GMP

Animal Medicine in Thailand

Mr. Pinpong Intarapanich
Bureau of Drug Control

Thai Drug Act related to Animal (Veterinary) medicine

GMP of Thailand

GMP standard and evaluate step for Animal (Veterinary) medicine of Thailand
“Drugs” means: Section 4. In this Act;
(1) Substances recognized by pharmacopoeias notified by the Minister.
(2) Substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness.
(3) Substances which are pharmaceutical chemicals or semi–processed pharmaceutical chemicals.
(4) Substances intended to affect the health, structure or function of the human or animal body.
“Modern drug” means a drug intended for use in the practice of modern medicine or the cure of an animal disease;

“Cure of animal disease” means any action performed directly on an animal body for the purpose of examination or treatment and includes the prevention of disease, elimination of disease, plastic surgery, castration or artificial insemination;
GMP of Thailand
GMP in The Area of ASEAN

ASEAN Economic Community
> Free flow of Goods, Services, Investment, Capitals, Skill Labor

ASEAN Economic Community Council

ASEAN Consultative Committee on Standards and Quality (ACCSQ)

Pharmaceutical Products Working Group (PPWG)

ASEAN MRA Taskforce on GMP Inspection

- Standardization and Harmonization
- Sharing information
- Avoiding duplication of GMP inspection
- Worksharing
GMP of Thailand
GMP in The Area of ASEAN

Signed on 10 April 2009
Thailand

ASEAN SECTORAL MRA on GMP Inspection

SCOPE:
• Human medicines

NOT:
• Traditional medicines
• APIs
• Biological products
• Radiopharmaceutical
• Investigational medicines

Joint Sectoral Committee (JSC)
For prescribed procedures for supervision
GMP in The Area of ASEAN MRA

The principles of the ASEAN MRA on GMP Inspection:
- Use the PIC/S GMP or equivalent standards.
- The assessment of quality systems should conform to PIC/S Requirements.
- The GMP auditor agency of each country must be registered.
- Member States must accept the GMP certificate or inspection report of the registered agency.
- Thailand has been the ASEAN listed inspection service and on the Panel of GMP Experts of ASEAN since 2014.
PIC/S Member of Thai FDA Thailand

- Thai FDA planned to achieve PIC/S membership by the year 2012. Both domestic manufacturers and public sector needed preparations before becoming a PIC/S member. For this matter, Thai FDA had informed and educated manufacturers since April 2005. In addition, Thai FDA had made an operational plan for 2005-2012 regarding PIC/S.

- The first submission for PIC/S membership was filed in 2006, and did not pass the qualification by PIC/S Assessment Team. The PIC/S submission status expired in 2012.”
PIC/S Member of Thai FDA Thailand

• The second submission to be PIC/S member was held in 2015
• Thai FDA was evaluated by PIC/S Assessment Team in March 2016
• The accession of Thailand / Thai FDA to PIC/S was performed in the PIC/S member meeting on 4-5 July 2016 in Manchester (UK)
• The PIC/S Committee invited Thailand’s Food and Drug Administration (Thai FDA) to join the Scheme as of 1 August 2016
• Thai FDA became the 49th PIS/S Participating Authority
Pharmaceutical Inspection Co-operation Scheme

Leading the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.

Accession of Thailand / Thai FDA to PIC/S
4 - 5 July 2016

At its meeting on 4-5 July 2016 in Manchester (UK), the PIC/S Committee invited Thailand’s Food and Drug Administration (Thai FDA) to join the Scheme as from 1 August 2016. Thai FDA will become PIC/S’ 49th Participating Authority.
https://www.picscheme.org/en/members

LIST OF PIC/S PARTICIPATING AUTHORITIES

By alphabetical order of the country/entity of each Participating Authority

Thailand

Food and Drug Administration (Thai FDA)

Ministry of Public Health
88/24 Tiwanon Road
Nonthaburi 11000
Thailand

Accession to PIC Scheme August 2016
GMP Standard for Veterinary Medical Products of Thailand

GMP standards cover:
• All veterinary medicinal products manufactured in Thailand
• All veterinary medicinal products imported into Thailand

GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS
• Part I
• Part II
• Annex

Annex 4 (Manufacture of veterinary medicinal products other than immunologicals)
Annex 5 (Manufacture of immunological veterinary medical products)
Veterinary medical products Import into Thailand

Situation on November 2016

**PIC/S Member**

- Preliminary assessment on Document by GMP inspector
  - GMP Certificate (Approved by Embassy)
  - And
  - GMP Audit Report
  - Site Master File
  - If No MOU
  - on site GMP Inspection
  - In the Future

**ASEAN Listed**

- Preliminary assessment on Document by GMP inspector
  - GMP Certificate (Approved by Embassy)
  - Or
  - GMP Audit Report

- On site Inspection
  - Not required

**Non PIC/S Member**

- Preliminary assessment on Document by GMP inspector
  - Certificate (Approved by Embassy)
  - And
  - GMP Audit Report
  - Site Master File
  - Plan, List of SOP, PQR, BPR, Record, Etc.

- On site GMP Inspection

**GMP Accreditation Sub-Committee**

**Registration Step**