MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP VIII ALL-RUSSIA GMP CONFERENCE

50 years GXP SID & GP

Approaches to Recognition of GMP Evidence between Malaysia and other countries

Belinna Abu Bakar
Section Good Manufacturing Practice (GMP)
National Pharmaceutical Regulatory Agency (NPRA)
Pharmaceutical Services Division
Ministry of Health Malaysia

Regulatory Requirement - NPRA

REGISTERED

Official Portal

NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

MINISTRY OF HEALTH MALAYSIA

Acceptable GMP Evidence

Pharmaceutical manufacturer located on a site within jurisdiction of a PIC/S Participating Authority - **Acceptable**

Pharmaceutical manufacturer not located on a site within jurisdiction of a PIC/S Participating Authority, GMP evidence issued the NDRA who is PIC/S PA - **Acceptable**

ASEAN Sectoral MRA on GMP Inspection for Medicinal Products

For pharmaceutical manufacturer located in an ASEAN member country, GMP evidence issued by the local NDRA is accepted if the NDRA is included as a Listed Inspection Service

ASEAN Listed Inspection Service under the MRA:

Health Science Authority (HSA), Singapore	National Pharmaceutical Regulatory Agency Ministry of Health Malaysia	National Agency of Drug and Food Control (NADFC), Indonesia	Food and Drug Administration of Thailand (FDA Thailand), Thailand	Food and Drug Administration of the Philippines (FDA Philippines), Philippines

Development & Implementation of the MRA

1st TF Meeting (August 2005, Singapore)

2nd TF Meeting (March 2006, Hanoi)

3rd TF Meeting (October 2006, Jakarta)

Special (Adhoc) Technical Meeting (April 2007 Hanoi)

4th TF Meeting (July 2007, Kuala Lumpur)

5th TF Meeting (February 2008, Vientianne)

6th TF Meeting (July 2008, Brunei Darussalam)

7th TF Meeting (May 2009, Manila)

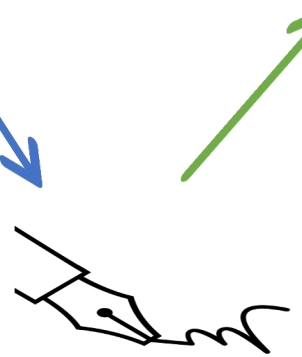
8th TF Meeting (July 2010, Yogyakarta, Indonesia)

9th TF Meeting (June 2011, Singapore)

1 → 2 → 3 → + → 4 → 5 → 6 → 7 → 8 → 9

Task performed includes:

- Identification of terms of reference, benchmark and framework of the MRA
- Gap analysis
- Preparation of the working draft of the MRA
- Discussion on the contents of the MRA
- Discussion on the legal aspects and implications of the MRA on all 10 ASEAN Member States



Task performed includes:

- Preparation of a set of Frequently Asked Question about the MRA
- Preparation of Operating Manual on Panel of Experts

ASEAN Sectoral MRA on GMP Inspection for Medicinal Products

Signed by the Economic Ministers of all 10 ASEAN Member States on 10th April 2009 in Pattaya, Thailand

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ORGANIZERS

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