

Overview of FUJIMOTO

 **FUJIMOTO CHEMICALS Co., Ltd.**



Slide Agenda

FUJIMOTO CHEMICALS

Who we are

- Company overview
- Products and services
- Manufacturing facility

Equipment List ~KINRAKU Plant~

- KINRAKU Plant
- SENBOKU Plant
- High Potency Active Pharmaceuticals



Slide Agenda

FUJIMOTO CHEMICALS

Who we are

- Company overview
- Products and services
- Manufacturing facility

Equipment List ~KINRAKU Plant~

- KINRAKU Plant
- SENBOKU Plant
- High Potency Active Pharmaceuticals



Company overview

Confidential

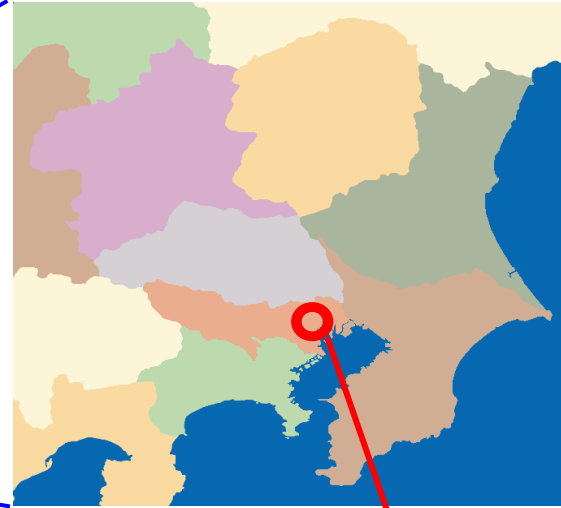
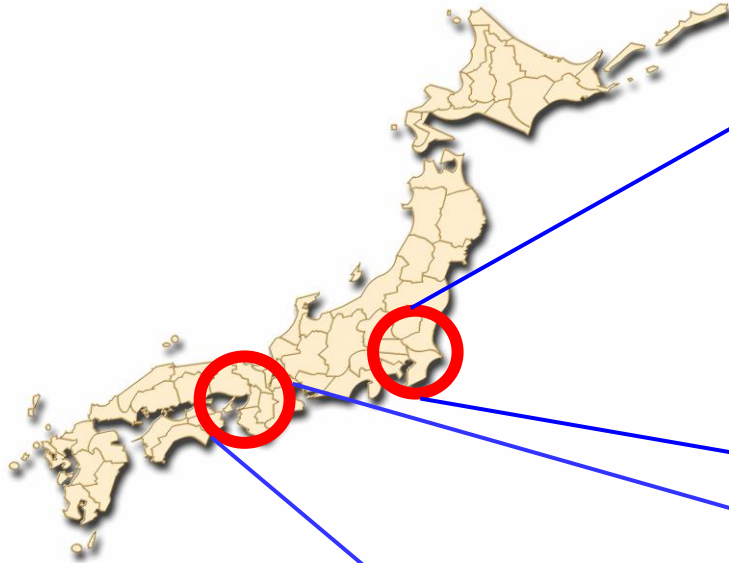
FUJIMOTO CHEMICALS

Corporate Name	FUJIMOTO CHEMICALS CO., LTD.
Representative	Kazumasa Fujimoto (President and CEO)
Date of Establishment	June 26, 1953
Headquarters	4-5-13 Dosho-machi, Chuo-ku, Osaka 541-0045, Japan
Employees	203 (April 01, 2020)
Main Business Activities	Contract manufacturing, development and trade of the following items: APIs, pharmaceutical intermediates, dyestuffs, industrial chemicals, etc.



Business Sites

FUJIMOTO CHEMICALS



Tokyo Branch

*KINRAKU Plant
and R&D*

SENBOKU Plant

Head Office



History of company

Confidential

FUJIMOTO CHEMICALS

- JUN. 1953** **FUJIMOTOCHEMICALSCO.,LTD.was founded**
- FEB. 1959** **Amagasaki Chemical Industries Co., Ltd. was founded**
- MAR.1966** **Kinraku Plant was established**
- JUN. 1970** **Senboku Plant was established**
- OCT. 1983** **Tokyo Branch was opened**
- OCT. 1990** **Research Laboratories was established**
- OCT. 2007** **FUJIMOTOCHEMICALSCO.,LTD.merged with Amagasaki Chemical Industries Co., Ltd.**



Products and services

FUJIMOTO CHEMICALS

We provide “One-Stop-Shop” service for exploration, scientific research, R&D and manufacturing. The following three are the main businesses.



