Current GMP Compliance Process and Future Possibility in Thailand

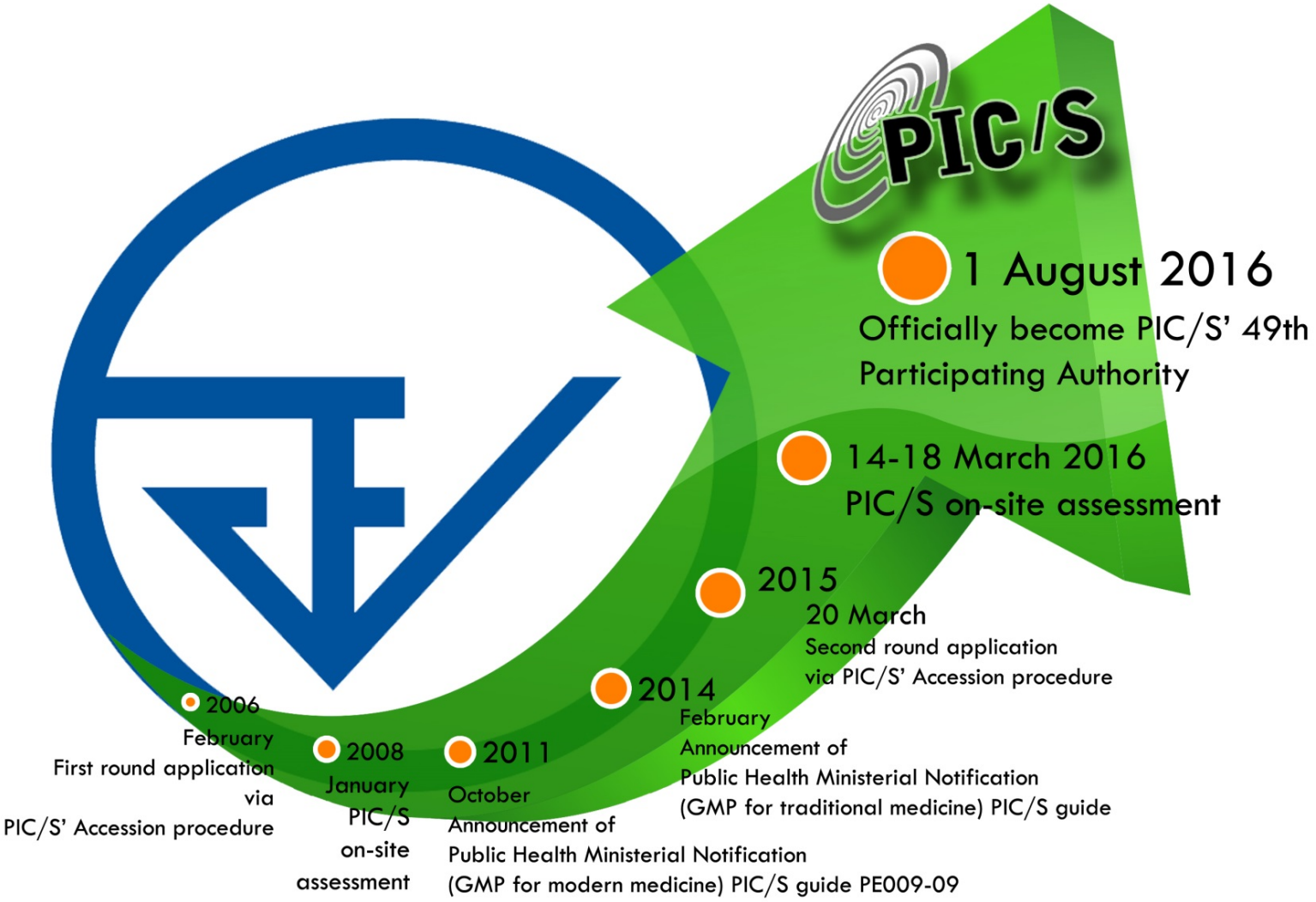
Suchart Chongprasert, Ph.D.

