

# Case Study

Supporting a Pharmaceutical Company  
with the Development of a Global Product in Japan

## Objective

Supporting a U.S. based pharmaceutical company with the development of a product strategy for commercialization in Japan.

## Challenge

A large US client with a global footprint was actively developing a drug product for sale on the global level. They intended to enter the Japanese market simultaneously with others around the world.

## Background

The client engaged ELIQUENT Japan's R&D team in order to assess and account for Japanese regulatory requirements through their development process. Since then, ELIQUENT Japan has worked closely with various local constituents (KOLs, PMDA, CROs, and others) to implement the program for Japan.

ELIQUENT Japan began the design of the Japanese development program and the client has utilized ELIQUENT Japan as a strategic partner across a broad spectrum of activities in various locations.

## Solution

**Stage One:** ELIQUENT Japan prepared an initial assessment report for the product development program that summarized opportunities and risk and prioritized a comprehensive list of indications to consider. The client utilized this report to initiate their product development program.

**Stage Two:** ELIQUENT Japan supported the client by managing and responding to PMDA consultations as they confirmed the development plan and prepared a complete data package for all relevant indications in Japan.

**Stage Three:** ELIQUENT Japan worked closely with the client to select and manage CROs to implement clinical trials in Japan. ELIQUENT Japan also led the selection and management of Key Opinion Leaders (KOLs) and the formation of an Advisory Board for the target disease area.

**Stage Four:** ELIQUENT Japan leveraged its in-house and external resources to prepare a comprehensive and compelling eCTD for Japanese submission. ELIQUENT Japan and the client collaborated closely to manage all inquiries from the PMDA across CMC, Non-Clinical, and Clinical areas.

## Japan Regulatory Solutions

ELIQUENT Japan partners with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Japanese market.. Learn more at [ELIQUENT.com](https://www.ELIQUENT.com)