Medical device manufacturing and sales agency service

Q&A

D-MAH Medical Japan Co., Ltd.

Contents

【Responsibilities of MAH】

How are the roles of the three parties—medical device manufacturer, MAH (your company), and distributor (our company)—divided?

Customer

The medical device manufacturer is responsible for the design, assembly, sterilization, and manufacturing management of the medical device.
The marketing authorization holder (MAH) assumes responsibility for quality control and sales management within Japan.
Distributors basically only sell to medical institutions.

I see. What exactly is the MAH responsibility?

MAH responsibility refers to ensuring product quality (QMS) and supervising whether it is used safely (safety management/GVP).
These tasks need to be performed routinely.

I see.
So, your company is the one that assumes this responsibility, right?

Yes, that's correct.

I don't think our company has the capacity to take on these obligations yet, so it's probably better to leave it to you…
Thank you very much.

【 Overview of manufacturing and sales agency services 】

I am thinking of starting manufacturing and sales of medical devices.
Could you explain what your contract manufacturing and sales service is?

Customer

To manufacture and sell medical devices, companies must first obtain licenses and approvals and obtain regulatory approval (certification) for their products.
Even after they are released onto the market, they must also thoroughly implement quality and safety management systems such as QMS/GVP, and undergo regular inspections by regulatory authorities!

I see. That sounds like a lot of work!

On behalf of your company, we take on these heavy responsibilities of marketing and call this service the “Contract Manufacturing and Sales Service.”

That would definitely make things easier for us.

Yes, In other words, our company will be the marketing authorization holder for this product, and your company will act as the general distributor (sales), selling the product in the market.

I understand. What exactly does the contract manufacturing and sales service do?

Customer

As a marketing authorization holder under the Pharmaceutical and Medical Device Act, we perform all of the following duties:

- Handling regulatory procedures for the product
- Acting as the point of contact with regulatory authorities
- QMS and GVP-related tasks

(Quality management, manufacturing management, and safety management duties)

- Market release judgment
- Management of foreign manufacturer registration
- Management of changes to products or manufacturing sites

That is very helpful!
Thank you very much!

【 Flow of manufacturing and sales agency service 】

What is the contract period for manufacturing and sales agency?

Customer

Well, normally it's 1 year contract, but we can flexibly accommodate your requests. Of course, contract renewal is possible.

What are the manufacturing and sales agency fees?

The costs of QMS and GVP operations for the target products include a monthly fixed license management fee and a product market release judgement fee.

The agency fee does not involve the purchase and resale of products.

So, rather than a purchase-and-resale model, it basically means paying a fixed monthly fee.

Yes, that's correct.
The payment for purchasing the products is made directly by the distributor to the manufacturer.

Our company is not involved in the product payments and does not engage in wholesale.
Therefore, please consider the distributor's purchase cost as the manufacturer's wholesale price.

That would be helpful.

