OVERVIEW OF SAKIGAKE DESIGNATION FOR DRUGS IN JAPAN
## What is Sakigake designation?

In 2015, MHLW promulgated new regulations known as “SAKIGAKE” that allows for dramatically accelerated regulatory pathways for drugs designated as breakthrough therapies addressing high, unmet medical needs with the additional condition that companies initiate early development and seek initial product approval in Japan.

## What are the benefits?

- Shorter lead time for PMDA Formal Consultations (1 month instead of 2-3 months)
- Prioritized NDA review
- Ability to submit English materials for pre-review
- NDA Review period shortened to 6-months
- Ability to submit Phase 3 study results following NDA submission
- Assignment of a PMDA manager to oversee the entire approval process, including issues related to conformity assurance, quality management, safety measures, review, etc
- Post-Marketing re-examination period extended up to 10 years
- Premium pricing increase of 10-20%

## What Drugs qualify for Sakigake?

- Drugs with a new and different mechanism of action from already approved drugs
- Drugs that treat either:
  - A serious life-threatening disease
  - A chronic disease which deteriorates patients’ QOL and for which there is currently no viable treatment
- Drugs that are expected to be more effective than currently approved treatments
- First approval targeted for Japan, and either (both preferable) of the following:
  - First in Human (FIH) Study conducted in Japan
  - Proof of Concept (POC) Study conducted in Japan
Do you need help registering your drug in Japan?

Global Regulatory Partners Japan can:
- Prepare your meeting with PMDA
- Prepare your registration dossier and submit to PMDA
- Register your manufacturing site with PMDA (FMA)
- Register your quality system with PMDA.
- Register your DMF with PMDA.

To learn more contact us today at info@globalregulatorypartners.com