User guide

Marketing license and site registration

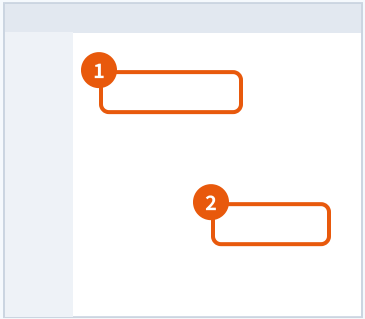
Prepare for the medical device marketing authorization license and manufacturing site registration, following the target license, the three officers, sites, procedures, application and license, with photos of the real screens.

The screenshots were taken with sample data.

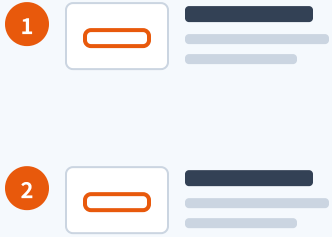
How to read this guide

- The numbered boxes on each screenshot show where to press or type. Read them together with the explanation of the same number in the right-hand column.
- The screenshots were taken with sample organization data.

What a page looks like



A photo of the screen. The numbered boxes show where to press.



The row with the same number shows a close-up of that place and what it does.

What you can do in Marketing license and site registration

- The product class and pathway tell you which license you need.
- Appoint the three officers, record qualifications, register sites and sign procedures in the order of the road. If a combination is not allowed, the reason appears before you appoint.
- The consultation and application timing is estimated backward from the launch month.
- Enter the license number and it is recorded in the company database. The license is valid for 5 years; when an officer changes, file the change within 30 days.

Who can use it

- Organization staff can view; organization administrators appoint, save and record the license.
- Each person enters their own qualifications (education and experience). Only they and organization administrators can see them.
- Procedures are signed by the three officers.

What this guide covers

1 Marketing license and site registration

The product class tells you the target license

Move staff into the three officer roles

Combinations that are not allowed show the reason before you appoint

Press a site's steps to see whether registration is needed

Create procedures from templates and ask the three officers to sign

Create procedures from templates and ask the three officers to sign

Work back from the launch month to see if you are on time

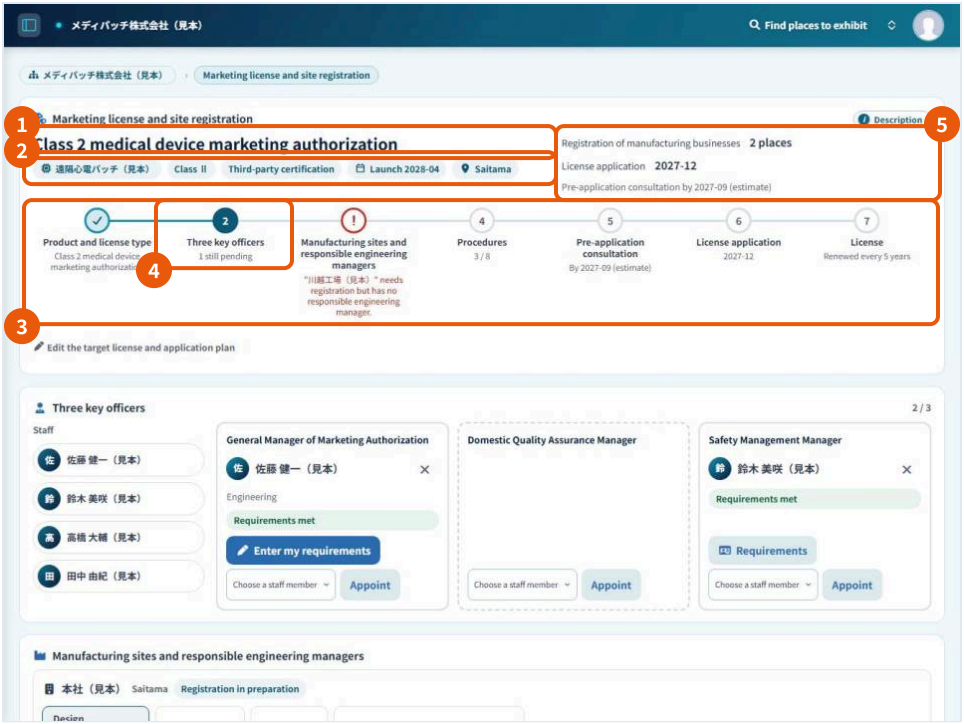
Enter the license number and you become a medical device maker in the company database

1

Marketing license and site registration

8 screens

The product class tells you the target license



1 **Target license**
A Class II certified product needs a Class 2 marketing authorization license.

