Welcome and workshop objectives by Chair of the ASEAN Joint Sectoral Committee on GMP Inspection

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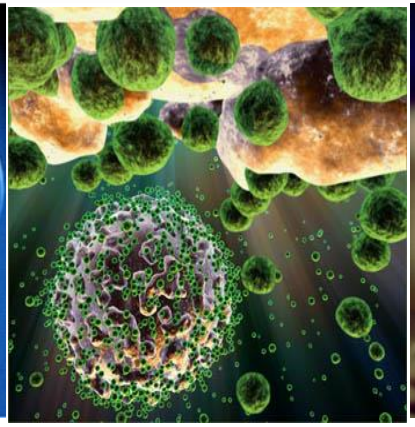
5 August 2018

Welcome & Workshop Objectives

1st ASEAN Overview Workshop on GMP for Biologicals/Biosimilars






Sia Chong Hock
Chair, ASEAN Joint Sectoral Committee (JSC) on GMP Inspection

Furama Resort, Da Nang, Viet Nam
5 August 2018

Geography of Asia & Southeast Asia

ASEAN :
Association of Southeast Asian Nations

- **Founded in 1967**

- **Comprises 10 Southeast Asian Member States**

North Korea

Japan

South Korea

China

Taiwan

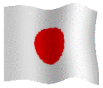
India

Southeast Asia

History on Creation of ASEAN Economic Community (AEC)

- **10 ASEAN Member States:**

  - Have very diverse racial, religious, socio-cultural, political, economic & geographical backgrounds
  - Face economic/business competition from :

 Taiwan : 23 million  South Korea : 50 million  Japan : 130 million

 Australia : 23 million  Canada : 37 million

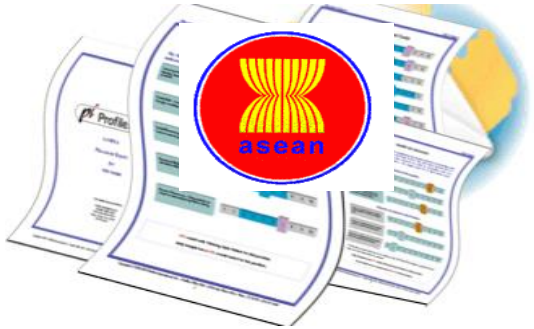
 USA : 300 million  EU : 500 million

 India : 1.3 billion  China : 1.4 billion

- A Combined Population of 650 million people
- A Combined Economy of US$2.5 Trillion
- May become 4th Largest World Economy by 2030

Strength can be Optimized through Creation of AEC 2015

ASEAN Sectoral MRA on GMP Inspection



Signed by Economic Ministers of

all 10 ASEAN Member States on 10 April 2009, Pattaya, THAILAND

- PIC/S Framework Used (by TF) as Basis for ASEAN MRA

- Covers Medicinal Products in Finished Dosage Forms

Benefits of ASEAN MRA on GMP Inspection & LIS

(1) Avoiding duplication of GMP Audits within ASEAN

(2) Saving time, resources & costs for regulators & industry

(3) Facilitating Trade in Medicinal Products across ASEAN

(4) Quicker Access of Medicinal Products by ASEAN Patients

(5) Harmonizing ASEAN Inspection System to that of PIC/S

(6) Increased Attractiveness of ASEAN to investors from China, Japan, Korea, US, EU & other larger economies

Alignment of MRA with the overall objectives of AEC 2015

Expanded Scope of ASEAN Sectoral MRA

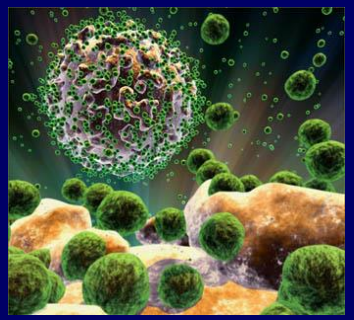
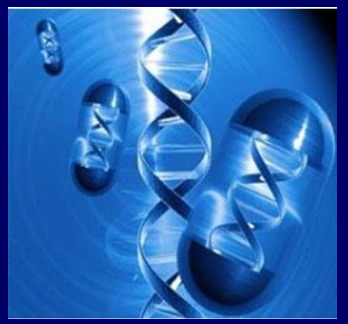
Currently, scope of ASEAN MRA covers only the manufacture of pharmaceuticals (drug products) in finished dosage forms



*ASEAN MRA **does NOT** include **Biologicals**, APIs*

Scope of MRA will be expanded to include:

- **Manufacture of Biologicals/Biosimilars**
- **Manufacture of APIs**

1st ASEAN Overview Workshop on GMP for Biologicals/Biosimilars

Introductory & Interactive Workshop – English Language from 8.30 am to 5.30 pm

Speakers' Faculty

Chair	: Elwyn Griffiths, DSc, PhD, UK
Co-Chair	: Dianliang Lei, PhD, WHO
Regulators/Inspectors	: Vimal Sachdeva, WHO & Sia Chong Hock, Singapore HSA
Industry Scientist	: Anil K Chawla, Switzerland; Dinesh Khokal & Yusdy Pan, Singapore

Workshop Objectives

1. To understand cGMP inspection framework for biologicals/biosimilars based on PIC/S or other equivalent cGMP standards

2. To promote active discussion amongst inspectors, reviewers & scientists from AMS concerning best practices to inspect manufacturers of biologicals/biosimilars

3. To identify areas of consensus, uncertainty or disagreement concerning inspection framework on cGMP for biologicals/biosimilars

Workshop Focus Themes

The workshop program covers the following elements:

- PIC/S / WHO GMP or other equivalent international GMP standards
- Importance of GMP in Controlling Cell Substrates & Production of Biologicals
- Viral Safety of Biological Products
- Pharmaceutical Quality System & Data Integrity
- Bottlenecks, e.g. Knowledge & Information needed for effective GMP Inspection
- Other Concerns, Challenges, Knowledge Gaps, Need for Intensive Training

Learning Objectives

- The workshop should increase ability and knowledge of participants to conduct inspection of biologicals/biosimilars manufacturing facilities under GMP framework
- Note : GMP inspection is an integral component of the registration and licensing of pharmaceutical and biological products

THANK YOU

1st ASEAN Overview Workshop on GMP for Biologicals/Biosimilars, Da Nang, Viet Nam