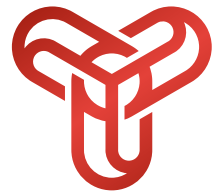


## COMPANY OF THE YEAR



**YAKUMED**  
YOUR PARTNER FOR SUCCESS IN JAPAN

### The World Leading Service Provider Highly Specialized in Pharmaceuticals and Orphan Drugs in Japan

[www.yakumed.com](http://www.yakumed.com)



Dr. Mohamed Oubihi,  
President and CEO

**T**he Japanese pharmaceutical market ranks as the world's third largest and operates within a distinct regulatory, business and cultural ecosystem. Equipped with extensive experience in navigating the complex framework, Yakumed is exclusively committed to leading and supporting pharmaceutical, gene therapy and medical device companies to establish a strong foothold in the Japanese market. With a highly respected multidisciplinary team of experts, Yakumed provides a comprehensive package of services that covers all aspects related to Japanese market. It spans the entire development and life cycle stages of a pharmaceutical product. It is the only company in the world to offer such wide range of services dedicated to Japan.

"We are not a conventional service provider. We are a committed long-term partner, leading our Pharma/Biotech clientele to unlock the potential of the Japanese market, overcome the challenges and achieve commercial success in Japan," says Dr. Mohamed Oubihi, President and CEO of Yakumed.

The firm has successfully supported 70 U.S. and European companies to develop, register and commercialize their pharmaceutical drugs in Japan. It provides a diverse range of services, including Japan's entry strategy, market research, business development and partnering, clinical development, regulatory affairs, market access, chemistry, manufacturing, and controls (CMC), supply chain, pharmaceutical distribution, pharmacovigilance, marketing strategies and commercial launch.

#### Addressing Pharma Industry Challenges with Robust Strategies and Excellent Execution

Providing the highest level of service quality is Yakumed's top priority. The time allocated to each product for Japan strategy, the meticulous attention to details when delivering services, and the sophisticated execution of intricate strategies contribute to the firm's strategic and operational excellence.

Yakumed's team comprises esteemed Japanese professionals with diverse subject-matter expertise. They are instrumental in providing world-class strategy advice and excellent operational support for the development, approval and commercialization of life-saving drugs in Japan.

"I am very proud of my team. Thanks to their deep insights, hard work and dedication we have built an excellent reputation," states Dr. Oubihi.

Yakumed's regulatory experts are among the best in the industry. They possess in-depth proficiency in non-clinical, clinical and CMC aspects for different types of products, leading clients to adhere to Japan-specific regulations and market standards. These experts skilfully navigate cultural and linguistic differences during regulatory interactions, filing procedures and engagements with the health authorities and key opinion leaders (KOLs). The team draws from their experiences as ex-senior executives in major pharmaceutical firms to guide international businesses through the shifting government landscape and evolving market regulations.

One of the strengths of Yakumed is the depth and rigour of its analyses, which combine findings from market research, regulatory intelligence, and feed-back from KOLs with the assessment of potential risks and mitigation strategies. Using such tools, Yakumed has provided critical information and strategic evaluation which informed key decisions of dozens of pharma companies throughout drug development, market access, registration, and commercialization in Japan.

In addition to supporting clients throughout the product development process, Yakumed also evaluates commercial prospects in Japan for newly developed pharmaceuticals and medical devices. Its commercial experts diligently analyse the market size, the positioning, future trends, and carefully craft marketing and distribution strategies to ensure that the products instantly reach patients seeking novel treatments.

The firm takes pride in the sophisticated strategies developed by its pricing and reimbursement experts to evaluate pharmaceuticals and medical equipment. The team devises action plans to optimise National Health Insurance reimbursement schemes and assists clients in negotiating

suitable product prices with Japan's Ministry of Health, Labour and Welfare (MHLW).

Yakumed also assists Biotech and Pharma companies to license-out or co-develop their products in Japan with a local partner. Leveraging its wide network of Japanese companies, the firm leads the selection of potential partners, due diligence and negotiation process. Numerous clients have benefited from Yakumed's leadership and support to succeed in Japan, eventually achieving milestones of product out-licensing and the establishment of their own affiliate entities.

#### The Real Impact is on the Lives of Patients



**We have proudly contributed to the development, approval and commercialization of numerous drugs which impact the lives of patients in Japan**

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The firm led and supported numerous U.S. and European companies specialising in orphan diseases and cancer with their successful entry into the Japanese market. These long-term projects included -among others- the evaluation of market commercial potential (market research),

KOL selection and interaction, clinical development and regulatory (PMDA consultations), Regulatory filing (Japan NDA), Orphan Drug Designation, Distribution and 3PL strategy and set up, Supply Chain preparations, establishment of a representative affiliate in and product launch in Japan. Currently, these multinational companies have accomplished sales of over \$100 million in Japan.

#### World-Leader in Regulatory, Development and Commercialization of Orphan Drugs in Japan

Yakumed offers a unique platform for strategic and operational aspects in regulatory, development and commercialization of pharmaceutical drugs and medical devices in Japan. The only one in the World in term of its breadth and coverage.

As MHLW is introducing new reforms which include the development and registration of Orphan Drugs, there are great opportunities in the future for orphan drugs and new technologies in Japan.

Dr Oubihi concludes "Yakumed has built a stellar reputation as a reliable company and partner for the development and commercialization of orphan drugs in Japan. We are very excited about the future! We will build on our strong legacy to carry on with our mission of introducing novel drugs to improve the health of patients in Japan".