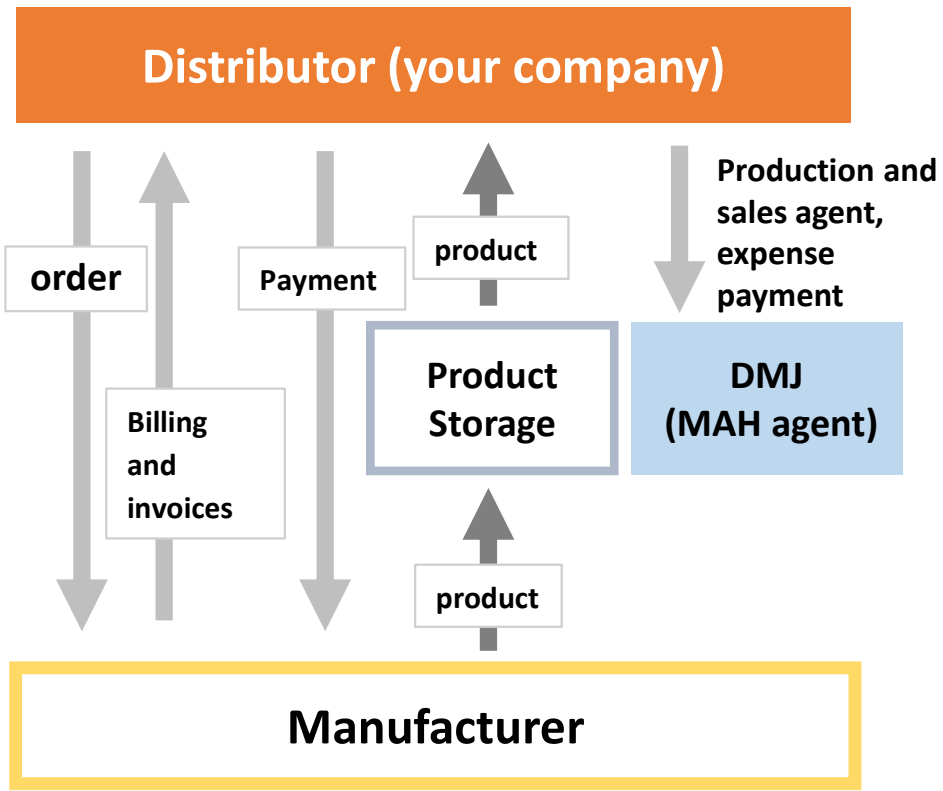
Customer

How do orders and payments to medical device manufacturers work?

Customer

Generally, your company will be responsible for placing orders with medical device manufacturers, and for making payments directly to the manufacturers.

Please see below for details.



Who will be the contracting parties and who will bear the costs for the manufacturing and sales agency service?

Customer

It depends on the case, but it is decided through discussion between the manufacturer (domestic or overseas) and the distributor.
In most cases, the distributor has borne the cost.

Will our company (the distributor) be purchasing products from you?

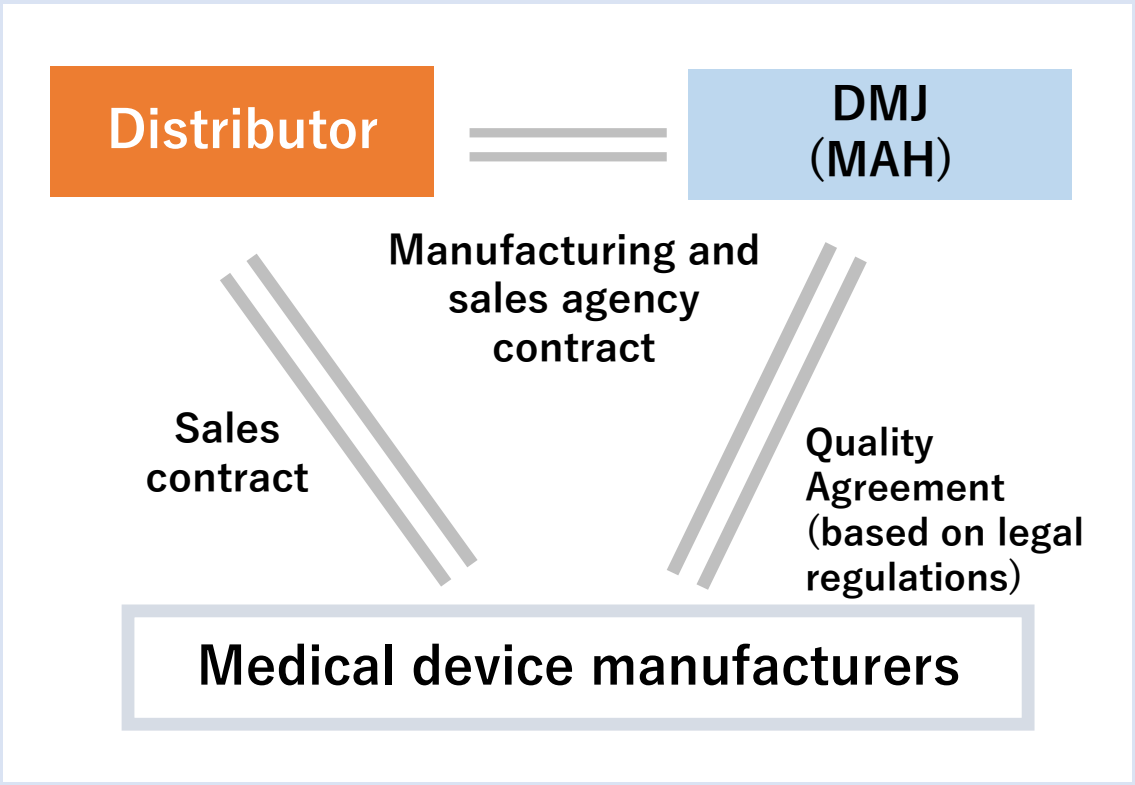
Our company conducts manufacturing and marketing operations under the Pharmaceuticals and Medical Devices Act, and, basically, we are not involved in the commercial transactions of the products.
The products are purchased under a direct agreement between the manufacturer and the distributor.

