PIC/S Update

Boon Meow Hoe

Dy Director (Overseas Audit Unit)

PIC/S Chair of Sub-Committee on Training cum Executive Bureau member (2024-2025)

Health Sciences Authority

PDA Parenteral Drug Association

2024 Pharmaceutical Manufacturing and Quality Conference

CONNECTING PEOPLE SCIENCE AND REGULATION®

PIC/S Update

Main Ballroom 1 and 2
Orchard Hotel (442, Orchard Road, Singapore 238879)
7 May 2024, Tuesday, 4:05 - 4:35 p.m.

PIC : Pharmaceutical Inspection Convention (Since 1970) 54 Years

PIC Scheme: Pharmaceutical Inspection Co-operation Scheme (Since 1995) 29 Years

PIC

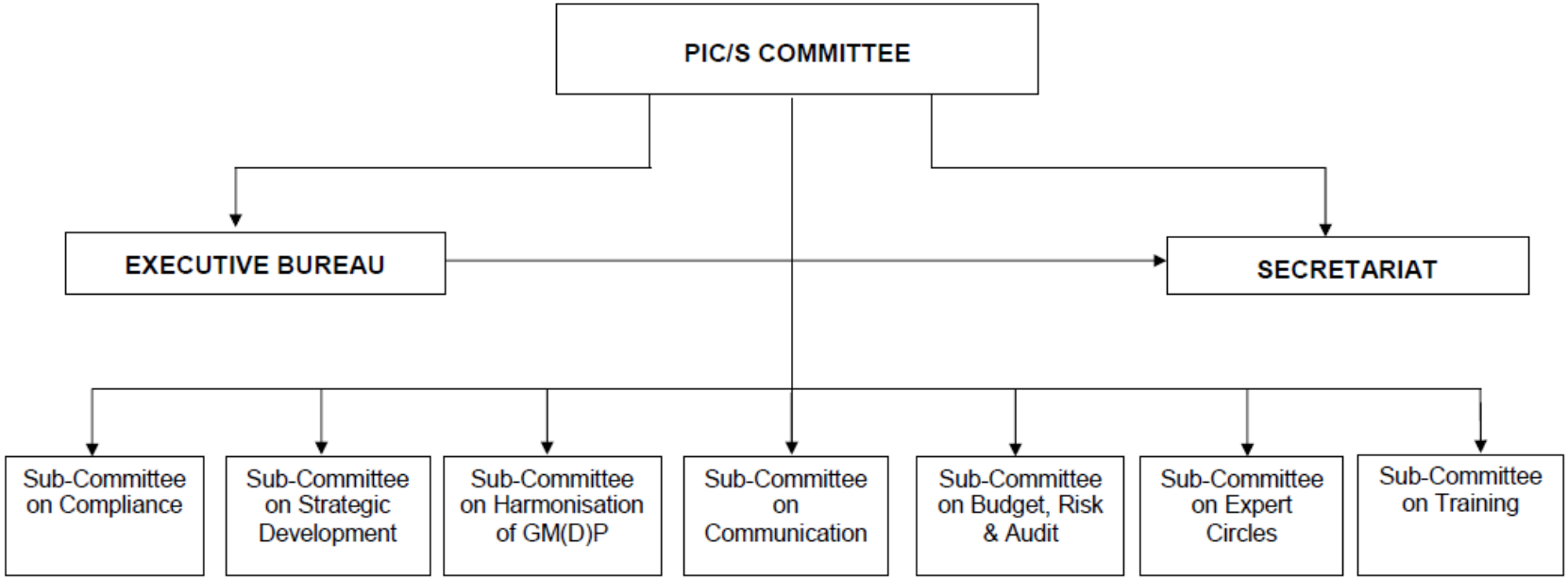
PIC Scheme

Convention:
legally binding, treaty

Scheme:
legally non-binding, agreement

PIC* & *PIC Scheme* now operate in parallel - jointly referred to as *"PIC/S"

Organisational Structure



Election & New Executive Bureau (2024 - 2025)

- The last PIC/S face-to-face Committee of Officials meeting was held on 6-7 November 2023 at Bangkok (Thailand)

