PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PIC/S Update – Recent activities and areas of focus

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Chair, PIC/S Subcommittee on Strategic Development
28 November 2023

Outline

- *PIC/S – who we are*
- *PIC/S Guide to GMP*
- *Harmonisation activities*
- *International collaborations*
- *Subcommittee on Strategic Development*

PIC/S – who we are

PIC/S Mission

PIC/S will strive to improve public health by leading ***development*** *and* ***implementation*** *of inspection frameworks for human and veterinary medicines through* ***harmonisation of standards*** *and offering* ***world class training*** *to regulatory inspectors around the globe.*

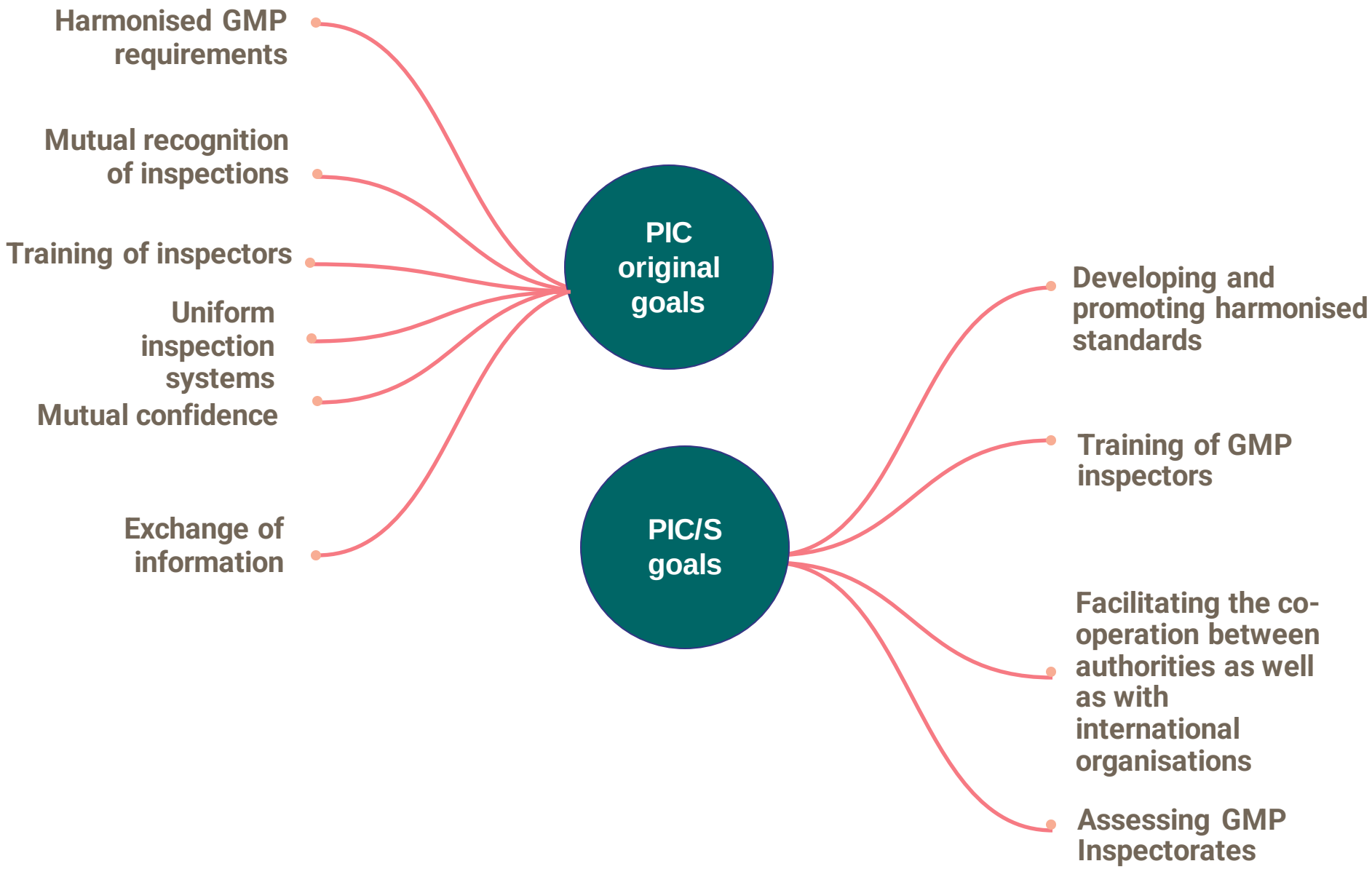
PIC/S Vision

To enable one inspection per site that is fit for all regulatory authorities in the benefit of public health.