If our company (the distributor) enters into a manufacturing and sales agency contract with your company, will there be no particular contract or negotiation between your company and the manufacturer?

When entering into a contract for manufacturing and marketing agency services with your company, there will be no specific contracts or negotiations between our company and the manufacturer on your behalf.

However, as a marketing authorization holder, in order to manage and maintain the quality of the manufacturer's products, we will directly establish agreements with the manufacturer regarding product quality and changes, as required under the Pharmaceuticals and Medical Devices Act (QMS regulations).

Please see below for details.



Thank you for the easy-to-understand explanation.

Customer

【Products eligible for manufacturing and sales agency service】

By the way, what kind of medical equipment do you handle?

Customer

Our company has obtained a Type 1 manufacturing and sales license, and can handle all medical devices, regardless of classification or whether they are for medical professionals or home use.

For example,
[Class I]
- Medical forceps, respiratory sensors

[Class II]
- Medical device programs, dental materials

[Class III]
- Carbon dioxide lasers, dental implants

[Class IV]
- Biological products

We have represented the manufacture and sale of over 70 products to date! Many of them are overseas products.

I understand. You have a lot of experience!

【 What is DMAH/MAH? 】

There's one thing I'd like to ask you...

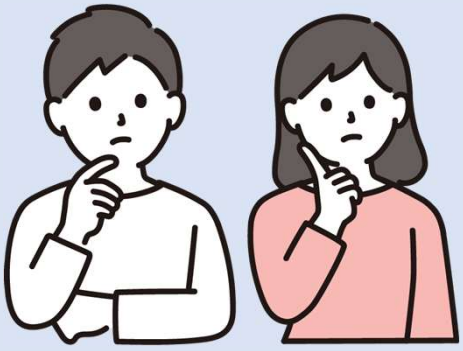
What is a DMAH (Designated Marketing Authorization Holder)?

Customer

Yes!
When a foreign manufacturer that holds its own product approval (certification) exports and sells medical devices in Japan, it is necessary to appoint a Japanese company as the importer/manufacturer/distributor.

This designated manufacturer is called a designated marketing authorization holder (DMAH).

I see...
What's the difference between a DMAH (designated marketing authorization holder) and a MAH (marketing authorization holder)?



That's right...
Basically, the work performed by DMAH and MAH is the same. The difference is who holds the product approval/certification.

In the case of DMAH, the foreign manufacturer is the product approval /certification holder, and in the case of MAH, the Japanese manufacturer/distributor is the product approval/certification holder.

Customer

I now understand the difference between DMAH and MAH.

Regarding the product we are considering,
will the overseas manufacturer have approval (DMAH) or should your company have it (MAH)?

In any case, it's safe to assume that the content of the manufacturing and sales agency service won't change much.

Yes, that's right!

I understand. Thank you!

【Management of manufacturing & quality control】

When using the medical device agency service, who is responsible for the manufacturing and quality control of the medical devices?

Customer

This will be led by our company, which handles manufacturing and sales.

Of course, we also monitor the manufacturing and quality control status of the manufacturing sites (both domestic and overseas). Please rest assured!

This is helpful as we want to deliver quality products to our users!

Even if we want to control quality, we don't even know how to do it...

Leave it to us!
Our QMS professional staff thoroughly manages quality control not only in-house but also for manufacturers.

【 About logistics 】

In addition to being a distributor, our company holds a license for medical device manufacturing (storage).

