

# **Approaches to recognition of GMP certificates between the countries of Southeast Asia”**

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(Myanmar FDA)**



- Official of Myanmar FDA is one of the member of PPWG.
- NRA under the MOH ;
  - Responsible for regulatory and quality assurance of Medicine.
  - FDA regulating Food, Pharmaceuticals, medical devices as well as registration and licensing of medicines, inspection of medicines outlet and manufacturers, quality surveillance, Safety Surveillances and Controlling promotional materials of medicines

# Pharmaceutical Administration in Myanmar



To protect the public from unsafe drugs-

- 1972 - Public Health Law
- 1992 October - National Drug Law, amendment (2014)
- 1993 August - Registration, E-submission amendment (2023)
- Notifications -
  - Manufacturing
  - Sales and Distribution
  - Importation
  - Labelling and Advertisement



MRAGMP Scope ~ finished dosage forms (**POM & OTC for human use**)  
excludes biopharmaceuticals, radiopharmaceuticals, traditional medicine and  
investigational medicinal products intended for clinical trial.

ASEAN Sectoral Mutual Recognition Arrangement for GMP Inspection of  
manufacturers of Medicinal Products signed on 10 April 2009 in Thailand which  
aims to facilitate the movement of medicinal products in ASEAN.



In PPWG, Joint Sectorial Committee of Mutual Recognition Arrangement for GMP Inspection of Manufacturers of Medicinal Products that review the TOR, Scope of GMP and capacity Building of Inspectors, In ASEAN, there is (5) countries that in line with ASEAN listed inspection Services. So Myanmar also recognized the GMP, ML certificate of those 5 Nation Regulatory Authorities ; Indonesia, Malaysia, Singapore, Thailand and Philippines.

Recognition and acceptance of the GMP Inspection reports/ certificates issue by the other party's Inspection service





Myanmar also recognized the GMP of PICs member countries and list inspection services.

- Myanmar follows the WHO Principle of Good Recognition and Reliance Practices of well function NRA. So reduce the work load/ burden of NRA.
- For imported products, Myanmar FDA don't inspect GMP of Factory FDA.
- Only reviewed the Site Master File (SMF) and inspection report of NRA, But FDA (Myanmar) inspect the GMP of Local manufacturing plant

In ASEAN Post Market Alert System of Pharmaceuticals and other products is very active Role in information sharing and exchange system.





## ASEAN PPWG

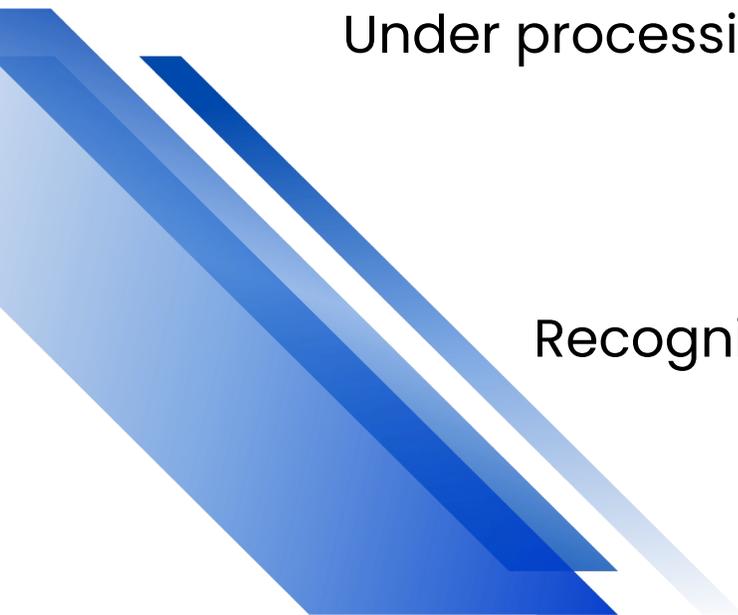
- Registration - ACTD And ACTR
- Variation Guideline
- MRA BE

GMP → MRA

expansion of Scope

Under processing → MRA ASEAN Pharmaceutical Regulatory  
Framework Agreement

Recognition ↔ Trust ↔ Reliance







VIII ALL-RUSSIA  
GMP CONFERENCE

ORGANIZERS



GENERAL PARTNER



STRATEGIC PARTNER



GEDEON RICHTER  
Health is our mission

GENERAL  
INFO PARTNER



GENERAL INFO AND  
ANALYTICAL PARTNER

*Фармацевтический*  
**ВЕСТНИК**

STRATEGIC  
INFO PARTNER

**ФАРМ  
МЕД  
ПРОМ**