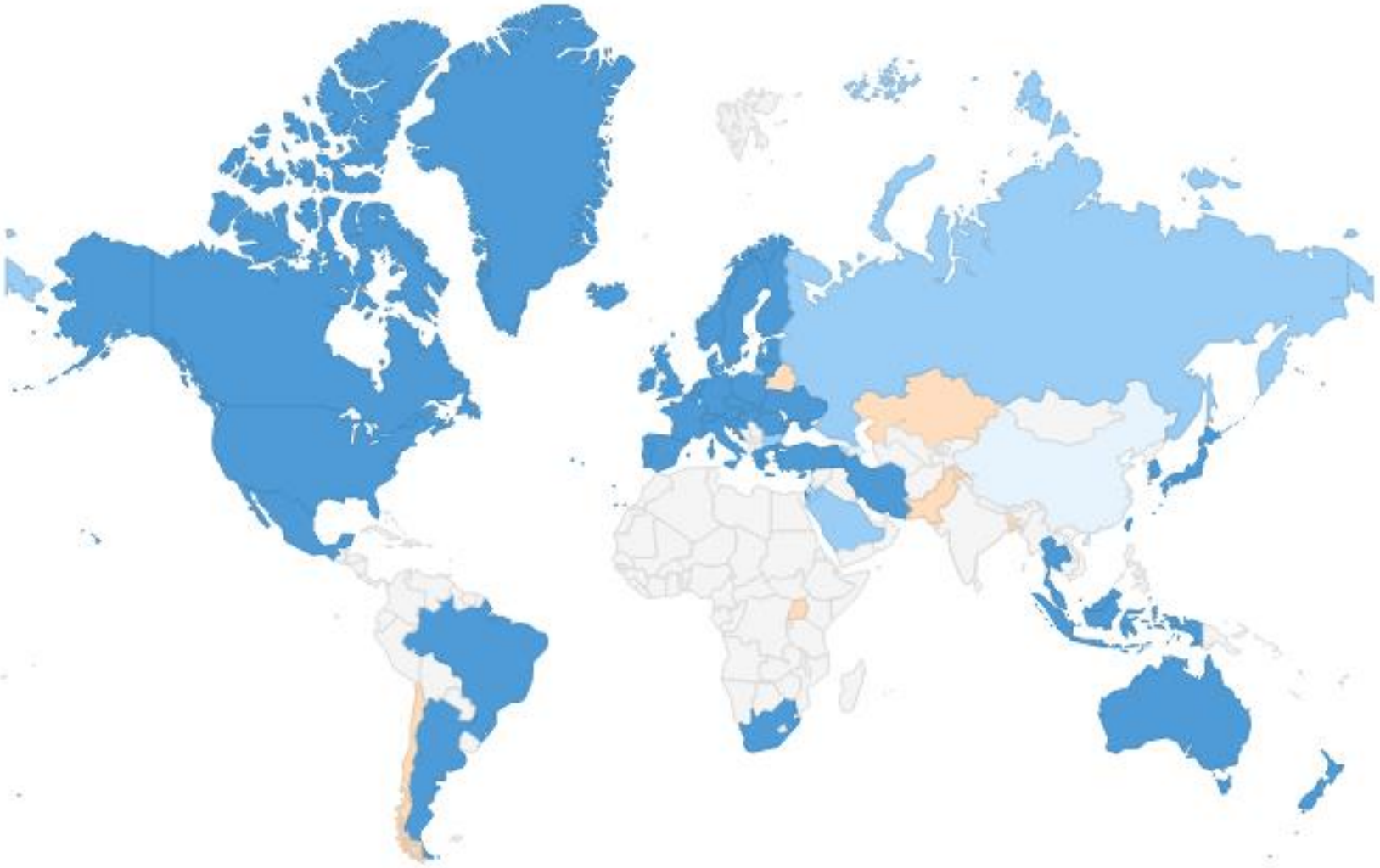
PIC vs. PIC/S

PIC	PIC/S
Convention	Scheme
Between countries	Between agencies
A formal treaty	An informal arrangement
Legally binding	Legally non-binding
Focus on inspection	Focus on training & developing guidelines for inspectors/inspectorates
Mutual recognition of inspections	Exchange of information on inspections

Goals breakdown



Members