PHARMACEUTICAL BUSINESS

- **Research & development**
 - process development, test method development, special technology, nucleotides technology
- **Contract manufacturing of API**
 - from milligram to ton scales
- **Quality assurance.**
 - quality assurance and production control system based on GMP



COSMETIC BUSINESS

- **Procurement of raw materials**
- **Sales of cosmetic ingredients**



CHEMICAL BUSINESS

- **Contract processing business**
- **Trading business**



Manufacturing facility

Confidential

FUJIMOTO CHEMICALS

We have highly pharmacologically active substance manufacturing facility.

We have multiple "highly pharmacologically active substance manufacturing facilities" that can manufacture from small (kg) to large (ton) scale.



It is possible to handle highly pharmacologically active substances up to Category 4.



We have a lot of inspection experience by the authority (incl. FDA) and customer audits and have been highly evaluated.

FDA Inspection performances

June 1991, May 1996, June 2000, June 2009, April 2013, March 2016, March 2019



Slide Agenda

Confidential

FUJIMOTO CHEMICALS

Who we are

- Company overview
- products and services
- Manufacturing facility

Equipment List ~KINRAKU Plant~

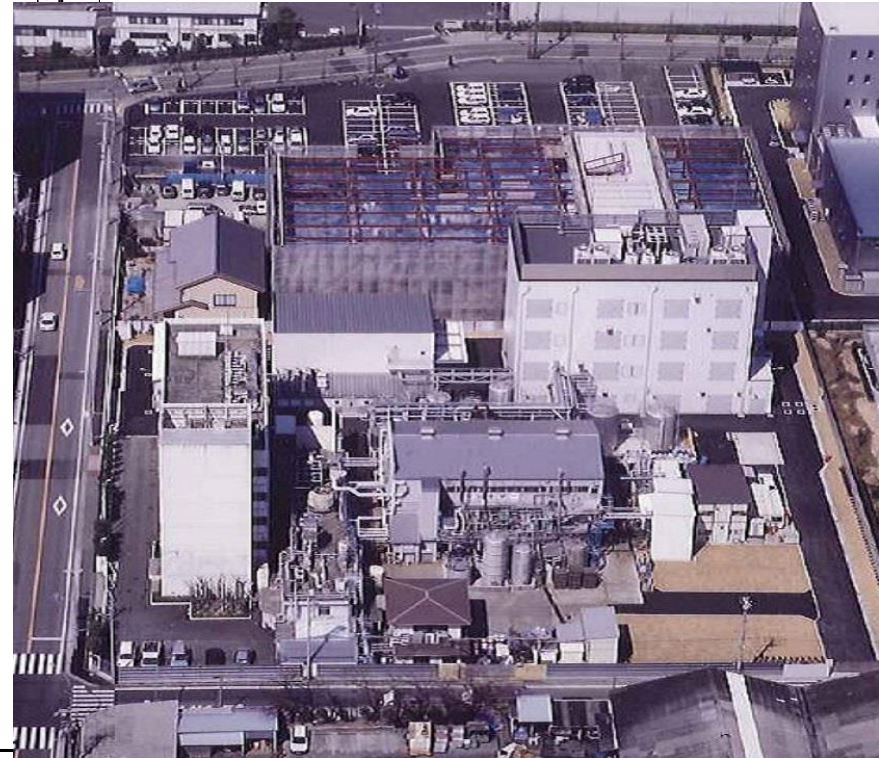
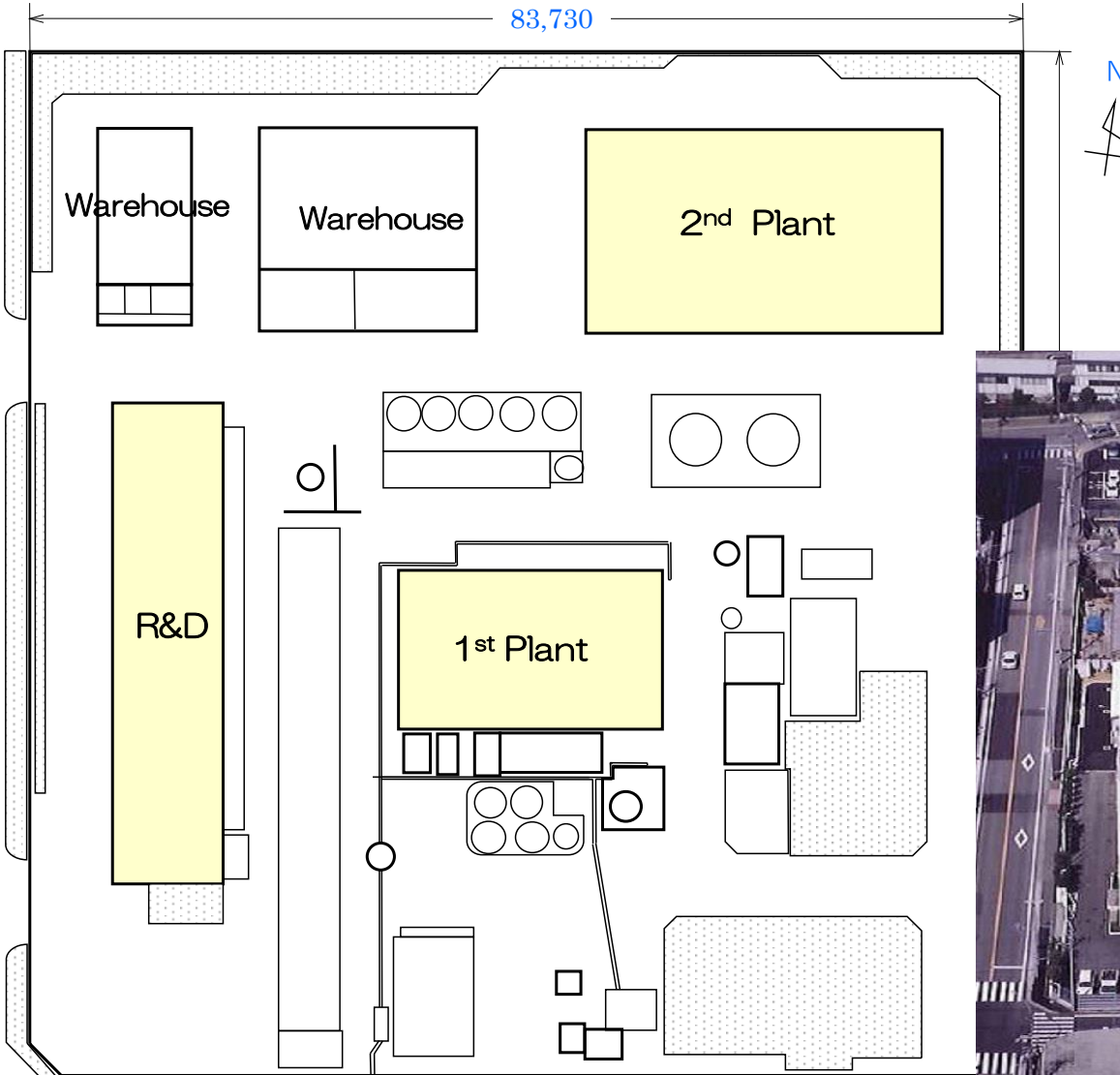
- KINRAKU Plant
- SENBOKU Plant
- High Potency Active Pharmaceuticals



