in the fields of investigational medicine production, analytical testing and pharmaceutical engineering.

Our aim is to contribute to the improvement of the value of customer's individual products through our state-of-art technologicaldevelopment, continuous manufacturing of "pharmaceutical products" and "health related products".

Furthermore, we deliver our solutions in a sustainable, eco-centric manner with a combination of purification, low-emission and carbon off-setting techniques designed to minimize the impact of our facilities on the environment and allow our clients to meet their Corporate Social Responsibility (CSR) goals.

Japan
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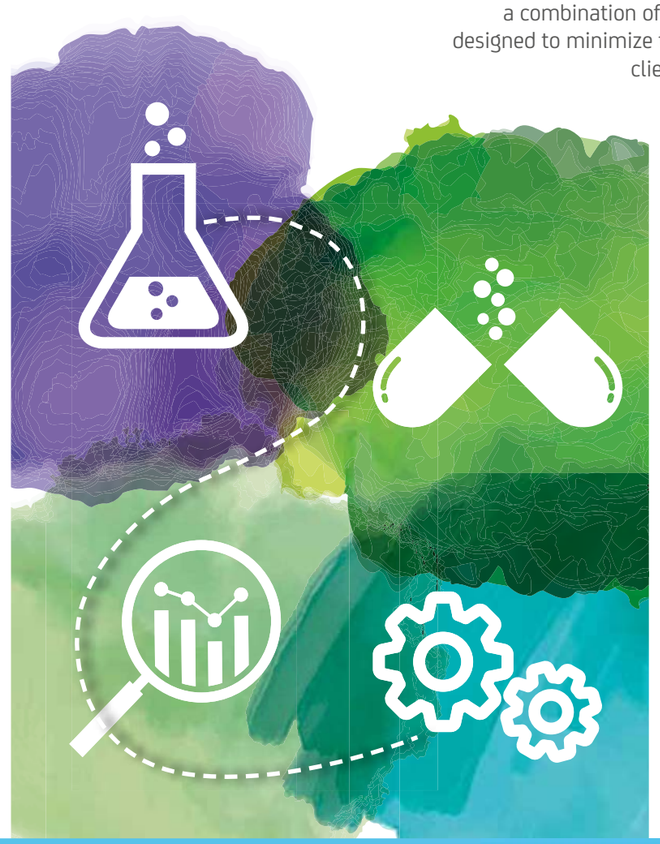
Made



Drug substance Development / manufacturing

Formulation Development / Manufacturing

Quality Management Analysis

Engineering Service

Stably supplying high quality products

that meet global standards to worldwide markets

Our FDA / EMA approved facility capability includes contract services specialized in the manufacture of high-quality products based on our comprehensive manufacturing technologies and quality control systems. We supply a world-wide client base. Our facilities have been inspected by international regulatory agencies including the US FDA and EMA.

① Tokushima Plant

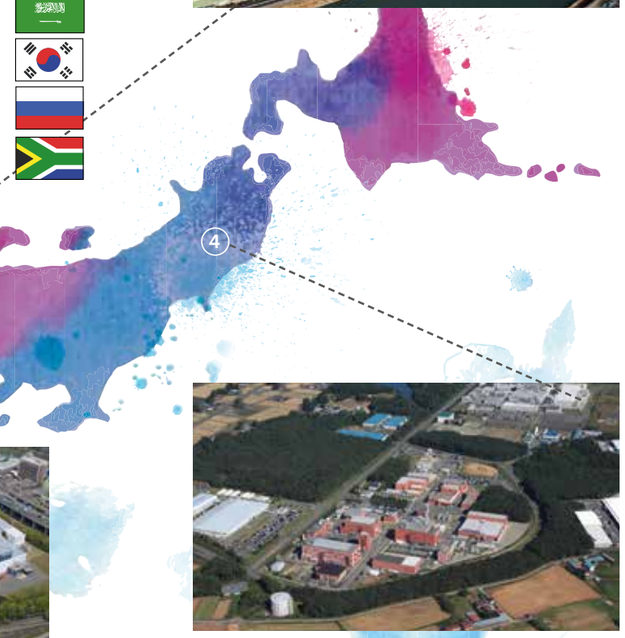
Established in 1976 in a pharmaceutical industrial park in Tokushima City, Tokushima Prefecture, this site manufactures general and highly pharmacologically active drug substance on a site of 15,019m².