- Election of the PIC/S Chairperson, Dy Chairperson, 7 Sub-Committees (SC) Chairpersons / Executive Bureau (EB) and the SC Dy Chairpersons for the period covering from 1.1.2024 – 31.12.2025

New PIC/S Executive Bureau (2024-2025)

PIC/S Chairperson: Mr Jacques Morénas (France / ANSM),

PIC/S Deputy Chairperson and
Chair of the Sub-Committee on Expert Circles (SCEC): Ms Kathleen Sinninger (US FDA),

Immediate past PIC/S Chairperson; Mr Paul Gustafson (Canada / ROEB),

Chair of the Sub-Committee on Communication (SC COM); Dr Kentaro Hara (Japan / PMDA),

Chair of the Sub-Committee on Compliance (SCC); Mr Henning Willads Petersen (Denmark / DKMA),

Chair of the Sub-Committe on Strategic Development (SCSD); Ms Jennifer Burnett (Australia / TGA),

Chair of the Sub-Committee on Budget, Risk and Audit (SCB); Dr Theresa Mullin (US FDA),

Chair of the Sub-Committee on GM(D)P Harmonisation (SCH). Ms Ying-Hua (Ellen) Chen (Chinese Taipei / TFDA),

Chair of the Sub-Committee on Training (SCT): Mr Boon Meow Hoe (Singapore / HSA)

New PIC/S Executive Bureau (2024-2025)

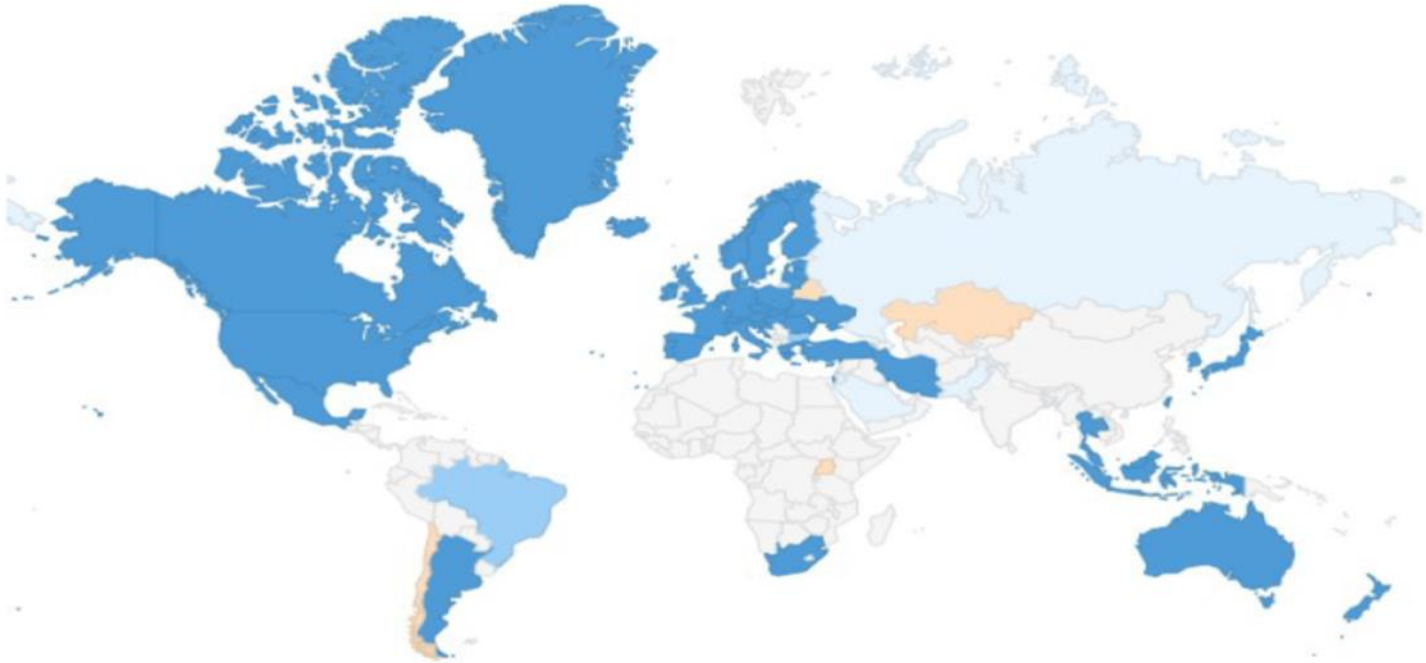
PIC/S Memberships

PIC/S 55th and 56th Participating Authority (w.e.f. 1 July 2023)

