



## CoreMed Corporation.

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### Company Description

#### **CoreMed is a Japan based Strategic Regulatory and Drug Development Consulting Firm.**

CoreMed Corporation, a Strategic Regulatory and Drug Development Consulting Firm, is founded in March 1998 in Osaka, Japan.

CoreMed has focused on regulatory affairs primarily since established.

We have been providing practical and strategic supports for designing regulatory/development strategies, analyzing the gap between data and regulatory requirements.

CoreMed covers all stages of development for pharmaceuticals, biopharmaceuticals and regenerative medicinal products, and encompasses CMC, nonclinical, clinical aspects.

We always watch pharmaceutical legislations and changes in regulatory environment closely. CoreMed think globally with understanding local requirements.

#### **Our services are:**

- Regulatory and development strategy
- Consultation meetings with the PMDA
- NDA submission
- Orphan drug designation application
- Responses to inquiries from the authorities
- Medical/Technical writing (CTD/eCTD, CSR, IB, Study Protocol)
- Master File Registration
- Foreign Manufacturer Accreditation
- Regulatory intelligence
- National Health Insurance Pricing
- Project management
- Support for legal proceedings (e.g. Expert witness)

### Company Details

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#### **Head Office**

Japan

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#### **Main Business**

医薬品・再生医療等製品に関するコンサルティング業務

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#### **President**

田村 昌美

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#### **Established**

1998年3月16日

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#### **URL**

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

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### Offices

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#### **Main Office**

Tsunenari building 3F  
2-1-21Kitahama, Osaka-shi Chuo-ku  
Osaka, Japan, 5410041

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