③ Settsu HQ and Plant

Established in 1968 in Settsu City, Osaka Prefecture, this plant is equipped with an integrated formulation and packaging facility on a site of 161,000m². It is the plant with the flexibility to handle small quantities and varied projects

② Amagasaki Site

The team at the Amagasaki site uses their abundant experience in global new drug development to conduct drug discovery from research to manufacture of investigational medicine. This site specializes in new technology development.



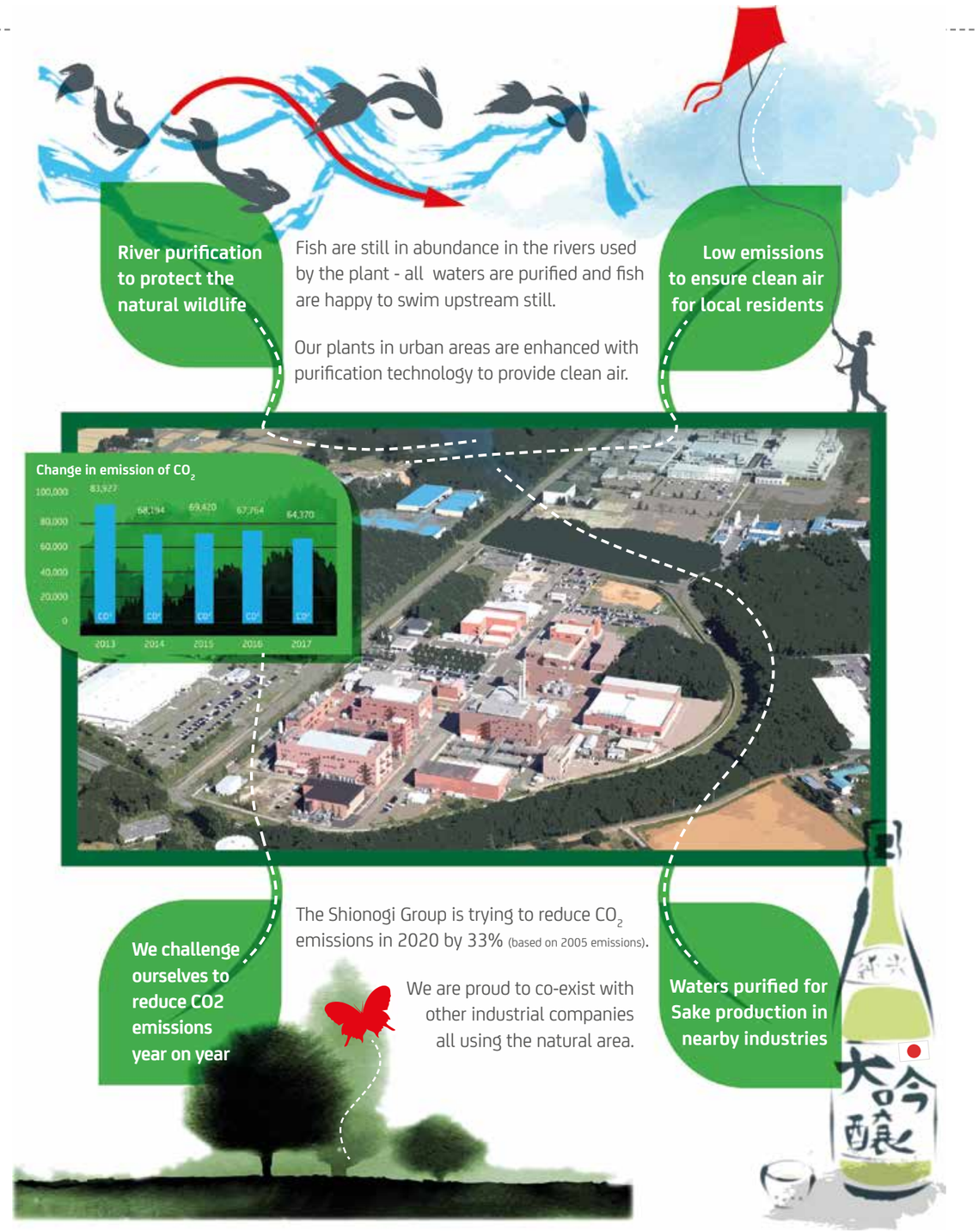
④ Kanegasaki Plant

Established in 1980 in Kanegasaki-cho, Iwate Prefecture, this site has integrated production facilities for Cephem and Carbapenem antibiotic drug substance, formulations and packaging on a site of 206,000m².

Our co-generation eco-system

for sustainable manufacturing

The Shionogi Group is committed to combating global warming and we are striving to reduce CO_2 emissions, and also We strive to protect water resources with Effective use of water resources and drainage through water quality management.



We offer the full pharmaceutical journey

providing value-added, high-quality products and services

Support for regulatory submissions, data collection for regulatory submission application and application support including: new drug applications or partial changes to approval matters.

SHIONOGI

Drug Substance /Process Development

Process design and development for drug substance (from reaction to isolation)

Process safety and environmental impact accessment

Improvement for manufacturing process (cost reduction, throughput improvement)

Synthesis of reference standards, impurities, and samples for Non-Clincial evaluation)

GMP testing, Environmental measurement analysis

Surface analysis:
Micro-area Morphological observation, Composition analysis and mapping analysis

Stability test/Quality test/validation for analytical methods

Environmental analysis:
Consultation for environmental management in compliance with law and regulation for pharmaceutical manufacturing facilities

Application Support

Data acquisition and support for regulatory submission