Bulgaria / BDA : 55th PIC/S Participating Authority

Saudi Arabia / SFDA : 56th PIC/S Participating Authority

Overview of PIC/S **56 Members** as of 6 May 2024 (dark blue)
4 Applicants (medium blue), 2 (Pre) Applicants (Pale blue)



4 Applicants (One frozen)

1) **China / National Medical Products Administration (NMPA)**

2) **Jordan / Jordan Food & Drug Administration (JFDA)**

3) **Philippines / Food and Drug Administration (FDA)**

4) **Russian Federation***

- ❖ Ministry of Industry and Trade of the Russian Federation (Minpromtorg Russia)
- ❖ Federal Service for Surveillance in Healthcare (Roszdravnadzor), including
  Federal State Budgetary Institution “Information and Methodological Center for Expertise, Accounting and Analysis of Circulation of Medical Products” (FGBU “IMCEUAOSMP” of Roszdravnadzor)
- ❖ Federal State Institution “State Institute of Drugs and Good Practices” (FSI “SID & GP”)
  Federal State Budgetary Institution "Scientific Center for Examination of Medical Devices" of the Ministry of Health of the Russian Federation (FSBI "SCEMD”)

* The membership application has been frozen.

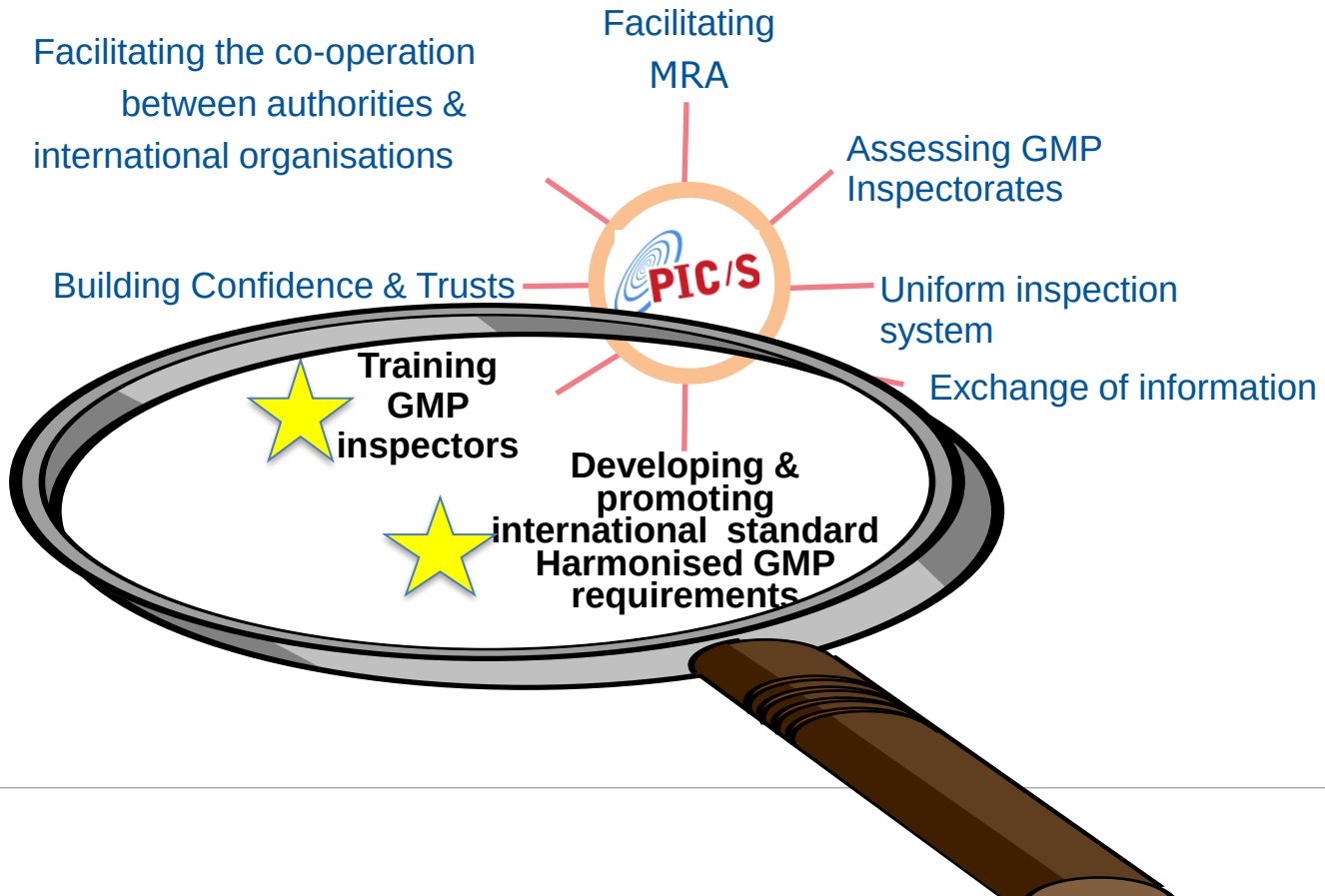
2 (Pre) Applicants

1) **Egypt** / Egyptian Drug Authority (EDA)

