

A Dutch SME is specialized in regulatory services for (bio) pharmaceutical and medical device companies and looks for a commercial agreement with a Japanese service provider that can assist a European company to enter the Japanese market.

Summary

Profile type	Company's country	POD reference
Business Offer	Netherlands	BONL20250113033
Profile status	Type of partnership	Targeted countries
PUBLISHED	Commercial agreement	• Japan
Contact Person	Term of validity	Last update
Noriko MITA	13 Jan 2025 13 Jan 2026	13 Jan 2025

General Information

Short summary

A Dutch SME partners worldwide with (bio)pharmaceutical and medical device companies. Important aspects of the services are the expertises to ensure regular requirements and the step by step approach while keeping in focus the achievement of business goals. The Dutch SME looks for a commercial agreement with a Japanese service provider or company that can help a European company to develop the Japanese market.

Full description

A Dutch company partners with (bio)pharmaceutical and medical device companies worldwide to ensure that regulatory requirements are met and business goals, such as quick market access and compliance, are achieved. The SME started in May 2014 with 1 employee and now the team has grown to 20 employees with a proven trackrecord of more than 350 international projects. It is a lean and powerful team with degrees in pharmacy, chemistry, biology, or related studies that strives to added value for the clients. Besides that the SME has a access to valuable network of specialized experts and companies.

The main categories of services of the Dutch SME are (bio)pharmaceutical services, services for medical devices

and regulatory operation services.
For details see the topic advantages and innovations.

The two core Key Performance Indicators (KPI) of the Dutch SME are quality and adherence to schedule and closely align with the Japanese culture, highlighting a strong synergy and shared commitment to excellence.
The Dutch SME has a long standing interest in Japan and visited a number of relevant Japanese events.

The Japan strategy of the Dutch SME is focused on two directions. First focus is on Japanese companies and/or service providers that want to enter and develop the European market. The second focus is on bringing non-Japanese clients that want to enter and develop the Japanese market.
This profile concerns the partnersearch for the second focus. The Dutch SME looks for support of Japanese service providers that can help to enter and develop non-Japanese companies to develop the Japanese market in the business of pharma products or medical devices.

The Dutch SME is looking for a commercial agreement with a Japanese service provider that can assist non-Japanese companies to enter and develop their Japanese life science oriented business.
Important aspects in the profile of the desired Japanese partner is making the connection between non-Japanese companies and the Japanese market and the Japanese local authorities.

Advantages and innovations

The most important advantage is one stop shopping for the offered services:

(Bio)pharmaceutical services

The SME supports the development and registration of medicinal product(s), such as small molecules, biologics, biotechnology derived products, and vaccines. Popular services are due diligence, gap assessment, agency interactions, chemistry-manufacturing-control (CMC) services and the crucial navigation through the complexity of regulatory requirements.

Services for medical devices

The SME supports the development and registration of the medical devices. such as class I to class III devices, including software, in vitro diagnostic and drug-device combination products worldwide. Popular services are quality management system implementation, clinical evaluation and product qualification. This diverse field encompasses everything from simple devices like needles to complex technologies such as MRI scanners.

Regulatory operation services

To make sure that an application conforms with all other requirements beside the scientific requirements the SME supports regulatory operations and provide publishing services. Popular services are the implementation of electronic Common Technical Document (eCTD) worldwide, submission preparation support, electronic submission support, document management system (DMS) support and regulatory information management (RIM).

Regulatory Operations services are essential in Regulatory Affairs, streamlining submissions and ensuring seamless compliance for (bio)pharmaceutical products and medical devices.

Technical specification or expertise sought

Stage of development

Already on the market

IPR Status

Secret know-how

IPR Notes

Sustainable Development goals

- **Goal 3: Good Health and Well-being**
- **Goal 9: Industry, Innovation and Infrastructure**
- **Goal 17: Partnerships to achieve the Goal**

Partner Sought

Expected role of the partner

Type of partner:

A Japanese service provider active in the healthcare market.

Role of the partner:

A Japanese service provider that supports a European company to enter the Japanese market.

Type of partnership

Commercial agreement

Type and size of the partner

- **SME 50 - 249**
- **Other**
- **SME <=10**

Dissemination

Technology keywords

- **06001015 - Pharmaceutical Products / Drugs**
- **06001013 - Medical Technology / Biomedical Engineering**

Targeted countries

- **Japan**

Market keywords

- **04006 - Cellular and Molecular Biology**
- **05007002 - Pharmaceuticals/fine chemicals**
- **05007007 - Other medical/health related (not elsewhere classified)**
- **05004004 - Medical instruments**

Sector groups involved