YOUR LOCAL MAH PARTNER IN JAPAN

Your Bridge to the Japanese Market.

Bringing global innovation to patients in Japan.

We partner with pharmaceutical companies worldwide to develop, register and commercialize innovative medicines in Japan.

GLOBAL INNOVATION

JAPAN

A local partner.
A shared ambition.

DEVELOPMENT / REGISTRATION / COMMERCIALIZATION

CUES PHARMALAB INC. TOKYO, JAPAN

01 / ABOUT CUES PHARMALAB

Global perspectives. Local commitment.

A Japanese pharmaceutical company, built to be your partner in Japan.

CUES PharmaLab Inc. (CPL), a subsidiary of CUES Consulting Inc., helps overseas partners bring innovative medicines not yet available in Japan to Japanese patients.

As a Marketing Authorization Holder (MAH), we connect regulatory strategy with clinical development and commercial operations.

01

Pharmaceuticals

Type I Pharmaceutical MAH License

02

Medical devices

Type I Medical Device MAH License

03

End-to-end operations

From development to commercial sales

02 / OUR EXPERTISE

A clear path to the Japanese market.

One local partner across the stages that matter to your Japan strategy.

01	Regulatory strategy	Build a Japan development strategy informed by PMDA consultation and the regulatory expertise of CUES Consulting.	PLAN
02	Clinical development	Integrate overseas clinical data into a focused Japanese clinical plan, with local requirements discussed with PMDA.	DEVELOP
03	Launch & commercialization	Coordinate marketing, sales and distribution through qualified partners, focusing on university hospitals and major medical centers.	DELIVER

03 / DEVELOPMENT APPROACH

Global data. A focused Japan strategy.

We use overseas clinical evidence to shape the Japanese development plan, with the aim of reducing local trial burden and supporting earlier approval.

01 **Global clinical data**
Review the existing overseas evidence.

02 **PMDA consultation**
Discuss the strategy and data requirements.

03 **Japanese clinical plan**
Define a focused local development program.

04 **Registration & market entry**
Work toward approval and launch in Japan.

04 / COMMERCIAL OPERATIONS

Focused reach. Coordinated execution.

CPL manages the MAH role while qualified outsourcing partners support sales and logistics.

MARKETING & SALES

From strategy to hospital engagement.

1. Marketing strategy & sales planning
2. Promotion & sales through partners
3. University hospitals & major medical centers

DISTRIBUTION

A route from product to patient.

1. Distribution & secondary packaging
2. Nationwide delivery
3. Supply to hospitals

LET'S WORK TOGETHER

Let's discuss your Japan strategy.

Start a conversation about your development and commercialization plans for Japan.

YOUR CONTACT

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