2) **Zimbabwe** / Medicines Control Authority of Zimbabwe (MCAZ)


PIC/S Vision
To lead the international development, implementation & maintenance of harmonised GMP standards & quality systems of inspectorates in the field of medicinal products
6

Goals breakdown



International GMP Harmonization and inspections?

International GMP Harmonization

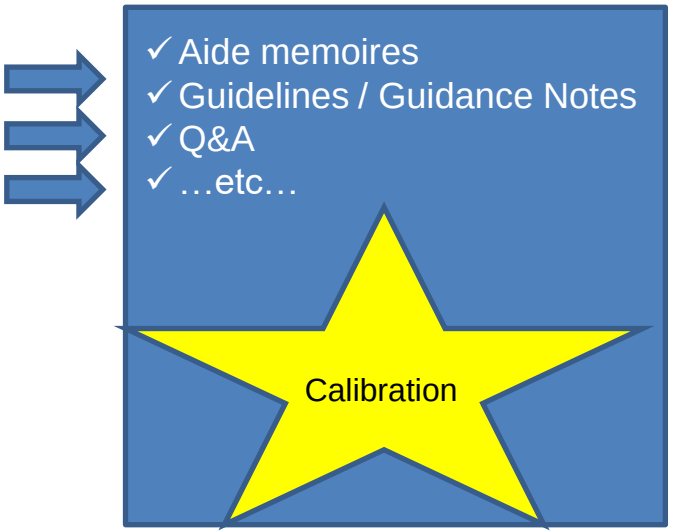
To have:

- Common GMP standard
- Guidance notes (for industry, for regulators)
- Q&A
- Single Point of Contact (SPOC) with 56 PAs (Committee member)

Adequate**?** **NO!**

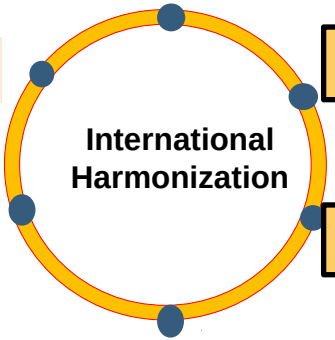
How PIC/S achieves International Harmonization of inspections and GMP?

- Having a single, common GMP standard & all Inspectorates operating a common Quality Management System are still very far away from the harmonization journey…
  - …**training** is vital …
  - …Other **additional training tools** are essential…
    - ✓ Working Groups…
    - ✓ Expert Circles….
    - ✓ Annual Seminar…
    - ✓ PIC/S Inspectorates' Academy (PIA)…
    - ✓ PIC/S Joint Visits Programme (JVP) …
    - ✓ Joint Reassessment Programme (JRP / JAP)…
    - ✓ New Inspectors Training Course
    - ✓ Coached Inspections Programme
    - ✓ …