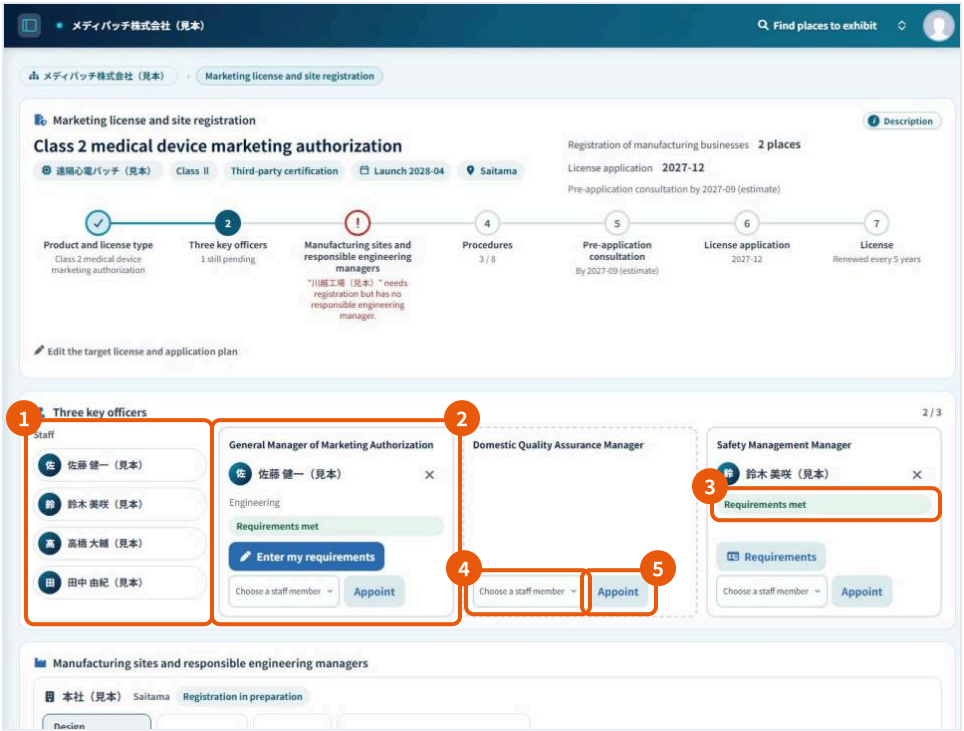
2 **Product and launch month**
Product, class, pathway and launch month from the development sheet, and the prefecture you apply to.

3 **Road to the license**
Seven stages: product and license type, the three officers, sites, procedures, consultation, application and license. Finished stages get a check.

4 **Current stage**
The first unfinished stage is highlighted. Press it to jump to that section.

5 **Registration and timing**
Number of manufacturing registrations, the application month and the consultation target.

Move staff into the three officer roles





Staff

Your organization's staff. Drag a person onto a role to appoint them.



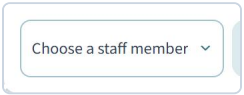
General manager

Shows who is appointed and whether they meet the requirements.



Requirements

Each person enters their education and experience. When they qualify, it says so here.



