

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

Summary

Profile type	Company's country	POD reference
Business Offer	Netherlands	BONL20250113032
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 Japanese (bio)pharmaceutical or medical device companies that aim to enter the European healthcare 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 (for example BioJapan).

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 first focus, Japanese companies in the business of pharma products or medical devices that want to enter the European market.

The Dutch SME serves as a linkage for Japanese companies and/or service providers that want to develop the European market. The main categories of services of the Dutch SME are:

- (Bio)pharmaceutical services
- Services for medical devices
- Regulatory operation services(including CE marking).

Further preparations are going on for the Dutch SME to be known in the Japanese market.

Besides the expertise of the Dutch SME also a profound knowledge and extensive network of partners in Europe is available.

The Dutch SME is looking for a commercial agreement with the Japanese (bio)pharmaceutical or medical device companies. Important aspects in the profile of the desired Japanese partner are:

- The Japanese company has already a proven business (track record) in the Japanese home market.
- The Japanese company wants to enter the European market or a Japanese service provider wants to assist a Japanese company but needs assistance from a European service provider to enter and develop the European market.

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 CE Marking, Medical Device Regulation (MDR) compliance, 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 company or a Japanese service provider active in the healthcare market. The healthcare product may be a pharmaceutical or a medical device.

Role of the partner:

A Japanese company or a Japanese service provider that is looking for a service provider and business partner to develop the European market.

Type of partnership

Commercial agreement

Type and size of the partner

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

Dissemination

Technology keywords

- **03004007 - Pharmaceuticals**
- **06001013 - Medical Technology / Biomedical Engineering**
- **06001024 - Medical Biomaterials**

Targeted countries

- **Japan**

Market keywords

- **05004004 - Medical instruments**
- **05007002 - Pharmaceuticals/fine chemicals**

Sector groups involved