Expert Circles

Joint Reassessment Programme

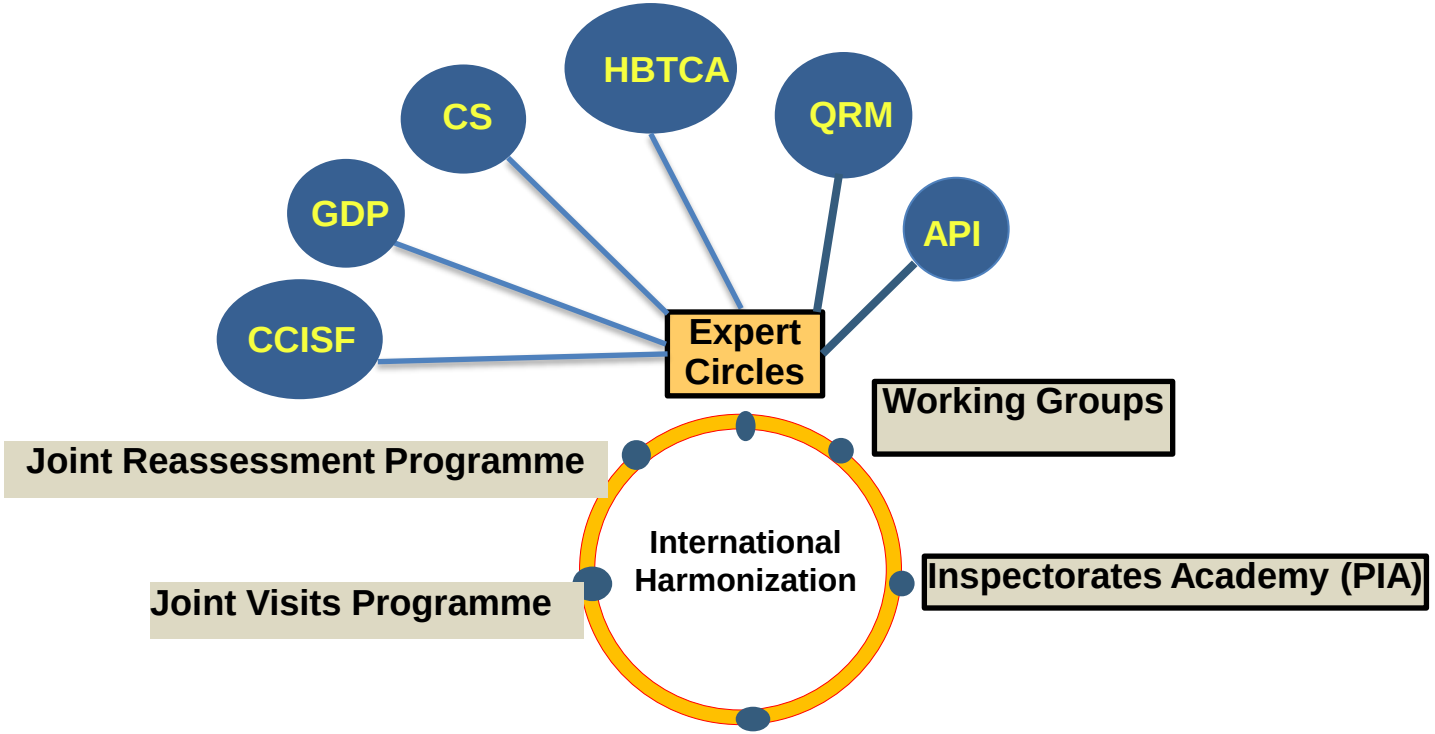


Working Groups

Joint Visits Programme

Inspectorates Academy (PIA)

Guides, recommendations & Quality systems


HBTCA
CS
QRM
GDP
API
CCISF
Expert Circles
Working Groups
Joint Reassessment Programme
International Harmonization
Inspectorates Academy (PIA)
Joint Visits Programme
Guides, recommendations & Quality systems

Expert Circles (ECs)

The **Expert Circle on QRM** had organised two events in 2022, it is planning to run a meeting on the revision of Q9(R1) in 2025.