Choose staff

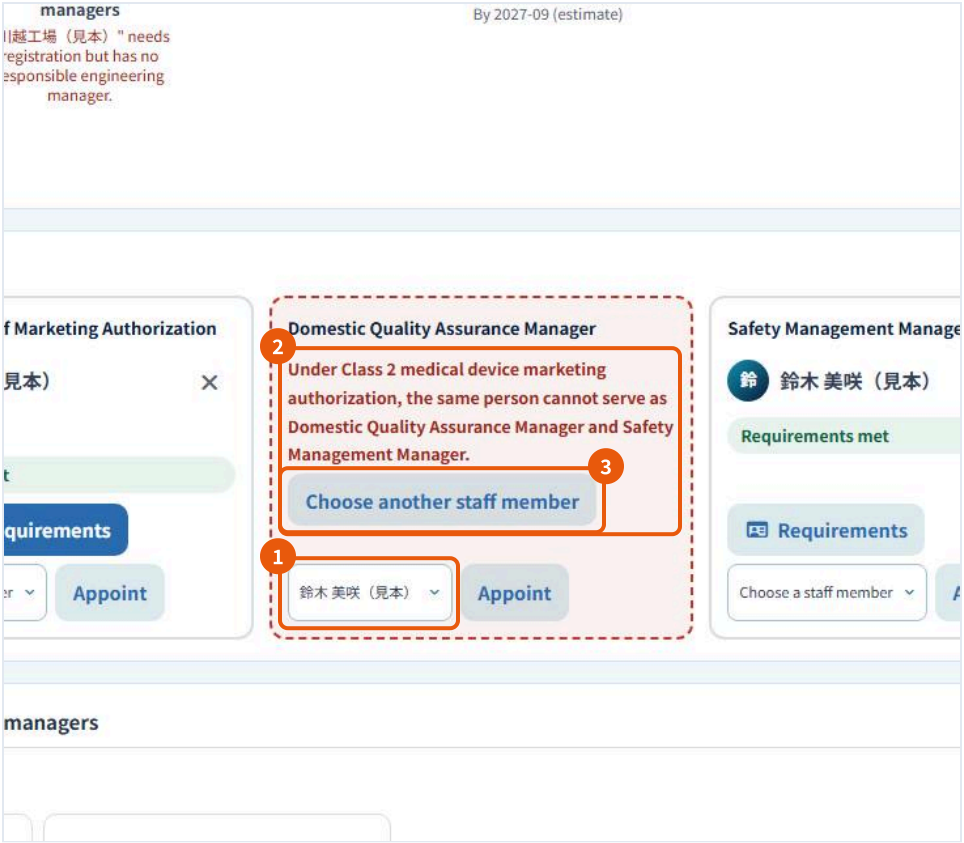
If you cannot drag, choose here. With a keyboard, press Space to pick up and use the arrows to choose a role.



Appoint

Press to appoint. The person gets a chat request to enter their qualifications.

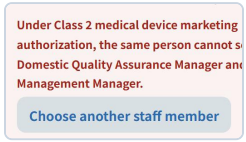
Combinations that are not allowed show the reason before you appoint



1 

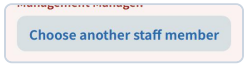
Choose someone who cannot combine

Choose Suzuki, the safety manager, as domestic quality manager.

2 

Why it is not allowed

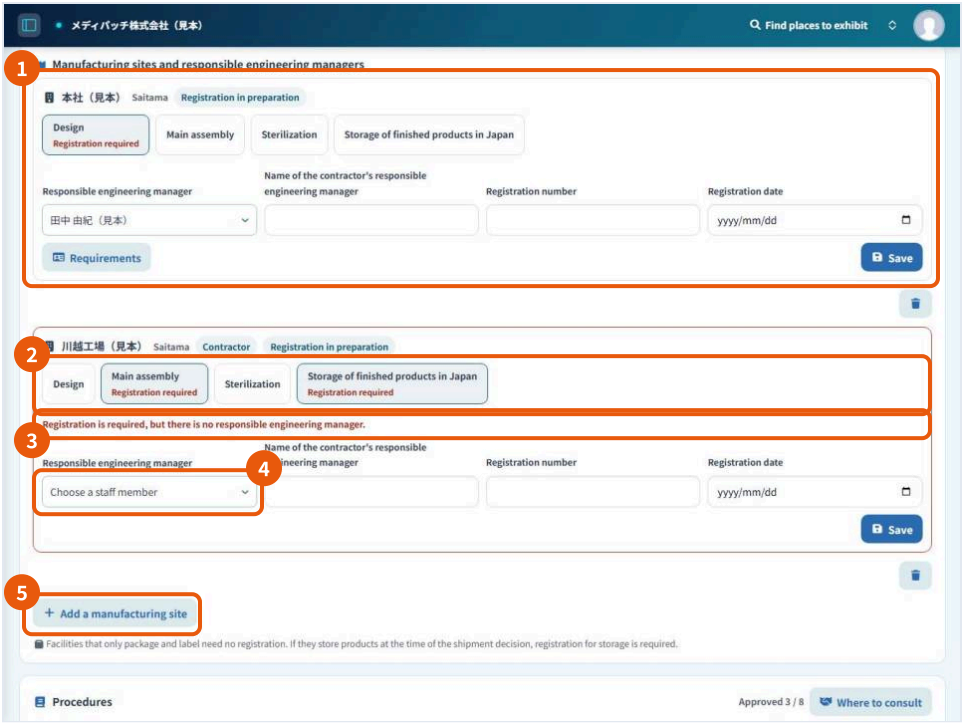
For a Class 2 license, the domestic quality manager and the safety manager cannot be the same person.

