



## MDREX JAPAN Co., Ltd.

### Company Description

MDREX JAPAN, as the Japanese branch of MDREX Korea, **provides a one-stop solution to help Korean client companies successfully enter the Japanese market** with their products and services.

Japan's medical device market ranks as the third largest in the world, and with the accelerating aging population, interest in medical services as well as beauty and wellness sectors is increasing. However, Japan operates a strict approval system centered on the PMDA (Pharmaceuticals and Medical Devices Agency), and in combination with the rigorous insurance procedures of the Ministry of Health, Labour and Welfare, sufficient clinical evidence and a systematic regulatory strategy are essential for introducing new products.

For these reasons, MDREX established its Japanese branch, MDREX JAPAN. Through collaboration with local partners, it provides Korean medical device companies with the most effective strategies and solutions related to regulations for entering the Japanese market.

MDREX JAPAN is an organization that provides comprehensive consulting and execution support for all stages of entering the Japanese medical device market, covering the full cycle from product approval to insurance listing, quality management, clinical trials, and post-market surveillance.

We systematically support regulatory and insurance strategies by handling PMDA approval and certification procedures, fulfilling the roles of DMAH/MAH, and providing assistance with GMP certification and health insurance reimbursement. Additionally, we serve as a strategic partner by covering market analysis, distribution strategy, clinical trial management, and post-market safety surveillance. Leveraging local networks and strengthening communication between the global headquarters and the Japanese market, we support the stable entry and dissemination of innovative medical devices and new technology products in Japan.

### Company Details

#### Head Office

Korea, South

#### Main Business

医療機器の日本市場参入支援 PMDA許可・薬事申請サポート DMAH・MAH業務代行 品質管理・GMP対応支援 保険収載・流通戦略コンサルティング

#### President

朴 宰玄 (パク・ジェヒョン)

#### URL

<https://www.mdrex.co.jp/>

### Offices

#### Main Office

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