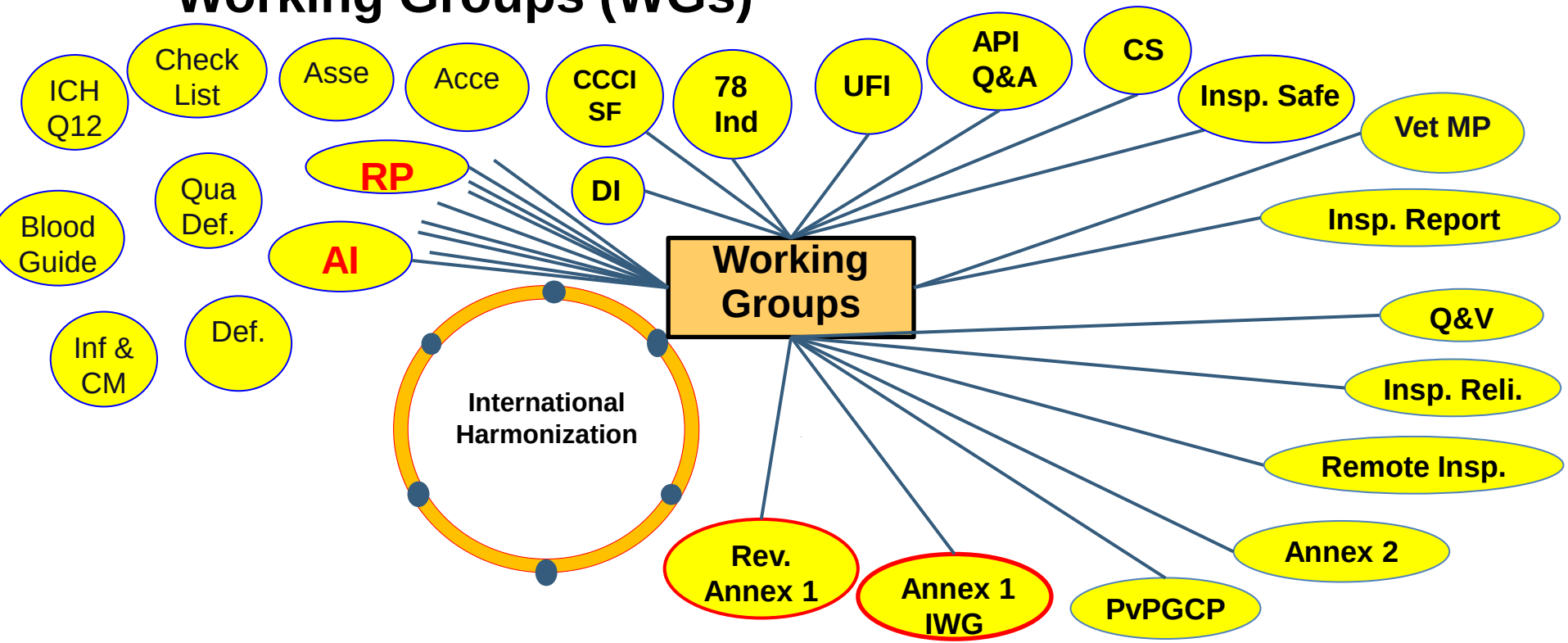
Hong Kong SAR, China / PPBHK has hosted the 6th **Expert Circle on GDP** meeting virtually on 29 Nov – 1st Dec 2023.

The Malta Medicines Authority will be hosting the 7th **PIC/S Expert Circle on GDP** meeting in Malta on 24th - 26th Sep 2024.

Malaysia / NPRA will be hosting the next **Expert Circle on HBTCA** meeting (Face-to-face) on 20-22 Aug 2024 in Kuala Lumpur (Malaysia).

A new **Expert Circle on GCP** and a new **Expert Circle on GVP** (Upgraded from WGs)

Working Groups (WGs)



Working Groups (WGs)

1) **Inspection Reliance**
2) **Remote inspection**
3) **Unique Facility Identifiers (UFI)**
4) **Inspector Safety**
5) **Revision to the PIC/S Inspection Report Format**
6) **Revision Annex 1 Drafting Group** (Joint WG with EMA & WHO)
7) **Annex 1 Implementation Working Group – Training**
8) **Revision of Qualification & Validation”** (PI 006-4 (Draft 4))
9) **Controlling Cross-Contamination in Shared Facilities (CCCISF)**
10) **Revision of Annex 2 –** With Austria/AGES**,** 2A Training in 2023