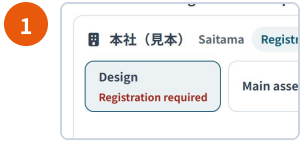
3 

Choose someone else

Press to clear the reason and choose again.

Press a site's steps to see whether registration is needed





Sites

Head office handles design; Tanaka is the responsible engineer.



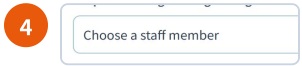
Steps

Check the steps the site handles. Each shows whether registration is needed.



No responsible engineer

A site that needs registration but has no responsible engineer shows the reason in red, and the road stage shows "!".



Responsible engineer

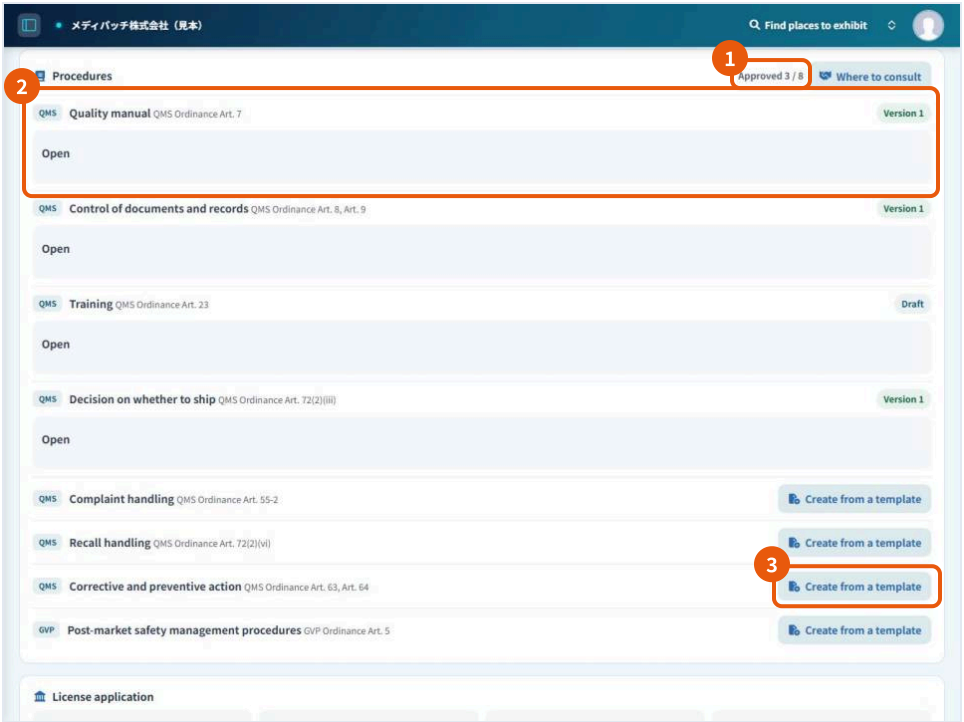
Choose from your staff, or enter the name of the contractor's engineer.



Add a site

Add a site with its name, prefecture, address and steps.

Create procedures from templates and ask the three officers to sign



1

Approved 3 / 8

Approved
How many of the required procedures are approved.

