IDEC

A VALIDANT COMPANY

REGIONAL EXPERTISE, GLOBAL REACH

Accelerate Entry into Japan & Enable One, Global Path to Market with IDEC

IDEC'S CAPABILITIES

Strategic Counseling

- Commercial Japanese Market Strategy
- Regulatory Japanese Development Plan
- KOL Management

Regulatory Services

- Regulatory Gap Analysis
- PMDA Consulting
- CTN Filing
- J-NDA/CTD Creation
- PMDA/MHLW Consultations
- J-MF/CMC Advisory

Commercial Support

- Japan Commercialization Advice
- NHI Pricing Advisory
- Business Alliance Management
- Licensing/Subsidiary Setup

IDEC offers regionally specialized regulatory guidance and end-to-end drug product support for pharmaceutical innovators seeking approval in the Japanese market—the third-largest in the world. A member of the integrated family of Validant companies, IDEC enables drug developers and manufacturers to meet the Japanese market's unique requirements as part of one, global go-to-market approach.

At IDEC, we serve as an external virtual development team for our clients, empowering them to navigate the highly nuanced requirements of the Japanese systems and regulations. In addition to our robust service offering, we provide unrivaled bilingual communications, comprehensive project management support, and deep Japanese regulatory and market expertise.

Gaining Global Access with the Validant Family of Companies

As a Validant Company, IDEC is proud to provide global regulatory services in collaboration with the Validant family of organizations. A worldwide provider of regional expertise in regulatory support, Validant offers drug makers everything they need to accelerate entry into the global marketplace, and IDEC is leading the charge in Japan.

Looking to sell your product in Japan? **Start here.**

Precise Regulatory Pathways, **Proven Market Expertise**

IDEC is a globally-minded consultancy with deep regional expertise in Japan. No other consulting firm offers the same level of regulatory support with the ability to partner and communicate with Japan's local constituents.

STEP 1

Identify & Establish Strategy

IDEC assesses and clarifies all opportunities and risks associated with your drug product's development as we establish an appropriate strategy.

- *Initial Assessment*

STEP 2

Confirm Strategic Development

We will meet with Japanese regulators on your behalf to confirm development strategies and requirements.

- *PMDA Consultation*
- *Potential Strategic Alternatives*

STEP 3

Implement Strategy

IDEC will commence Japanese development with in-house and virtual resources, and we will perform enhanced licensing negotiations.

- *License Program*
- *Commence Development*
- *Potential Strategic Alternatives*

STEP 4

From Submission to Market

IDEC will prepare and submit your J-NDA package through to review and approval. Once secured, we will partner with local constituents to bring your drug product to market.

- *Prepare*
- *Submit*
- *Review J-NDA*

Japan has specific requirements— IDEC provides specific solutions.

Whether Orphan Drug Designation (ODD), the Sakigake Breakthrough Designation, or Unapproved Drug Designaiton, the regulatory experts at IDEC have navigated all Japanese approval pathways. We have performed FDA- and EMA-related clinical and non-clinical data and document gap analysis to ensure Japanese requirements are met, and we've built strategies for implementing Japanese requirements into the global processes of drug innovators from around the world.

No other regulatory partner is as well-suited to help you navigate the Japanese regulatory landscape.

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Streamline your entry into the Japanese market with IDEC.

Start today by visiting **www.idec-inc.com.**