Working Groups (WGs) continue…

11) Aide Memoire on Tissues and Cellular Therapy Products Inspection

12) Computerised Systems (Revised Annex 11 & Chapter 4)

13) Data Integrity

14) Revision to Blood Guidance Documents

15) Veterinary Medicinal Products (VMP)(Revised Annex 4 & 5)

16) Confidential Informants

17) Training Materials for ICH Q12

18) Quality Defects Procedures

19) Harmonisation of Classification of Deficiencies

20) Informants and Compliance Management

Working Groups (WGs) continue…

21) Working Group on the Revision of the Accession Guidelines

22) Working Group on the Drafting of Pre-Accession Guidelines

23) Interpretation of Audit Checklist

24) WG on GCP & GPvP ⇨ Expert Circle on GCP & Expert Circle on GVP

25) Proposal to establish a new **WG on Artificial Intelligence** with a view to upgrade it to a new **Expert Circle on Artificial Intelligence(AI)**

26) Proposal for establishment of a new **WG on Radiopharmaceuticals**

PIC/S Annual Seminars

2022 PIC/S Seminar

The seminar's topic was "Inspecting the Pharmaceutical Quality System (PQS)". Hosted by **Ireland/HPRA** in Dublin (Ireland), on 3 to 7 Oct 2022. It was combined with the 1-day PIC/S' 50th Anniversary Symposium

2023 PIC/S Seminar

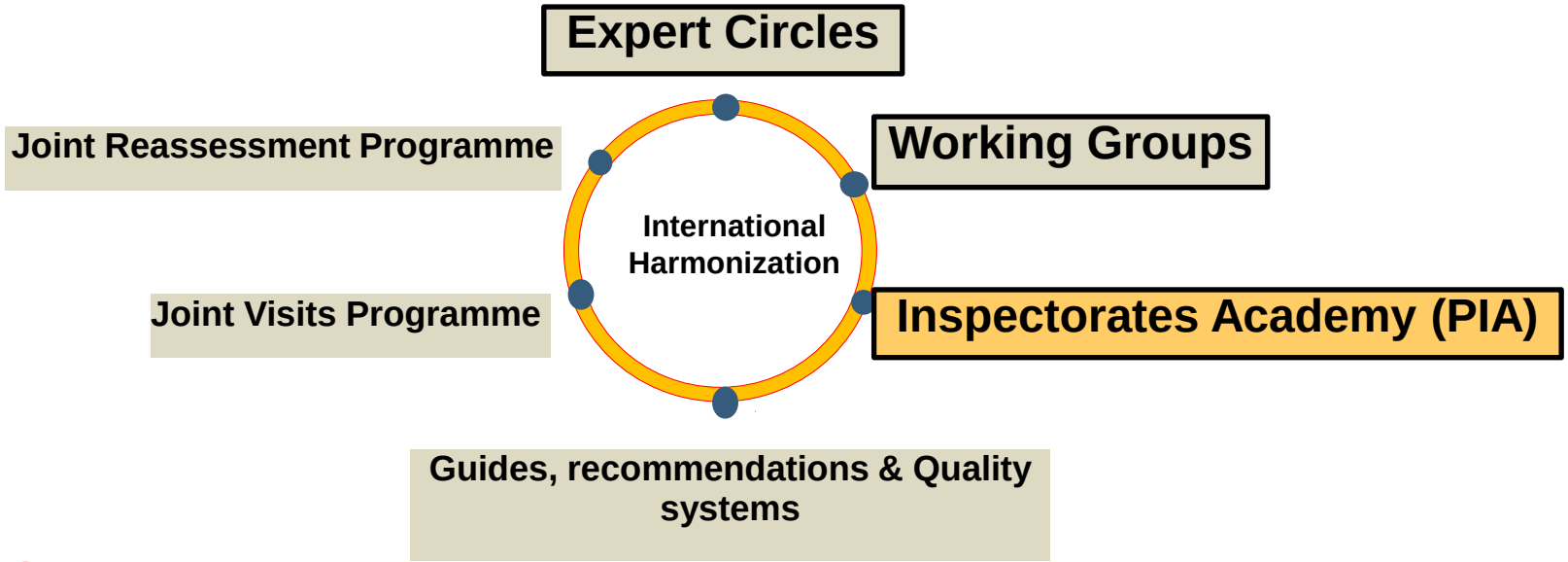
The seminar's topic: "Soft Skills that Make a Good GMP/GDP Inspector in 2023". It was hosted by **Thailand / Thai FDA** in Bangkok (Thailand) from 6 to 10 Nov 2023.