2

QMS Quality manual QMS Ordinanc
Open

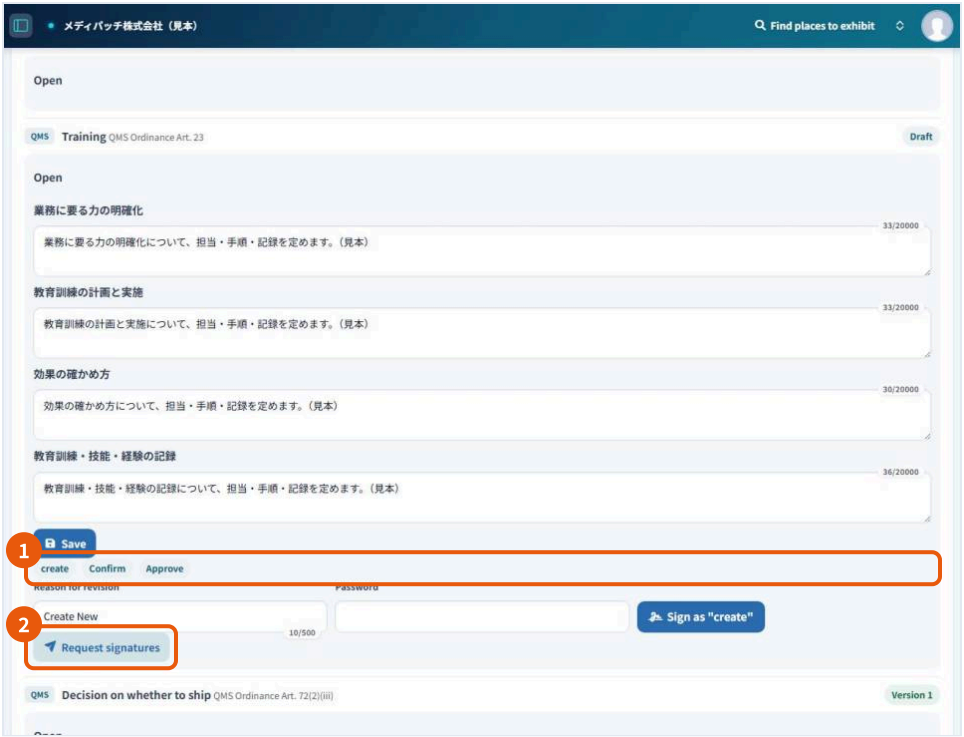
Approved procedure
With all three signatures (author, reviewer, approver), it becomes version 1.

3

Create from a template

Create from template
Creates a draft with the items from the ordinance.

Create procedures from templates and ask the three officers to sign



1 create Confirm Approve

Signatures

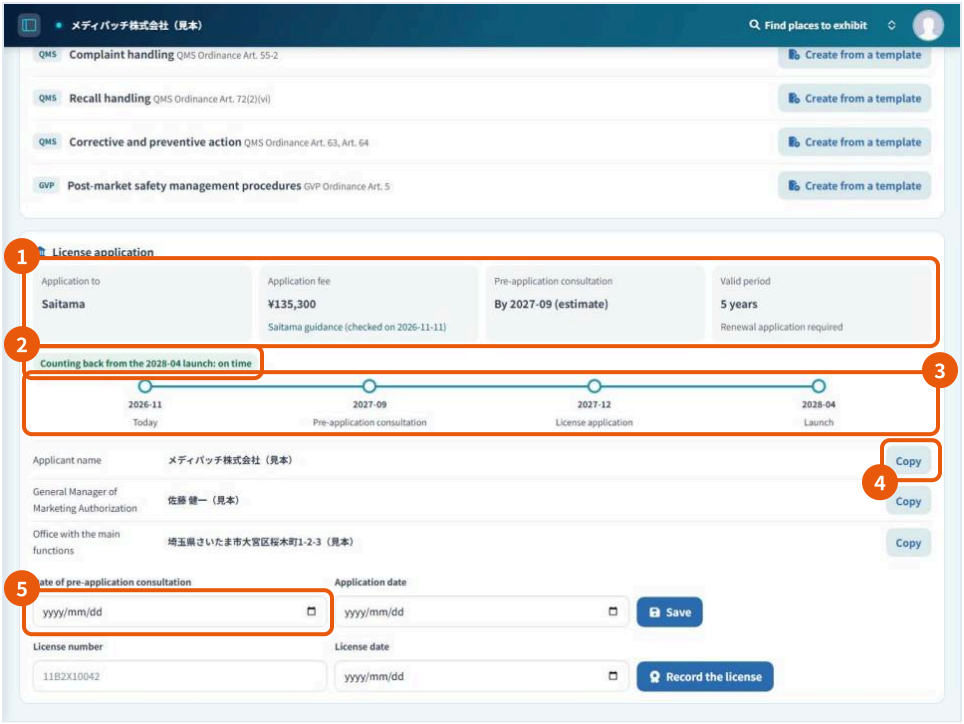
Sign as author, reviewer and approver in order, re-entering your password. Editing the content voids earlier signatures.