Food and Drug Administration
Thailand

Thai FDA

CONTENTS

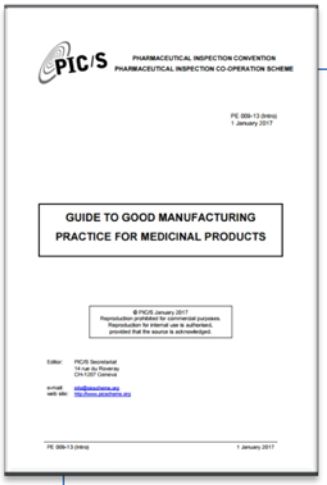
Journey towards PIC/S Membership



GMP Compliance Process

Current GMP Standards

PIC/S Guide to GMP for Medicinal Products, PE009-12



In process of revising the requirement standards for Chapters 1, 2, 6, and 7 to meet PE009-13, effective 1 Jan 2017

Current GMP Compliance Process

Principle:

apply the same compliance process for either domestic or overseas manufacturers to assure the public the quality of medicinal products wherever they are manufactured

In Practice:

different procedural tracks between domestic and overseas manufacturers may be applied depending on several factors, in particular for overseas manufacturers, as they are required to comply with their own countries GMP regulations and/or other international GMP standards

Current GMP Compliance Process [2]

For domestic manufacturers,	For overseas manufacturers,
• 100% on-site GMP inspection	• a *Reliance Model* based on reliable prior GMP inspection is adopted to some extent

Current GMP Compliance Process : Overseas Manufacturers [3]

Program I: Document Verification Program

For the equivalency with domestic GMP inspection, i.e., three (3) channels

ASEAN MRA GMP Listed Inspection Services;	GMP Certified by PIC/S Participating Authorities;	GMP Certified by Non PIC/S Participating Authorities

Outcome of the Verification:

On-site inspection waived or required

Current GMP Compliance Process [4]

Program II: On-site GMP Inspection

- determined case by case based on established criteria, including when a verification result cannot assure the equivalency of the GMP practices with local GMP regulation
- document review required priory for preparation followed by on-site inspection

GMP Compliance Document

Current Document Requirements

Depending on if the manufacturers fall on what tracks, in general, the following documents are required

- **Latest GMP Certificate with a validity period of at least 6 months;**
- **Latest GMP inspection report;**
- **Site Master Files (SMF) in either PIC/S or Non PIC/S format**
- **List of inspection by authorities in the past 5 years**
- **List of regulatory actions in the past 5 years, etc.**

Current Compliance Documents [2]

- At the time of submission of a marketing authorization application for medicinal products and when renewal required periodically
- For Document Verification Track: GMP certificate validity expires; proof of GMP compliance is required
  - follow the document requirement procedural tracks
  - submit the documents within 6 months after the expiration of the GMP certificate
- For on-site GMP inspection, next inspection to be conducted before the expiration of a GMP certificate validity period

Current Compliance Documents [3]

- **Please consult available guidelines regarding documents required for the assessment for GMP compliance**
- **Consultation process available both the document verification and on-site inspection programs**

GMP Compliance Review

Current GMP Compliance Review

Time periods for a document review vary based on the procedural tracks chosen

For Document Verification:

- **30-90 business days depending on:**

if manufacturers are certified by countries on the ASEAN GMP MRA Listed Inspection Service, or certified by PIC/S or Non PIC/S Authorities

For on-site inspection,

- **Document assessment prior to on-site inspection: 90 business days**
- **a lead time for on-site inspection after documents assessment varies from manufacturer to manufacturer**
- **On-site inspection: normally 5 days**

Current GMP Compliance Review [2]

- **Renewal of GMP compliance required**
- **For Document Verification** :
  submission of documents as required
  when a GMP compliance period expires

Current GMP Compliance Review [3]

- **For on-site inspection,**
  - **Routine GMP inspection as that of domestic manufacturers required**, unless later
    - the manufacturers are GMP certified by other PIC/S authorities; or
    - located in ASEAN country and are certified by the authority of the same country on the ASEAN GMP MRA List,
    - **choose to follow the document verification channel**
  - **GMP validity period varies based upon the degree of GMP compliance found on the last inspection**

Future Possibility

Future Possibility: Principle

Maximizing the most efficient use of the work done satisfactorily in GMP inspection areas among comparable drug regulatory authorities

i.e., no unnecessarily repeat the same work

Future Possibility

Mechanisms to work together closely among regulatory authorities with comparable GMP inspection systems should be explored, developed, and implemented to avoid any unnecessary repeat of the same kind of work and help to promote ***mutual acceptance*** or ***recognition*** of GMP inspection


THANK YOU
FOR
YOUR ATTENTION