Customer

If we enter into a manufacturing and marketing authorization contract with your company, would it be possible to have foreign products delivered directly to us?

Yes, it is possible.

Of course, you can also outsource to a logistics company. As we are affiliated with Suzuyo Co., Ltd., we can handle everything from obtaining regulatory approval to logistics.

That's efficient!

Will it be possible for our company (the distributor) to obtain permission to manufacture and sell the product in the future?

Of course it is possible!

We also provide support for product transfer procedures, obtaining manufacturing and sales licenses, and establishing QMS/GVP.

【 Regarding product defects 】

What happens if a product is defective when it is imported from a foreign country?

Customer

The MAH (our company) cannot repair or modify the product.
You will need to return it to the manufacturer or ask a specialist to handle it.

I see. By the way, can we also outsource repairs, maintenance, and customer support services?

We are sorry, but at the moment we are unable to provide repairs, maintenance, or contact you for inquiries. Please contact your company or a specialist to handle these.

I've got it.

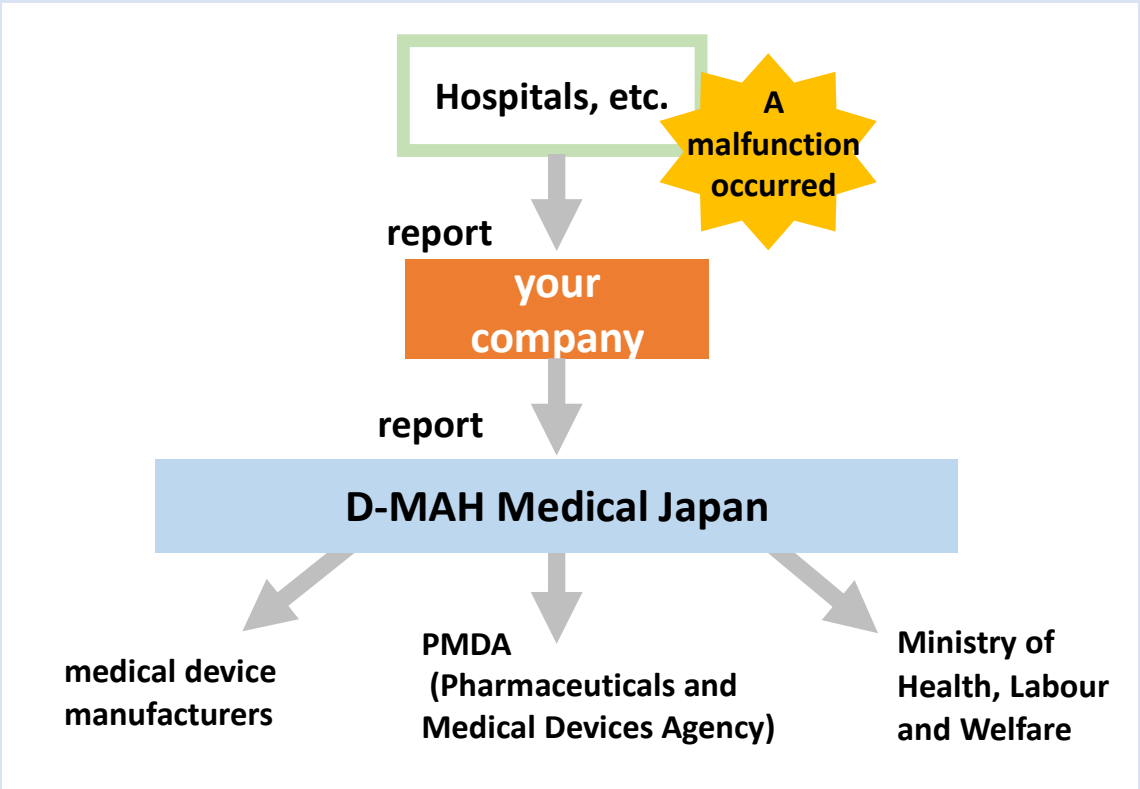
By the way, what should our company (the distributor) do if we receive a report of a malfunction or health damage caused by medical equipment?

Customer

Please report this to the Marketing authorization holder (our company).