Layout of KINRAKU Plant

Confidential

FUJIMOTO CHEMICALS





Equipment List ~KINRAKU Plant~

Confidential

FUJIMOTO CHEMICALS

<i>Equipment</i>	<i>Material</i>	<i>Size</i>	<i>Number</i>
<i>Reactor</i>	<i>GL</i>	<i>50 ~ 5000L</i>	<i>23</i>
<i>Temp: -15 ~ 120 °C</i>	<i>SUS</i>	<i>50 ~ 6000L</i>	<i>27</i>
<i>Centrifugal separator</i>	<i>SUS</i>	<i>20 ~ 42 inch</i>	<i>14</i>
<i>Pressure filter</i>	<i>SUS</i>	<i>0.3 ~ 0.8m³</i>	<i>2</i>
<i>Conical dryer</i>	<i>GL</i>	<i>250L</i>	<i>1</i>
<i>Shelf-type dryer</i>	<i>SUS</i>	<i>10 ~ 20m³</i>	<i>4</i>
<i>Column separator</i>	<i>SUS</i>	<i>23 ~ 1150L</i>	<i>8</i>



Equipment List ~Pilot Plant in KINRAKU~

FUJIMOTO CHEMICALS

<i>Equipment</i>	<i>Material</i>	<i>Size</i>	<i>Number</i>
<i>Reactor</i>	<i>GL</i>	<i>200L</i>	<i>1</i>
	<i>GL</i>	<i>500L</i>	<i>1</i>
	<i>GL</i>	<i>1500L</i>	<i>1</i>
	<i>GL</i>	<i>2000L</i>	<i>1</i>
	<i>GL</i>	<i>3000L</i>	<i>1</i>
	<i>HAS</i>	<i>500L</i>	<i>1</i>
<i>(~1.0MPa Autoclave)</i>			
<i>Centrifugal separator</i>	<i>SUS</i>	<i>30 inch</i>	<i>2</i>
<i>Shelf-type dryer</i>	<i>SUS</i>	<i>10m³</i>	<i>1</i>

