International Harmonization Efforts

International harmonization reduces duplicate regulations and facilitates **global market access**

🌍 IMDRF

International Medical Device Regulators Forum - Global regulatory harmonization forum

📋 GHTF Legacy

Global Harmonization Task Force - Predecessor to IMDRF

IMDRF Member Countries

- United States (FDA), Europe (EC), Japan (MHLW), Canada (Health Canada)
- Australia (TGA), Brazil (ANVISA), China (NMPA), Russia (Roszdravnadzor)
- South Korea (MFDS), Singapore (HSA)

Key Harmonization Documents

- **SaMD Framework:** Software as Medical Device classification and regulation
- **UDI Guidance:** Unique Device Identification system
- **Clinical Evidence:** Clinical evaluation principles
- **Risk Classification:** Risk-based classification principles
- **AI/ML Framework:** AI medical device regulatory guidelines

✅ Benefits of Harmonization

Reduced duplicate testing, shortened approval time, cost savings

🎯 Future Direction

AI/ML specialized regulations, expanded use of real-world evidence

💡 **Key Point:** Following IMDRF guidelines allows you to simultaneously meet regulatory requirements of multiple countries, making global market entry efficient