***56** members (at Jul 2023)*

- ***6** Associated Partners*
- ***4** Applicants*
- ***2** Pre-applicants*
- ***6** Former pre-applicants*

Recent membership changes

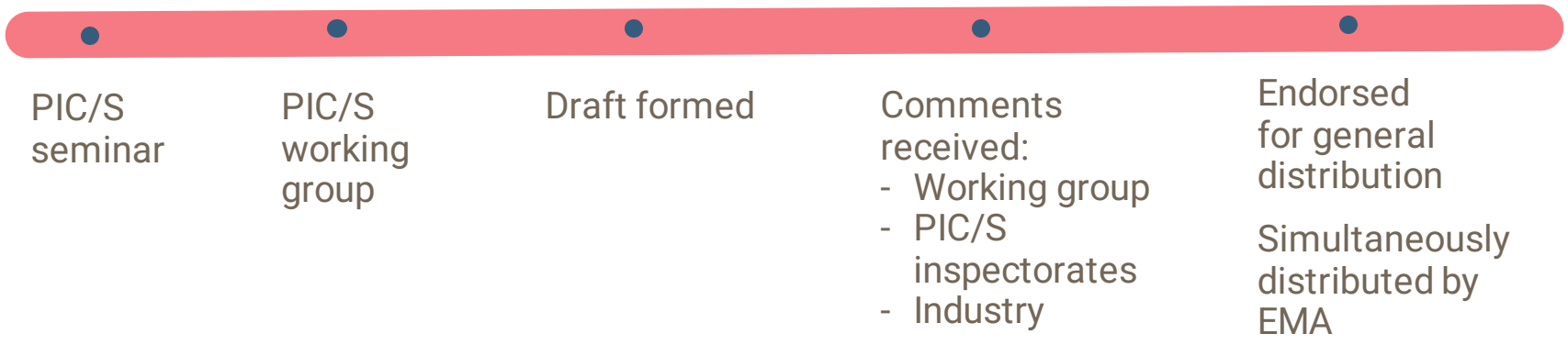
PIC/S Committee of Officials Meetings

- Geneva, March 2023
  - *Bulgaria*
  - *Saudi Arabia*
- Bangkok, November 2023
  - *Membership application from China*
  - *Pre-accession application from Egypt*

