Certified for success:
using the CEP Procedure to elevate quality and drive trust
23-24 September 2025, Budapest, Hungary

Session III The power of GMP inspections

The role of PIC/S : Inspections of API manufacturers globally

Hirofumi Suzuki
PIC/S Secretariat
Pharmaceutical Inspection Co-operation Scheme

Agenda

Part I – Setting the Scene

- Challenges in a Global API Environment
- The Role of PIC/S in this Global API Environment

Part II – Key PIC/S Activities Supporting GMP Inspection Reliance

- PIC/S : A Global Membership Network
- Sharing of GMP Inspection information
- Building trust
    - Harmonised GMPs
    - PIC/S API Expert Circle
    - Harmonised Training of GMP Inspectors (PIA)

Part III – Collaboration with EDQM

- Cooperation Framework (2007 MoU)

Agenda

Part I – Setting the Scene

- Challenges in a Global API Environment
- The Role of PIC/S in this Global API Environment

Challenges in a Global API Environment

Global Dependence on a Limited API Manufacturing sites

- **Over 70%** of APIs are produced in a small number of countries, especially in **Asia**
  - ⇒ One API site may supply **20+ countries**
  - ⇒ **Supply chain** can be complex
- **Disruptions** (e.g., pandemics, geopolitics, quality issues) affect global medicines supply

Regulatory authorities rely heavily on foreign inspections

- Raises important questions:
  - Can we **rely on** / **trust** each other's inspection outcomes?
  - How can we **coordinate inspections** more effectively?
  - How can we **reduce inspection duplication**?

The Role of PIC/S in this Global API Environment

PIC/S provides the framework for international cooperation between Regulatory Authorities to deal with this global API environment

PIC/S contributes by

- **Harmonising GMP standards & inspection methods**
  → Ensures consistent oversight of API manufacturing worldwide
- **Fostering mutual confidence among authorities**
  → Enables reliance on each other's inspections, avoiding duplication
- **Contributing to inspections information sharing globally**
  → Facilitates information exchange, sharing of inspection plans and reports
- **Supporting capacity-building & training**
  → Enhances inspector competence through standardized training

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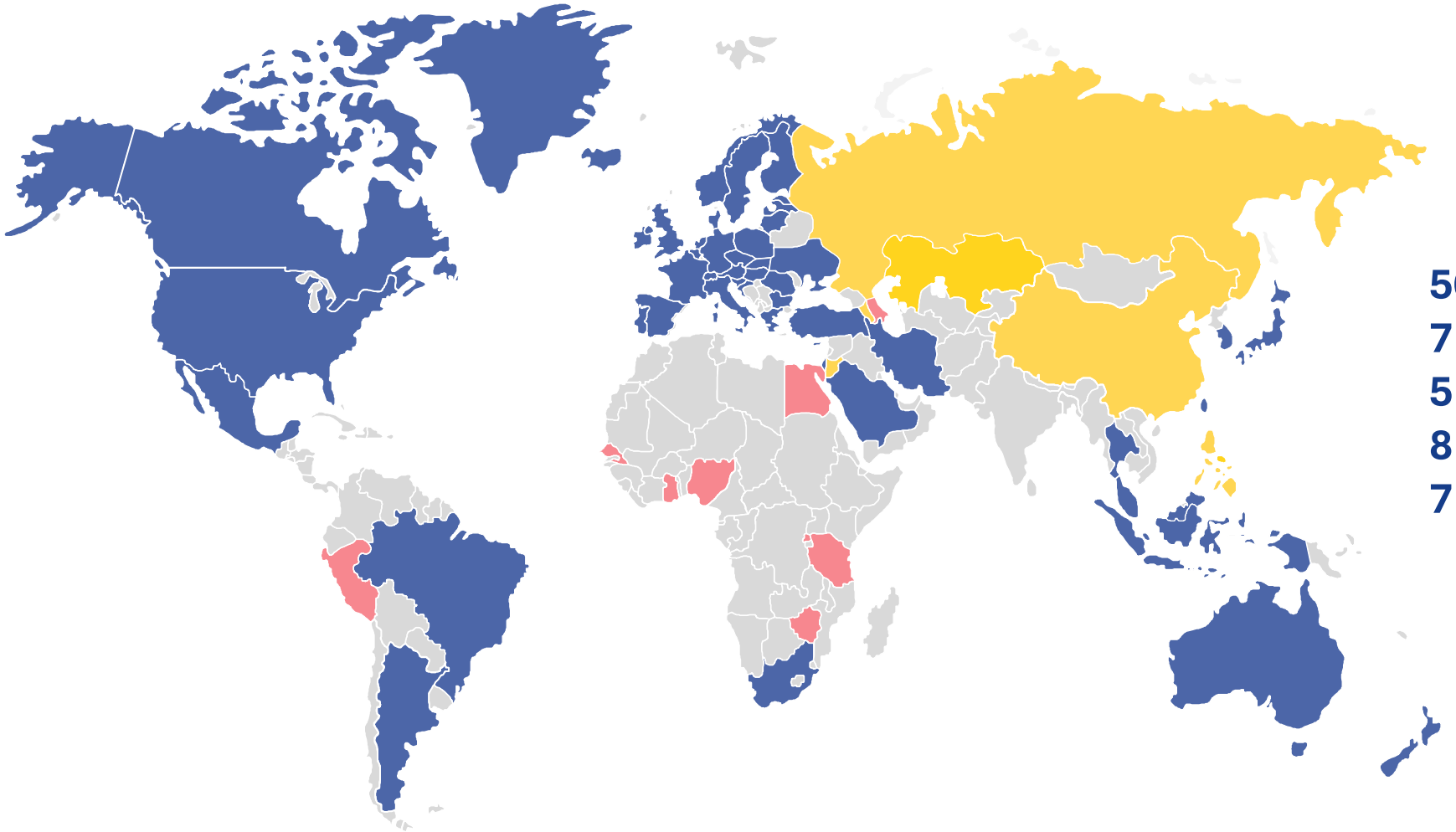
PIC/S : A Global Membership Network



