Meet precisely and rapidly with medical needs,
continue to provide innovative and safe products and services.

J-Sol Medical

COMPANY PROFILE

Company Profile

Company name	J-Sol Medical Co., Ltd.
Headquarter location	2-5-16 Shimo-ochiai, Shinjyuku-ku, Tokyo 161-0033, Japan
Telephone no.	81-3-6914-4804
Fax no.	81-3-3950-6680
License holder for	Type I Marketing Authorization Holder of Medical Device Medical Device Manufacturer Specially controlled medical devices selling/ leasing Cosmetic Quasi drug ISO13485 certified

Greeting from President

Since our establishment in 1977, we have handled numbers of import approval of the latest medical devices from overseas ;we also sell our own products and provide all kinds of pharmaceutical affairs consulting for our clients. These experiences made us a professional company in the field of pharmaceutical affairs for medical devices and quasi-drugs. We appreciate all your supports over the years.

In Japan, the second biggest market of medical devices, despite of its world leading technology and the techniques of manufacturing raw material, Japan is having a trade imbalance with more than 65% of their medical devices depends on imports.

In 2015, we have employed excellent new staff in the development and production department; in addition, we have installed new medical device manufacturing equipment. “Realizing ideas” is our motto. Based on the Japanese spirit of “Monozukuri” (craftmanship), we work hard to improve the expertise of our staff. Together with our long built pharmaceutical affairs consulting business, we will unerringly and speedily provide our customers with highly value-added products that are both innovative and safe. Moreover, we aim to become a company with global vision that contributes to medical development by providing our most up-to-date knowledge such as best practices gathered through our domestic and overseas business partners.

We thank you again and look forward to having your further support.

Takeshi Oi **President, J-Sol Medical Co., Ltd.**

Provide a "One-stop-solution" service

By linking with small and middle size companies that understand the market needs, we provide a centralized service from consulting to system building and follow-up.
Such a "One-stop-solution" service maximizes the satisfaction of our customers.

Good release into the market

Inspection

Our staffs who have received regular education training inspect products carefully based on requirement, pack/label required by regulations for inspection passed products. As a Marketing Authorization Holder, we can dispatch product into the market after making product release decision according to QMS.

Production

Transfer production system in accordance with QMS ministry ordinance to your company or to other related manufacturers.

QMS Conformity

Review SOPs for Marketing Authorization Holder/Manufacturer, review records (delivery, deficiency, corrective actions etc.) and support until the inspections finished.

Preparation of application

Acquire data from overseas manufacturer, prepare application, answer questions asked by authorities.

Safety Efficacy

Support communication with testing institutions for electrical safety, biological safety tests and animal tests.

Verification

Provide data measurement regarding the efficacy of medical device.
We support the communication with testing institutions if we outsource the procedure.

Prototype

Make prototype of product based on specification. We make prototype in our own facility.
Moreover, as we are equipped with a 100,000 class level clean room, we can make prototype in the clean room according to the requirement of customers.
We also outsource the production of prototype to our business partners.

Specification

Meet and discuss the requirement of customers to decide the specification of product.

From development to follow-up, *we coordinate the whole process.*

Providing pharmaceutical affairs solution

Since our establishment in 1997, we have been consulting the preparation of import medical device approval application to the Ministry of Health, Labor and Welfare. We know how to solve the problem that a small and middle size company has to face when they try to enter into the medical device industry. Especially, as a registered Manufacturer and a Marketing Authorization Holder, we have excellent reputation in preparing QMS Inspections for our customers and we can provide the best solution for those customers who have difficulties in preparing SOPs etc.

Application has been an obstacle to most of the companies and that is why almost 65% of the medical devices used in the Japanese market are imported from overseas. However, we believe that quite a number of these devices can be manufactured domestically and as a “Medical device total solution” company, we will keep on meeting the needs of different kind of medical devices.

Our company provides medical total solution

Support and prepare the documents need for notification and approval application to PMDA

Support from the preparation of notification and approval application to authorities need for the selling of medical device to acquisition of approval after application.

Support and prepare approval application to notify bodies

Support from the preparation of approval application to notify bodies need for the selling of medical device to acquisition of approval after application.

Consulting of testing requirement needs for medical device evaluation

Advise the testing requirement needs for the evaluation of efficacy and safety of medical device. We also introduce testing institution specialized in safety test.

Consulting of QMS

For those customers involving in design/development, it is obligated to receive QMS inspections from notify bodies or PMDA. We support the preparation of documents need for the inspections.

Consulting of pharmaceutical affairs strategy

Advise the best way to enter the medical device market. As our company has acquired the Type I Marketing Authorization Holder, our customers can release all kinds of medical device into the market through us.

Consulting of medical device storage

Our company holds Registered Manufacturer class warehouse needs for storing medical devices.

Centralized service from application preparation to product handling

As operation dealing with medical devices requires deep expertise and that is why medical devices related companies are specialized in different domains such as companies that prepare application/approval, companies that store medical devices, and companies that support the QMS inspections etc.

We contribute to our customers by providing a total solution for medical devices and our customer can cut their cost through centralization of all the operations through our services. We also have staffs fluent in English who are ready to support communication with overseas companies and provide translation for import.

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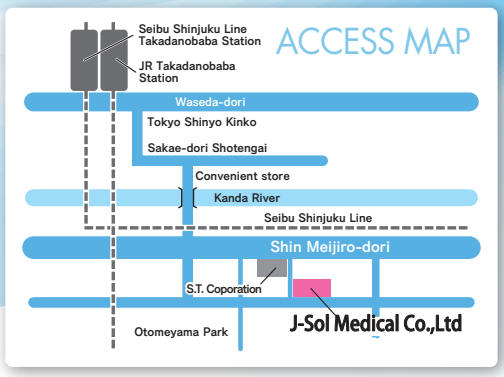
Low cost
(Contract with us that can provide centralized operation)

Enterprise A
(Pharmaceutical Affairs Consultant)

Enterprise B
(Manufacturer, Marketing Authorization Holder Approval)

High cost
(Contract with several companies)



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URL：https://www.j-sol-medical.co.jp

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