PIC/S Guide to GMP

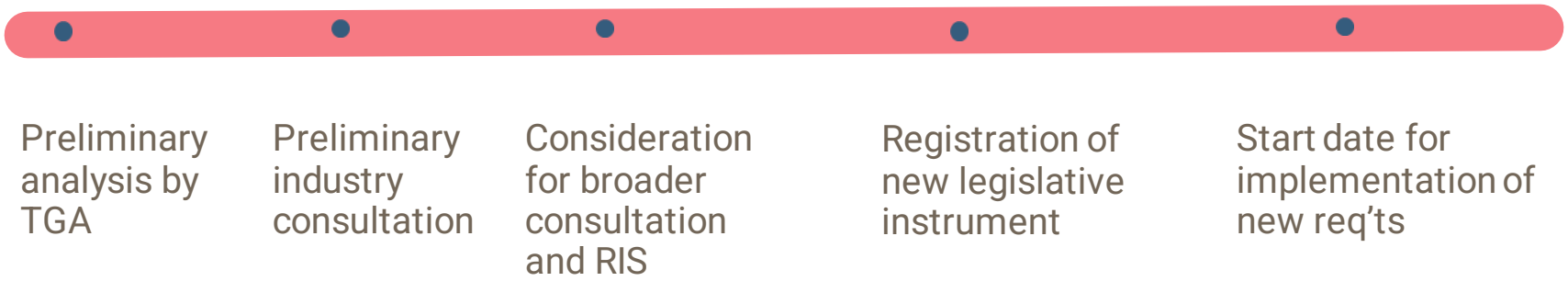
PIC/S GMP Guide

- *Equivalent to EC GMP Guide (almost identical with some differences e.g. 'Qualified Person' vs. 'Authorised Person')*
- *Basic GMP Guide (Part I)*
- *GMP Guide for APIs (Part II)*
- *Annexes*



PIC/S GMP Guide – adoption in Australia

- Gap analysis by TGA
- Input from TGA/Industry Working Group on GMP (TIWGG)
- Government assessment on need for a Regulatory Impact Analysis
- Creation of new legislative instrument as Australia's 'Manufacturing Principles' – transition period as required



Status of Adoption of PIC/S v16 in Australia

- Gap analysis (completed)
  - Annex 13 *Manufacture of investigational medicinal products* – minor changes only
  - Annex 16 *Authorised person and batch release* – new, therefore assessed against existing guidance (2019); major and minor differences

- Industry consultation
  - Initial feedback received
  - TIWGG – Technical Working Group to review guidance and propose approach for Annex 16

Harmonisation activities

International Harmonisation

Expert Circles and Working Groups

Expert Circles

- APIs
- Controlling Cross Contamination in Shared Facilities
- Human Blood, Tissues, Cells & ATMPs
- Quality Risk Management
- Good Distribution Practices
- Good Clinical Practices
- Good Pharmaco-Vigilance Practices

Working Groups

- Revision of Annex 1 (joint WG with EMA/EC and WHO)
- Revision of Annex 2
- Harmonisation of Classification of Deficiencies
- Data Integrity
- Controlling Cross-Contamination in Shared Facilities
- Revision of PI 006
- Unique Facility Identifiers (UFI)
- Inspector Travel Safety
- Veterinary Medicinal Products
- Quality Defects
- Informants

Working Groups

- Revision of Blood guidance documents
- Aide Memoire on Tissues and Cellular Therapy Products Inspections
- Computerised Systems
- Third Party Funding
- Revision of the PIC/S Aide Memoire on QRM Implementation
- ICH Q12 Training Material
- PIC/S Inspection Reliance
- Remote Assessment
- Revision of Inspection Report Format