56 members
7 Associated Partners *
5 applicants
8 pre-applicants
7 former pre-applicants
as of September 2025

Member
Pre-applicant
Current applicant

PIC/S : Sharing of GMP Foreign Inspection Information

Current system Regarding Foreign Inspection Plan Sharing

PIC/S Secretariat

Twice a year

① Requesting update

② Send updates

③ Send revised file

PIC/S PAs & POs

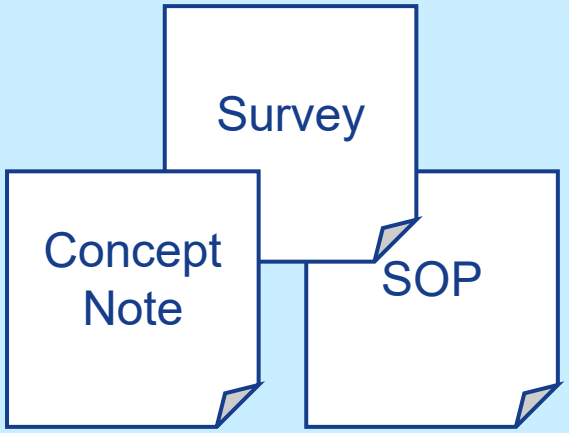
① Update directly

② View stored file

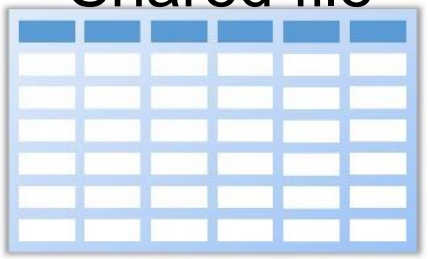
Anytime

and/or

New system
(online DB sharing)

