



Q&A License Holder in Korea

Contents

Q&A License Holder in Korea.....	1
Question 1 – What is a license holder ?	2
Question 2 – What are the duties of a license holder?	2
Question 3 – Is the importer the license holder?.....	2
Question 4 – How to change the license holder?	2
Question 5 – How to become license holder?	3
Question 6 – How about products which I’m distributing but I’m not the manufacturer? What to deliver as KGMP certificate?	3
Question 7 – What are the different options for my products licensing?	3

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Question 1 – What is a license holder ?

Answer – A license holder is the equivalent of a European Representative or a US agent. It is an established place of business in Korea responsible to place the product on the market. It may be also involved in the registration of the product but it's not an obligation. The license holder is the owner of the product license. From that perspective, it has legal responsibilities locally (penalties will apply in case of infraction).

Question 2 – What are the duties of a license holder?

Answer – The license holder is responsible for the following:

- Customs clearance – though it can be done by the distributor through a contract
- Report any design/manufacturing changes to the MFDS
- Communicate with MFDS in case of incident, adverse event, recalls
- Communicate with manufacturer in case of recalls, advisory notice

Question 3 – Is the importer the license holder?

Answer – The importer is usually the license holder but as said in Question 2, the clearance and inspection can be subcontracted to the distributor

Question 4 – How to change the license holder?

Answer – There are 2 cases:

- The former license holder is not willing to cooperate: the products have to be re-registered with the new license holder
- The former license holder is willing to cooperate: the transfer can be done by establishing a contract between the two license holders and declaring the change to the MFDS. A couple of weeks are needed for the change to be effective



Question 5 – How to become license holder?

Answer – To become a license holder, a company needs a registered place of business in Korea. It is also required to have a quality manager as a full time employee.

Question 6 – How about products which I’m distributing but I’m not the manufacturer? What to deliver as KGMP certificate?

Answer – Whoever is importing products, must provide a valid product license AND a KGMP certificate. For class 1 products, since a KGMP certificate is not required only the product license is necessary.

Question 7 – What are the different options for my products licensing?

Answer – There are 3 options summarized below with pros and cons:

- Option A: Appoint the distributor
- Option B: Appoint a specialist of regulatory affairs in Korea
- Option C: Establish a branch/subsidiary in Korea

See the chart below for a quick comparison between the different options:



Options for local representation in Korea

	Distributor	Dedicated License Holder	Branch/Subsidiary
Ease in Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Experience	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
in registration			
Cost	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flexibility	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Post-Market	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Ownership	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Total	3 “<input checked="" type="checkbox"/>”	3 “<input checked="" type="checkbox"/>”	3 “<input checked="" type="checkbox"/>”

Source: Fictitious data, for illustration purposes only

Each of the above option is valid depending on your priorities.

The main driver for companies to switch from Option A to B is to separate the commercial part from the regulatory part and being more flexible with their distributors.

The move from Option A (or B) to C is usually driven by the goal to get complete ownership of the process.