Cleanroom: class 100,000

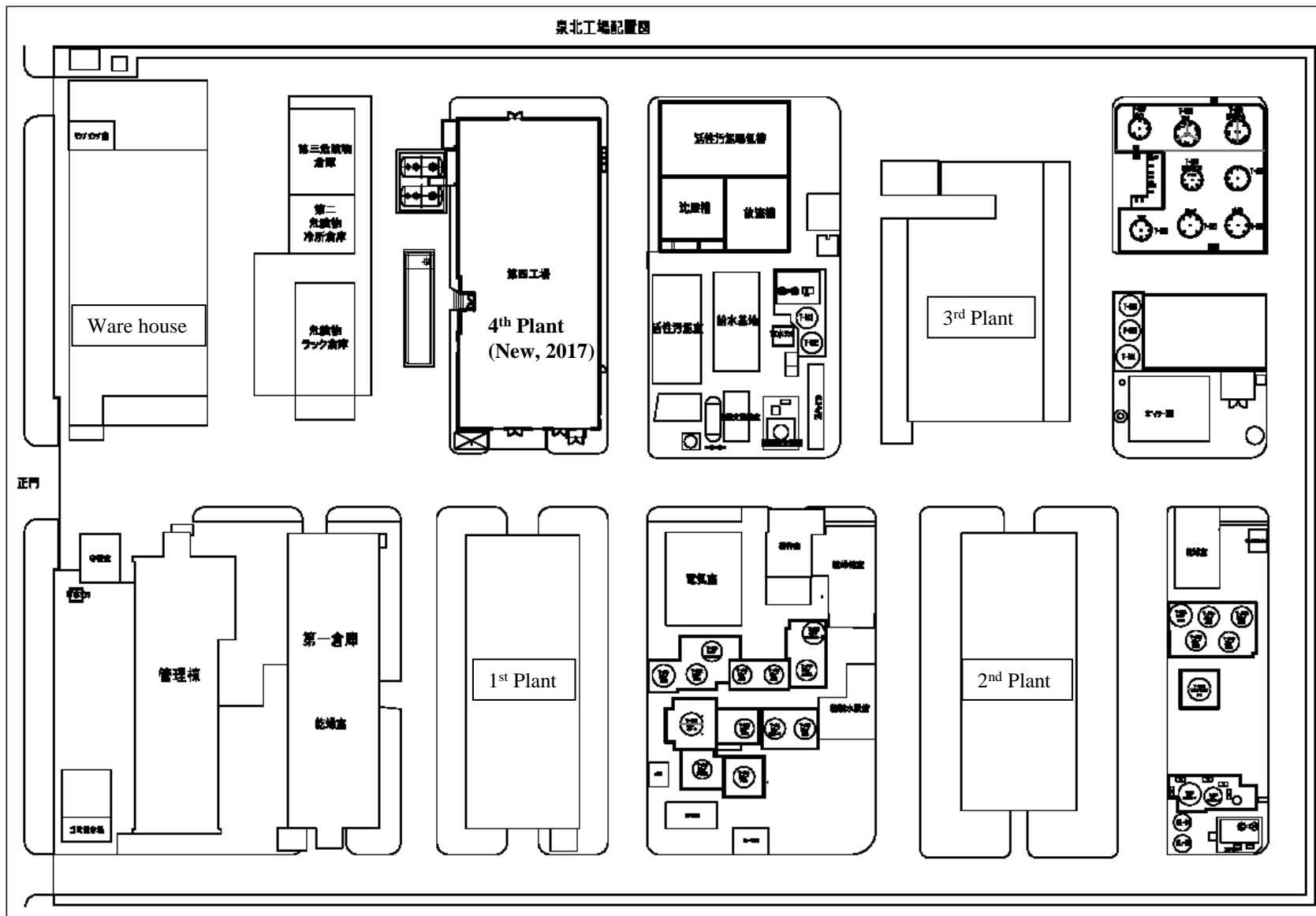




Layout of SENBOKU Plant

Confidential

FUJIMOTO CHEMICALS





Equipment List ~SENBOKU Plant~

Confidential

FUJIMOTO CHEMICALS

Equipment	Material	Size	Number
Reactor	GL	600~10000L	41
Temp:-15~120°C	SUS	300~6000L	9
	HAS	5000L	1
		(~1.0MPa Autoclave)	
Centrifugal separator	SUS	42~48 inch	17
Pressure filter	SUS	0.3~0.8m ³	2
Multistage-type pressure filter	SUS	1.3~5.6m ³	2
Conical dryer	GL	1500~2580L	4
Shelf-type dryer	SUS	10~20m ²	3
Vibrating feeder dryer	SUS	1150 & 1570L	2