2 Request signatures

Ask for signatures

Press to send the officers a chat request to sign.

Work back from the launch month to see if you are on time



1

Application to

Saitama

Office and fee

The prefecture, fee, consultation target and validity. The fee is shown only when confirmed from the prefecture's guide.

2

Counting back from the 2028-04 launch

On time

Shows whether the application and consultation fit the launch month. If not, the reason is shown.

3

2026-11

Today

Backward timeline

Today, consultation, application and launch month, as estimates.

4

Copy

Copy

Copy the name, general manager and office for the application form.

5

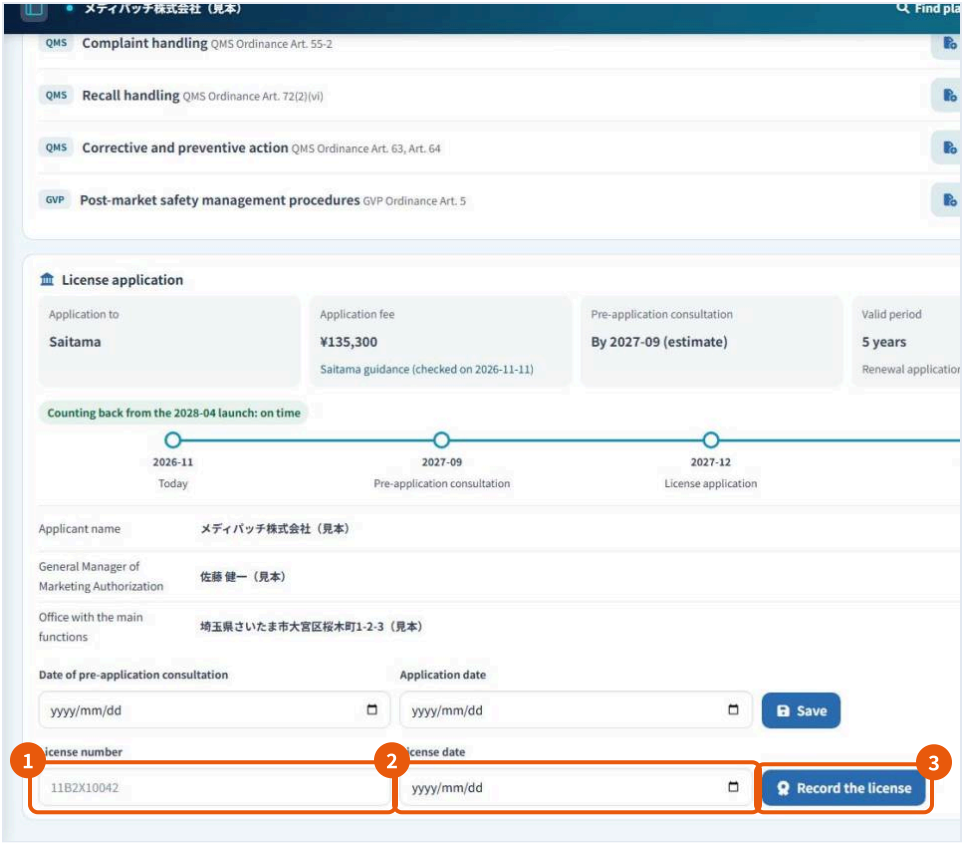
Date of pre-application consultation

yyyy/mm/dd

Consultation date

Enter the date you consulted the prefecture and the road moves forward.

Enter the license number and you become a medical device maker in the company dat…



1 License number

11B2X10042

License number

Enter the number on the license. If the format is wrong, the reason is shown and nothing is saved.

2 License date

yyyy/mm/dd

License date

Sets the 5-year validity and when renewal reminders are sent.

3 Record the license

Record the license

Once recorded, the company database shows you as a verified medical device maker.

If you need help

- Check the rules in the guide of the prefecture you apply to. Open it from "Open the prefecture's guide" on the screen.
- Use "i Description" at the top right of a screen to see how that screen works.
- The latest version of this guide is at https://cpk.jp/manual/pdf