Analytical technology research and test method

Design and development of analytical methods for drug substance/ formulation process development

Design and development for Impurity evaluation methods (High sensitivity, micro analysis)

Design and development of Analytical methods for evaluation of the cleanness of manufacturing environment and cross-contamination

Formulation Design

Formulation Design (Oral, Injection, topical etc.)

Functional/Special Formulations (orally disintegrating tablets, multilayered tablets, sustained-release tablets, solid dispersions, bitter masking formulations, granules, dry syrups, etc.)

Improvement of existing products(improvement for dissolution, stability and stabilization for production)

Manufacturing of investigational medicinal products

GLP-Compliant production for Non-Clinical samples

Manufacturing of investigational drug substance and medicinal products

Various chemical synthesis (ca. 1-200kg) and formulations (Solid, Injection/Topical etc.)

Packaging Development

Packaging and Labelling design (Oral, Injection and Topical etc.)

Functional Packaging design (Barrier /child resistance packaging etc.)

User and environmentally friendly packaging

Commercial Manufacturing

Drug substance/intermediate/ commercial products(Oral/ Injection/Topical etc.)

Commercial production for not only general medicine but also special formulation developed on consignment and highly potent compounds

Manufacturing and supply to global market, and response to inspection by each regulatory authority

Industrialization

Industrialization (scale up and process optimization)

Technology Transfer (In-house, alliance CMOs)

Pharmaceutical Enginnering Services

Planning for new manufacturing plant, renovation, plant management

New plan, remodeling, renewal for production equipment

New construction, Remodeling and Renewal for HVAC, Pharmaceutical water and utility facilities

Validation services (URS, DQ, IQ, OQ including consultation for document prepration)

GMP audit service

Maintenance services (Periodic inspection/Maintenance, SOP cfreation)

Calibration(Monitoring system, Quality control facilities, measurement control systems)