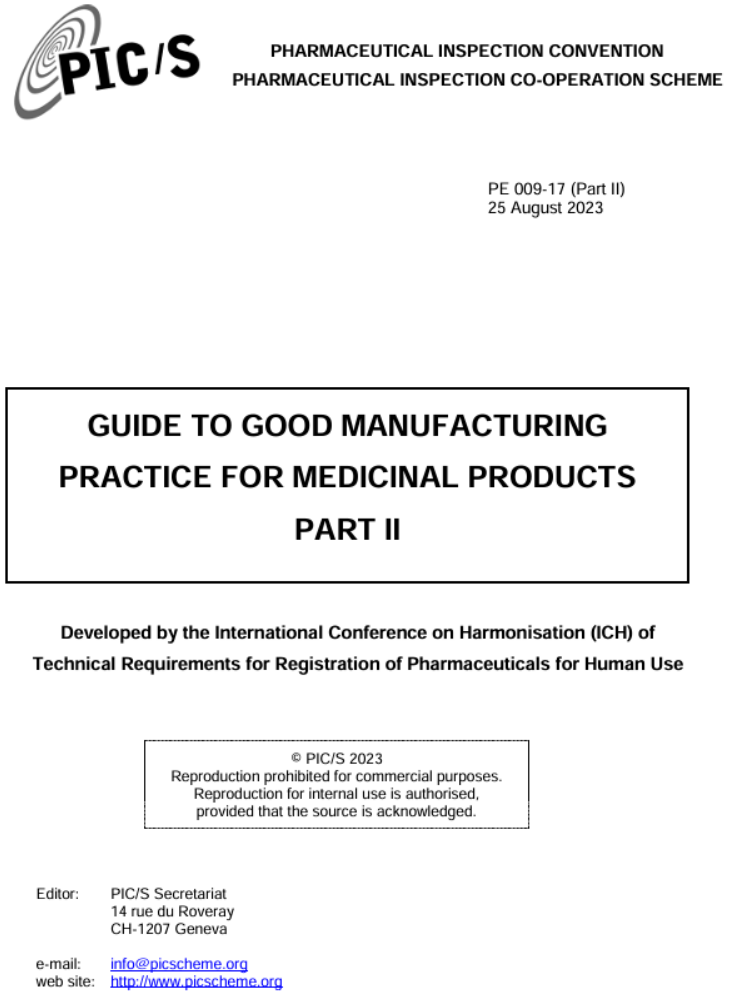


Shared file



Online Database

PIC/S : Building Trust – Harmonised GMP



PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 009-17 (Part II)
25 August 2023

GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS PART II

Developed by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use

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- ICH Q7 is originally based on a PIC/S draft guideline on API,
- adopted by PIC/S in 2001 as a stand-alone guide (PE 007)
- Then integrated as part II of the PIC/S GMP Guide in 2007
- Revised in 2014 to integrate QRM principles

PIC/S : Building Trust – API Expert Circle

PIC/S Expert Circle on APIs established in 2005 and has met regularly worldwide between 2005 and 2019 (hosted by EDQM in 2015)

- Key contributions over the years have included:
  - Actively developing and maintaining a common approach and equivalent interpretation of the ICH Q7 Guideline.
  - Developing the **PIC/S Aide Memoire on API (PI 030-1**) in addition to contributing to the ICH Q&A document on Q7.
  - Playing a strong role in training through the **API International Training Programme** set up for inspectors and - for some training segments (Q7) - also for industry.

- The Expert Circle has recently been re-established and is currently developing a new mandate as well as expanding its focus on training through development of **API e-learning modules** and an **API curriculum for the PIC/S Inspectorates' Academy**

PIC/S : Building Trust – Harmonised Training the PIC/S Inspectorates' Academy (PIA)

❑Overview of PIA

- A PIC/S initiative to establish a web-based educational centre under the PIC/S umbrella
- Aims to harmonise and standardise GMP inspector training internationally
- Provides both general and advanced training, and serves as a platform for discussion and knowledge sharing among regulators
- Offers a single point of access to all PIC/S training activities, to be implemented in various stages

❑API-related Training Material Development

- Developing an API Curriculum covering GMP inspections of API manufacturing sites
- Develop training material (e-Modules) based on the PIC/S GMP Guide Part II / ICH Q7, with financial support from ICH
- Designed to equip GMP inspectors with the knowledge required for API inspections

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Part III – Collaboration with EDQM

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6. PIC/S–EDQM Cooperation

PIC/S–EDQM Memorandum of Understanding (2007)

❑ Purpose

- ✓ Establish a framework for co-operation between PIC/S and EDQM
- ✓ Focus on APIs and blood, tissues & cells
- ✓ Promote information sharing and training of GMP inspectors
- ✓ Non-binding and without legal effect

❑Scope of Co-operation

✓ APIs

- Exchange information on planned inspections
  - ✓ EDQM: via the CEP certification inspection programme
  - ✓ PIC/S: via information from PAs on inspections in non-PIC/S countries
- Joint training of GMP inspectors specialised in APIs
- Mutual invitations to meetings, conferences, workshops (PIC/S Committee, Expert Circles, EDQM training events)
- Consultation on guidance documents related to API inspections

✓ Blood, tissues & cells

- Co-operation in inspector training and drafting guidance documents

Thank you for your attention

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