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THE CHALLENGES OF DEVELOPING DRUG DELIVERY DEVICES FOR THE JAPANESE MARKET

In this article, Olivia Houselander, Business Development Manager at Owen Mumford, outlines some of the challenges of developing drug delivery devices for the Japanese market and shares details of the company's latest two products to gain approval in Japan.

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It is no secret that breaking into new markets is a challenge within the drug delivery device industry. Nevertheless, that does not mean that device manufacturers should fail to make the effort, even if a market's regulatory regime is tough. Japan, for example, is widely recognised as one of the most stringent markets for certification, where devices are regulated by the Pharmaceutical and Medical Device Agency under the Pharmaceutical and Medical Devices Act.[1–6]

Owen Mumford Pharmaceutical Services has been working in the Japanese market for over 25 years and has a proud history of developing combination products within it with its partners (Figure 1). While it was hard work to gain the first product certifications, the results have been more than worth the initial effort.

> "Despite being home to numerous multinational medical device corporations, a significant proportion of Japanese medical devices come from foreign manufacturers."

UNDERSTANDING MARKET REQUIREMENTS

Despite being home to numerous multinational medical device corporations, a significant proportion of Japanese medical devices come from foreign manufacturers, with the country importing approximately 35% of its medical devices.[7] There is a great deal of opportunity; an ageing population has created one of the largest medical device markets in the world, with it being estimated to reach over US$29 billion (£23.2 billion) in 2024.[8] As a result, many suppliers are prepared to accept the potential length of time to market and the regulatory costs associated with the Japanese market, despite the challenges.

The product registration process has become more friendly to foreign manufacturers since changes to its regulations in 2014, with new registration pathways for manufacturers and expanded third-party certification options – but a number of challenges still remain.[9] The EU's CE mark and US FDA approval are not accepted as equivalent to Japanese certification – although having them certainly speeds up device registration. Foreign manufacturers seeking medical device registration in Japan can look to work alongside a third-party "Designated Marketing Authorisation Holder" to help them register in Japan and liaise with the regulatory authorities. This is particularly useful for companies that do not have ready access to Japanese speakers within their teams, as it is necessary to submit all the required regulatory information in Japanese – another barrier to entering the market.

For medical device registration in Japan, applicants must submit a comprehensive dossier detailing device safety, performance and manufacturing quality control systems.[10] Once this has been navigated successfully, stringent quality control measures are implemented. These measures ensure continued compliance with the initial standards, safeguarding the quality of devices throughout their lifecycle. Japan's robust post-market surveillance system monitors any adverse events caused by devices and takes rapid action if safety concerns arise.[10] Once approved, device registrations do not expire, but quality management system certificates must be renewed every five years.

A QUARTER CENTURY IN THE JAPANESE MARKET

Owen Mumford Pharmaceutical Services has a long track record of navigating the Japanese market, with several successful partnerships over the last 25 years. Most recently, the company has launched two combination products onto the market.

Figure 1: Owen Mumford Pharmaceutical Services has been working in the Japanese market for over 25 years and has a proud history of developing combination products with its partners.

UniSafe Safety Syringe

The UniSafe® safety syringe was launched with Owen Mumford Pharmaceutical Services' exclusive distribution partner and its commercial alliance in Japan. The device enables the safe injection of a biosimilar used with cancer medicines. It is Japan's first long-acting biosimilar for this application and can be administered once per chemotherapy cycle, starting the day after treatment is completed.

UniSafe is a springless, passive safety device for 1 mL prefilled syringes, designed to overcome some of the challenges of traditional spring-based safety systems. Its key design elements prioritise reliability and ease of use. The absence of a spring means that UniSafe prevents accidental activation before injection. The secure plunger mechanism helps to prevent the chances of the product being reused or accidental spillage before a full dosage is administered. The design is critical for preventing needlestick injuries, with the passive safety mechanism ensuring that the device is safe as soon as the plunger is fully depressed. With an estimated 525,000 cases of needlestick injuries in Japanese hospitals annually, devices such as UniSafe are key to improving safety within the industry.[11]

Bespoke Autoinjector for Rheumatoid Arthritis

Owen Mumford Pharmaceutical Services has also been working alongside a Japanese pharmaceutical company to develop its product, approved to deliver a novel drug for rheumatoid arthritis (RA). The autoinjector is a bespoke, single use disposable autoinjector, designed and manufactured by Owen Mumford Pharmaceutical Services. Estimates vary on the number of sufferers of RA in Japan, but most studies put the number at around 0.75%–1% of the population, meaning a total of between 800,000 and 1 million patients.[12,13]

The autoinjector's key features prioritise usability and patient safety. The device includes an easy-grip cap and body, which are exceptionally helpful for RA patients who are self-administering treatments and may have reduced grip and dexterity. The two-step injection process is one fewer than many autoinjectors on the market; Patients only need to remove the cap and fully depress the injector onto the injection site to undertake the injection, with no need to press a button to begin the procedure. Owen Mumford Pharmaceutical Services was responsible for managing the entire development project, using its expertise to conduct multiple human factors studies to validate the usability of the device and scale up manufacture. This partnership dates back to 2019, and Owen Mumford Pharmaceutical Services is also working alongside partners to develop replica training injectors.

CONCLUSION

There are clearly distinct challenges in trying to get a drug delivery device to market in Japan as a foreign manufacturer. Not only must companies contend with some of the world's most stringent regulations, but all documentation must be submitted in Japanese. Yet, the market size and propensity for importing medical devices means that there are significant opportunities for those willing to tackle the regulatory challenges and potential length of time to market.

ABOUT THE COMPANY

Owen Mumford is a major healthcare company and device manufacturer that commercialises pioneering medical products, both under its own brand and as custom device solutions for the world's major pharmaceutical and diagnostic companies. Owen Mumford's goal is to enhance access to diagnostics, encourage adherence to treatment and reduce healthcare costs, making a world of difference to a world of people.

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ABOUT THE AUTHOR

Olivia Houselander joined Owen Mumford as a Product Manager in 2008 and currently serves as an accomplished Business Development Manager in the Pharmaceutical Services division. In this role, she applies her extensive experience in medical devices, marketing strategy and product launch and development to support continued business growth and create innovative product launches, making her an asset in the dynamic healthcare landscape.

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