Quality System Requirements

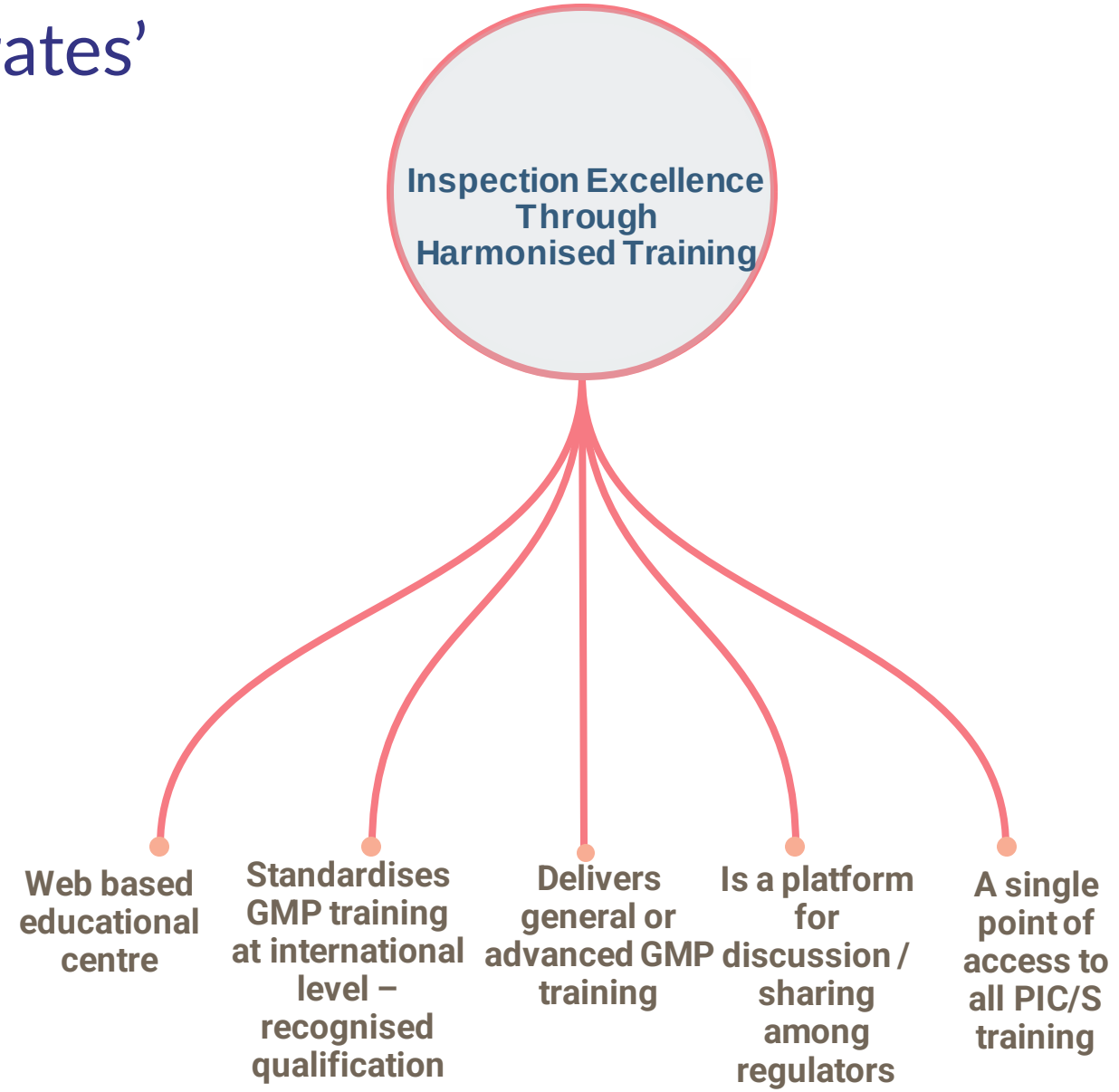
Aim:

Adopt a common standard for quality system requirements – to ensure consistency in inspection standards between National Pharmaceutical Inspectorates.

In return this facilitates mutual recognition of those Inspectorates.

- Organisation and Management
- Quality Improvement & Corrective / Preventive Action
- Complaints
- Issue & Withdrawal of Licences and GMP certificates
- Handling Suspected Quality Defects & Rapid Alert System
- Liaison with OMCL
- Sub-Contracting and Assessing
- Quality Manual
- Administrative Structure
- Documentation and Change Control
- Records
- Inspection Procedures
- Inspection Resources
- Internal Audit

PIC/S Inspectorates' Academy



Website: https://www.picscheme.org/en/pia-home

Recent publications

2023

- Aide-Memoire on the Inspection of Good Distribution Practice for Medicinal Products in the Supply Chain' (PI 044-1)
- Questions & Answers (Q&A) document regarding the PIC/S GDP Guide' (PS/INF 22/2017)

2022

- Concept paper on the revision of Annex 11 (computerised systems) of the EU-PIC/S GMP Guide – *consultation closed January 2023*
- Annexes to PIC/S GMP Guide PE 009-16
  - Annex 1 - GMP Guide on the manufacture of sterile products – *came into force 25th August 2023*
  - Annex 13 - Manufacture of Investigational Medicinal Products – *came into force 1 February 2022*
  - Annex 16 - Certification by the Authorised Person and Batch Release - *came into force 1 February 2022*