We will respond to administrative requests and take the necessary measures in accordance with the QMS Ministerial Ordinance and the GVP Ministerial Ordinance.
If you are notified of a malfunction or health hazard, please report it as soon as possible and provide as much detailed information as possible, and we will handle the rest.

Please see below for details.



I understand. Thank you!

【About Sales】

If we outsource manufacturing and sales to your company, will our company be the only distributor of the product?

Customer

Of course, that's correct.
Unless specifically instructed by your company, we will not outsource the delivery of products to any other party, so please rest assured.

I have one more question...If we entrust your company with manufacturing and sales, are there any restrictions on our (the distributor's) promotional activities?

There are no restrictions. You are free to create and distribute catalogs as you wish.

In addition, in accordance with advertising regulations under the Pharmaceutical and Medical Device Act, we will check the content of advertisements before their distribution.

It's actually a good idea to check the ads beforehand.

Yes, feel free to sell as you wish, as long as you comply with the regulations!

【MAH fees and contracts 】

Since this is a newly introduced product, there may be months when there are no sales records (import records).
In this case, will there still be manufacturing and sales agency fees?

Customer

Under the Pharmaceutical and Medical Device Act, as the marketing authorization holder (our company), we are required to carry out QMS and GVP operations regardless of sales performance.

Therefore, manufacturing and sales agency costs will be incurred.

In addition, inspection costs and other work-related costs that vary with quantity are generally not incurred.

If the supply of the product is stopped or sales are discontinued, what will happen to the manufacturing and sales agency contract?

The work will be completed once the certifications/approvals have been processed.
If such a schedule is planned, please contact us as early as possible.

Understood. Thank you very much.

【 Pharmaceutical and Medical Device Act Procedures 】

Customer

Who handles the product's Pharmaceutical and Medical Device Act procedures?

Everything is handled by the MAH (our company).
We obtain the necessary information from the manufacturer and handle not only new approval (certification) but also any subsequent change applications, so you can rest assured.

Regarding the product's trade name, we will reflect your company's preferences.

I see. Also, when medical devices manufactured at overseas manufacturing facilities are imported into Japan, do QMS inspection organizations go overseas to inspect them?

To inspect the manufacturing plant's QMS (manufacturing management and quality control) for compliance, document inspections and/or on-site inspections will be conducted on a case-by-case basis.

That's a bit worrying.

We will check the QMS status of the manufacturing plant in advance and provide advice as necessary, so please rest assured!

That would be helpful!

【 Medical Device QMS and ISO 】

Customer

This is a general question, but what is the difference between ISO13485 and the QMS Ministerial Ordinance?

ISO13485 (※1) is an international standard for quality management systems for medical devices.

The QMS Ministerial Ordinance (※2) is a standard for manufacturing management and quality control of medical devices under Japanese law (Pharmaceutical and Medical Device Act).
This was established based on ISO 13485 (※1) from the perspective of ensuring international consistency, but there are some differences in content.

I see.
I've heard that having ISO certification is beneficial for QMS inspections...

Yes, the inspection process will be simplified.
Since our company is ISO-certified, the process is mostly streamlined, which also shortens the time to market.

Speed is important, so this is a great advantage.
Thank you.

※1 ISO 13485:2016
Medical devices --Quality management systems --
Requirements for regulatory purposes
※2 Ministry of Health, Labour and Welfare Ordinance No. 169 (December 17, 2004)
Ministry of Health, Labour and Welfare Ordinance on Standards for Manufacturing and Quality Control of Medical Devices and In Vitro Diagnostic Reagents

Company Profile

Company Name: D-MAH Medical Japan Co., Ltd.
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TEL: +81-3-5614-2759 / **FAX:** +81-3-5614-5020
Representative Director: Hideki Fujitsuka
Affiliated Company: Expartner Japan Co., Ltd.
Licenses & Certifications:

・Marketing Authorization for Class I Medical Devices (License No.: 13B1X10004)
・Marketing Authorization for Class II Veterinary Medical Devices (License No.: 5 Seihan Ryo II No. 202)
・ISO 13485:2016 Certified Facility

Business Description

Medical device manufacturing and sales agency services (QMS, GVP services)

Regulatory procedures (approval, certification, notification)

Other regulatory-related consulting services

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