APAC Regulations - Asia-Pacific Region

The Asia-Pacific region has **diverse regulatory systems by country**, and **harmonization efforts** are underway

JP Japan (PMDA)
Pharmaceuticals and Medical Devices Agency

KR Korea (MFDS)
Ministry of Food and Drug Safety

CN China (NMPA)
National Medical Products Administration

AU Australia (TGA)
Therapeutic Goods Administration

SG Singapore (HSA)
Health Sciences Authority

TW Taiwan (TFDA)
Taiwan FDA

Key Features

- **Japan:** Class I-IV classification, SAKIGAKE system (priority review for innovative devices)
- **Korea:** Class I-IV classification, fast-track review for innovative medical devices
- **China:** Class I-III classification, strict clinical trial requirements
- **Australia:** TGA recognizes EU CE marking (under certain conditions)
- **Singapore:** Fast approval, references ASEAN medical device guidelines

AHWP (Asian Harmonization Working Party)

- A collaborative body for harmonizing medical device regulations in the Asian region
- Member countries: Japan, Korea, China, Australia, Singapore, Taiwan, etc.
- Promotes harmonization based on IMDRF principles

💡 **Key Point:** When entering the APAC market, it is important to understand regulatory differences by country and collaborate with local partners or regulatory consultants