2024 PIC/S Seminar

Will be hosted by **Brazil / ANVISA on** Revised Annex 1 on "New Annex 1 on Sterile Products", which will take place in Brasilia (Brazil) on 6-8 November 2024.

2025 PIC/S Seminar

Will be hosted by **Hong Kong SAR, China / PPBHK,** Theme: TBC; Date: TBC


Expert Circles
Joint Reassessment Programme
Working Groups
International Harmonization
Joint Visits Programme
Inspectorates Academy (PIA)
Guides, recommendations & Quality systems

PIA = PIC/S Inspectorates' Academy

Inspection Excellence Through Harmonised Training

Joint EMA-PIC/S-WHO Annex 1 Implementation Working Group (IWG)

Departure of several members of the former Joint PIC/S – EMA – WHO Revised Annex 1 drafting Working Group led by Ali (France / ANSM). Following publication and revised Annex 1 entry into force of 1 on 25 August 2023.

A *new Joint Implementation Working Group (IWG)* has been established with the following mandate:

"The mission of the Working Group is to develop training materials that facilitate a common interpretation and understanding of revised Annex 1 (published in August 2022), revisions to documents related to Annex 1, and involvement in training events organized with the abovementioned aim (e.g. PIC/S Seminar, webinars.)

Joint EMA-PIC/S-WHO Annex 1 Implementation Working Group (IWG)

(i) **Main Group**: This IWG will have the following key tasks: (1st TC held on 19 Jan 2024)

- Develop training materials (presentations, video materials, workshops, case studies etc.) focused on changes adopted in the new Annex 1. These materials will be used for below-mentioned training events, for webinars (if organized) and for the development of PIA e-module.

(ii) **Sub-Group 1:** Review and update technical PIC/S documents related to Annex 1:

➢ 1-1 Revise the document "Interpretation of Annex 1" (based on the updated and revised Swissmedic document), including harmonized Q&A related to Annex 1

➢ 1-2: Thoroughly revise Annex 1 related PIC/S documents, including the following documents and any other materials identified by the WG.

1) PIC/S Recommendation on sterility testing (PI 012-3, dated 25 Sep 2007);
2) Isolators used for aseptic processing (PI 014-3, dated 25 Sep 2007)
3) Sterility testing (PI 014-2, dated 25 Sep 2007); and
4) PIC/S Validation of Aseptic Processing 2011 (PI 007-6, dated 1 Jan 2011).

Joint EMA-PIC/S-WHO Annex 1 Implementation Working Group (IWG)

(iii) **Sub-Group 2** to support the organisation of training events including:

- To provide necessary support and contribute to the development of EC /EMA Annex 1 Training event (Brussels) 17-19 April 2024
- To provide necessary support and work together with Brazil / ANVISA on the development of the PIC/S 2024 Seminar program (4 - 8 Nov 2024).

Joint EMA-PIC/S-WHO Annex 1 Implementation Working Group (IWG)

In short,

(1) EC / EMA Annex 1 Training (Brussels) 17-9 Apr 2024, in person & virtual) – recorded and be part of the training package of PIA's e-module training for manufacture of sterile medicinal products

(2) PIC/S 2024 Seminar (Brasilia / Brazil, 4-8 Nov 2024) To be recorded and be part of the training package of PIA's e-module training for manufacture of sterile medicinal products

(3) Any area / topic not covered in abovementioned (1) and (2) would be identified or area which the abovementioned 2 event did not adequately cover; PIA will develop PIA's module / webinar

Joint EMA-PIC/S-WHO Annex 1 Implementation Working Group (IWG)

- Any activities within the A1IWG should work in synergy, without significant overlap and duplications
- Ultimate goal is to provide inspectors with sufficient information and training materials related to new Annex 1 and its changes adopted in 2022
- PIA's e-module: provide comprehensive training package including inspectors know-how (how to inspect)

Thank you!

Q &A

Any technical questions / discussions are welcome