High Potency Active Pharmaceuticals



Concept ①

Confidential

FUJIMOTO CHEMICALS

Batch Size : 5 kg/batch ~ Aprx. 100 kg/batch

OEL : 0.15 ~ 1.0 $\mu\text{g}/\text{m}^3$

Compliance of ICH Q7

⇒ Multi Purpose Plant for various type of APIs or Intermediates

【Hygiene Control】

- Performance evaluation of containment (Once a year)
- Handling as Clean Room (All Working Chambers)
 - ⇒ 1. Management as CLASS100,000
 - 2. Control of Temperature and Humidity (22 ± 3 °C、 50 ± 10 %RH)



Concept ②

Confidential

FUJIMOTO CHEMICALS

【First Containment】(Scattering Prevention)

- Using Isolator and Split Valve
 - Installation of Close System filter (Each Devices)
- ⇒Prevention of Powder Scattering and Direct Contact for Human Body

【Second Containment】(Containment of Working Chamber)

- Classification of Manufacturing Area
- Control of Differential Pressure
- Installation of Air Lock Room (with Inter Lock)
- Exhaust Ventilation via Double HEPA Filter



Equipment List ①

Confidential

FUJIMOTO CHEMICALS

● Kinraku Plant

	Material	Size	Number	P.S.
Reactor	GL	65L	1	-
		200L	1	-
		500L	1	-
	SUS	500L	1	~1.0 Mpa
Centrifugal Separator	SUS	36inch	1	-
Filter & Dryer	GL	250L	1	Conical Type
	SUS	60L	1	-
Pressure Filter	GL	15L	1	-
Grinding Machine	-	-	1	Jet Mill
	-	-	1	Speed Mill
Column Separator	-	80L	1	-
	-	140L	1	-



Equipment List ②

Confidential

FUJIMOTO CHEMICALS

● Senboku 3rd Plant

	Material	Size	Number	P.S.
Reactor	GL	1500L	2	–
		3000L	1	–
		5000L	1	–
Centrifugal Separator	SUS	36inch	1	–
Filter & Dryer	HAS	2500L	1	–
Grinding Machine	–	–	1	Jet Mill
	–	–	1	Speed Mill



Equipment List ③

Confidential

FUJIMOTO CHEMICALS

● Senboku 4th Plant

	Material	Size	Number	P.S.
Liquid Charge Equipment Dropping Tank	GL	1000L	1	—
	SUS	1000L	2	—
		2000L	1	—
Powder Charge Equipment Chamber of Powder	SUS	1500L	2	—
Reactor	GL	3000L	1	—
		8000L	2	—
		10000L	2	—
	SUS	500L	1	—
Centrifugal Separator	SUS	42inch	1	—
Filter & Dryer	HAS	2500L	1	—
Grinding Machine	—	—	1	Jet Mill 1000L Mixer



Grinding Machine

Confidential

FUJIMOTO CHEMICALS

Kinraku Plant

Type	Throughput	High Potency Active	P.S	Particle Size(D50)*
Pin Mill	1-10kg/hr	-	Screen: 0.3~3mm Usable N2gas	10~20 μ m
Jet Mill	0.1-1kg/hr	Acceptable	Air Consumption: 0.5Nm ³ /min	2~3 μ m
Pin Mill	1-10kg/hr	Acceptable	Screen: 0.3~2mm	10~20 μ m
Pin Mill	1-10kg/hr	Acceptable	Containment with Flexible Isolator Equipment of Multi-pin Rotor	10~20 μ m

* : Reference Value

Senboku Plant

Type	Throughput	High Potency Active	P.S	Particle Size(D50)*
Jet Mill	1-30kg/hr	-	Air Consumption: 3.2Nm ³ /min Unusable N2gas	2~3 μ m
Jet Mill	1-15kg/hr	Acceptable	Air Consumption: 1.8Nm ³ /min	2~3 μ m
Jet Mill	1-30kg/hr	Acceptable	Air Consumption: 3.6Nm ³ /min Mixable of grinded powder by 1000L Mixing Machine	2~3 μ m

* : Reference Value

If you have any interest, please feel free to contact us!



FUJIMOTO CHEMICALS Co., Ltd.

<https://www.fujimoto-chem.co.jp/>