International collaborations

Associated Partner Organisations

PIC/S has signed co-operation agreements with :

- *European Commission (EC)*
- *European Medicines Agency (EMA)*
- *European Directorate for the Quality of Medicines (EDQM)*
- *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)*
- *United Nations International Children's Emergency Fund (UNICEF)*
- *World Health Organization (WHO)*
- *World Organisation for Animal Health (WOAH)*

Broader involvement with …

ASEAN	Association of South East Asian Nations
EC	European Commission
ECA	European Compliance Academy
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
EEA HMA	Heads of Medicines Agencies of the European Economic Area
ICMRA	International Coalition of Medicines Regulatory Authorities
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
ISPE	International Society for Pharmaceutical Engineering
PDA	Parenteral Drug Association
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization
WOAH	World Organisation for Animal Health

Subcommittee on Strategic Development

Subcommittee on Strategic Development (SCSD)

Our mandate –

to define PIC/S' strategy and future policy and make proposals on how to improve the structure and the operation of PIC/S

Our membership –

Australia (Chair), Switzerland (Dep Chair)

Argentina, Austria, Brazil, Canada, Chinese Taipei, USA

Activities and outcomes

- *Introduction of subcommittee structure (2014)*
- *Develop strategic policies*
  - *2023-2027 Strategic Plan*
- *Review and make recommendations on changes to the PIC/S mandate*
- *Develop proposals to improve cooperation activities*

Product Quality Knowledge Management System PQ KMS

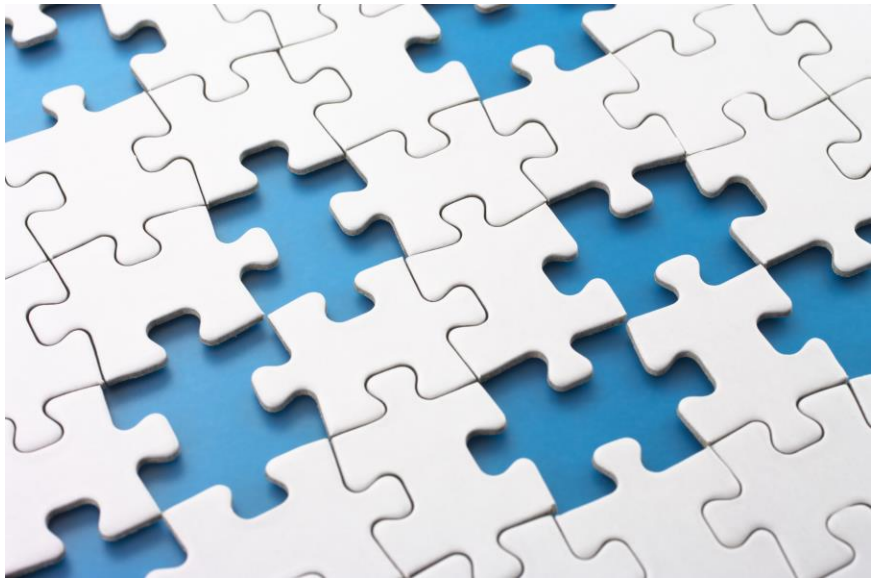
- Joint reflection paper from
  - ICMRA
  - ICH
  - PIC/S
  - International Pharmaceutical Regulators Programme (IPRP)
- Streamlining post-approval changes, reliance on PQS and life cycle management
  - ICH Q10, Q8, Q9, Q12

PQ KMS

Harmonisation

- Format and data expectations for regulatory submissions
- Same standards for
  - Regulatory reviews
  - Assessments
  - Inspections

PQ KMS cont.



Relying on

- Submission of same dossier to all jurisdictions
- Leveraging collective resources
- Information sharing between agencies
- PIC/S SCSD –
  - Facility identifiers
  - Revised Inspection report format

PIC/S Contacts

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Thank you