Japan based IT venture is offering regulatory compliance support to life sciences and pharma industries

Summary

Profile type	Company's country	POD reference
Business Offer	**Japan**	**BOJP20250318002**
Profile status	**Type of partnership**	**Targeted countries**
PUBLISHED	**Commercial agreement** **Outsourcing agreement**	**• World**
Contact Person	**Term of validity**	**Last update**
Enrico FRANZIN	**18 Mar 2025** **18 Mar 2026**	**18 Mar 2025**

General Information

Short summary

A Japanese IT venture is providing regulatory compliance support to EU pharmaceutical industries operating with Japan. The company knowledge of Japanese eCTD (electronic Common Technical Documents) submission procedures combined with its IT solutions allow a reduction of 70 – 80% of all submission preparation time and costs. The company knowledge also covers EU and USA similar procedures. A commercial agreement will be finalized with EU partners.

Full description

The Japanese company is a Tokyo-based IT venture company founded in February 2010 that specializes in support and IT solutions for electronic regulatory submissions within the pharmaceutical industry. Their IT service provides a Total Solution for eRegulatory Submissions in the pharmaceutical sector.

The Japanese company can support overseas pharmaceutical companies with IT solutions to support electronic regulatory submissions. For example, they have extensive experience in eCTD (electronic Common Technical Documents) submissions and can support applications for Japanese eCTDs. In addition, their IT solutions can support pharmaceutical and CDMO (Contract Development and Manufacturing Organizations) companies with applications and updates for DMF (Drug Master File) submissions.
The Japanese company’s solutions have already been adopted by several major Japanese pharmaceutical

companies, and the company is expecting global growth in 2025.

The company is looking to partner under a commercial agreement with EU pharmaceutical companies that are eager to streamline their submission filing processes, and companies that are submitting applications for pharmaceutical products to the EMA (European Medical Agency), PMDA (Pharmaceutical and Medical Device Agency: Japan), or FDA (Food and Drug Agency: USA).

Advantages and innovations

The Japanese company IT solutions can support pharmaceutical companies to streamline their electronic submission process.
The company's primary IT solution for streamlining pharmaceutical applications can support:

1. Global lifecycle management and viewing for eCTD with cloud base.

2. Decrease of time, manpower and costs spent on the submission process by improving the accuracy of submission-ready documents with rule-based RPA (Robotic Process Automation) systemized for regulatory affairs for pharmaceuticals.

The products have proved results of reducing 70 – 80% of all submission preparation time and costs.

Technical specification or expertise sought

Stage of development

Sustainable Development goals

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

IPR Status

IPR Notes

Partner Sought

Expected role of the partner

The Japanese company would like to partner with EU pharmaceutical companies in need of an innovative and efficient process streamlining IT solution under a commercial agreement. Specifically, they would like to connect with those in charge of regulatory affairs within pharmaceutical industries. Ideally, a multi-year contract is negotiated for a yearly subscription.

Type of partnership

Commercial agreement

Outsourcing agreement

Type and size of the partner

- **SME 11-49**
- **Big company**
- **SME <=10**
- **SME 50 - 249**

Dissemination

Technology keywords

Market keywords

- **09003005 - Consulting services**
- **05007002 - Pharmaceuticals/fine chemicals**

Targeted countries

- **World**

Sector groups involved