A Japanese company offers services to EU companies for the regulatory approval process in Japan in pharmaceuticals and biotechnology

Summary

Profile type	Company's country	POD reference
Business Offer	**Japan**	**BOJP20230206002**
Profile status	**Type of partnership**	**Targeted countries**
PUBLISHED	**Outsourcing agreement**	**• World**
Contact Person	**Term of validity**	**Last update**
Alessandro PERNA	**6 Feb 2023** **5 Feb 2025**	**25 Jan 2024**

General Information

Short summary

A Japanese company who has been engaged in CRO (Contracted Research Operation) services is looking for EU companies in the sector of pharmaceuticals and biotech to offer their supporting for regulatory process under an outsourcing agreement.

Full description

This Japanese company has a 35-year-long experience supporting foreign pharmaceuticals and biotech companies by consulting, studying and coordinating that enables to help obtaining official approvals given by Japanese authorities such as PMDA (Pharmaceuticals and Medical Devices Agency).

They also offer to be an ICCC (In-Country Clinical Caretaker) of potential partners that makes ease of entering into the Japanese market without establishing their own representative office or having a specific CRO. In particular, their consultation service helps their clients to get useful tips in making a strategy that is needed to be filed with PMDA.

Since the company notices that the demand for clinical trials and consultations requested by non-Japanese companies is increasing year by year, they would like to collaborate with European Union pharmaceutical and biotech companies.

Advantages and innovations

It is known that Japanese regulatory approval process is quite intricate, especially for non-Japanese companies, even though the Japanese pharmaceutical market size is considered as the second largest in the world, and its growth rate is attractive.

The Japanese company offers support to prepare necessary data and/or document in line with submission of clinical trial-related materials to PMDA.

They offer more than 10 consultation services to potential partner that would help them to fulfil necessary requirements in a timely manner.

The company conduct over 50 protocols of clinical studies from overseas companies based on their 35 years of service. It would help EU companies entering the Japanese market.

Technical specification or expertise sought

Stage of development

Sustainable Development goals

- **Goal 3: Good Health and Well-being**

IPR Status

Partner Sought

Expected role of the partner

Potential partner should be a company or R&D organisation in the sector of pharmaceutical or biotech, and the partner does not have any branch or representative office in Japan.
EU CROs can also be considered as potential partners.

Type of partnership

Type and size of the partner

Outsourcing agreement

- **Big company**
- **SME <=10**
- **SME 50 - 249**
- **R&D Institution**
- **SME 11-49**

Dissemination

Technology keywords

Market keywords

- **05007002 - Pharmaceuticals/fine chemicals**

Targeted countries

- **World**

Sector groups involved

- **Health**