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What is the PPWG?

The Pharmaceutical Product Working Group

was established in
1999

by the **Association of Southeast Asia Nations Consultative Committee**

What is its Mission?

The PPWG's mission is to **bring the ASEAN nation's pharmaceutical regulations** in line with **international standards**. Along with the AFTA (ASEAN Free Trade Area) its aim is to facilitate international trade, without compromising on drug quality, efficacy and safety.

What is it Doing?



Discussing existing **technical guidelines** and **regulations**



Studying the **steps other regions have taken** to align with international technical guidelines and regulations











The **harmonization** of technical guidelines and regulations



The **development of Common Technical Documents** between the ASEAN nations, with a view to reaching a Mutual Recognition Agreement (MRA)

Pharmaceutical products covered by the PPWG include New Chemical Entities (NCES), biotech products, major and minor variation products and generics.

ASEAN Guidelines Harmonization

ASEAN Guidelines	Leading Country	Harmonized with Guidelines	Status
Process Validation	Singapore 	EU	 Approved and Implemented
Analytical Validation	Thailand 	International Council for Harmonization (ICH)	
Bioavailability/Bioequivalence and Variations	Malaysia 	EU	
Stability Studies	Indonesia 	ICH Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F), EMA Guideline, WHO Guideline	 Adopted
Safety Studies	Philippines 	ICH S1A, S1B, S1C(R), S2A, S2B, S3A, S3B, S4, S5(R2), S6, S7A, M3), without modification	
Efficacy Studies	Thailand 	ICH E1, E2A, E2C, E3, E4, E6, E7, E8, E9, E10, E11	