Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Boon Meow Hoe
PIC/S Deputy Chairman
PIC/S Executive Bureau Member
PIC/S Sub-Committee on Training Chairman
PIA Project Management Steering Committee Chairman

Presentation to
6th APAC
5th April 2017
Tokyo Japan
Agenda

1. Overview of PIC/S
   - What is PIC/S?
     - PIC/S Membership
     - GMP Standard
     - Training

2. International Harmonization
   - PIC/S Partners & Other Organisations
   - PIC/S Working Groups
   - PIC/S Expert Circles

3. Other
   - PIA
   - Last PIC/S Committee Meetings (Geneva, Feb 2017 and Manchester July 2016)

4. Q&A
What is PIC/S?

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<th>PIC</th>
<th>PIC Scheme</th>
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<tr>
<td>Pharmaceutical Inspection Convention</td>
<td>Pharmaceutical Inspection Cooperation Scheme</td>
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**PIC**
- Established 1970
- Convention
- Between 18 countries
- Formal Treaty
- Legal status
- Focus on inspection
- Mutual recognition of inspections

**PIC Scheme**
- Established 1995
- Scheme
- Between 49 Agencies (NDRA) in the field of GMP for human or vet. use
- An informal arrangement (purely technical, non-political, & not-for-profit Association under Swiss law)
- Has no legal status (Not legally binding)
- Focus on training & developing guidelines
- Exchange of information

Both operate in parallel under the logo/abbreviation: “PIC/S”
PIC/S: PIC and PIC Scheme

PIC
A formal Convention between Countries
Since 1970 – 47 years old (a matured person)

PIC Scheme
A Cooperation Scheme between Authorities
Since 1995 – 22 years old (a thriving young lady!)

Then “married” together as PIC/S!
“To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products”.
Achievement of PIC/S Goal

PIC/S Goal to be achieved by:

- Developing and promoting harmonised GMP standards and guidance documents.
- Training competent authorities, in particular GMP inspectors.
- Assessing (and reassessing) GMP Inspectorates.
- Facilitating the co-operation and networking for competent authorities and international organisations.
THAILAND / FDA JOINS PIC/S as from 1 August 2016 (49th Member)
## Accession dates (1/3)

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### Accessions dates (3/3)

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<td>47) Hong Kong SAR</td>
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<td>48) Croatia/HALMED</td>
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<td>49) Thailand FDA</td>
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49 PIC/S Members (as at 4 April 2017)

5 PIC/S Applicants & 1 Pre-Applicant

Blue: 49 PIC/S Members
Yellow: 5 Applicants
Red: 1 (Pre-) Applicant
5 PIC/S Applicants & 1 Pre-Applicant

5 Applicants

- Brazil/ANVISA
- IRAN / IFDA
- Mexico / COFEPRIS
- Turkey/TMMDA
- Italy (Vet) / DGSAF

1 Pre-Applicant

- Kazakhstan / CCMPA
Agencies showing interest in joining PIC/S

- Armenia / SCDMTE
- Saudi Arabia / SFDA
- Vietnam / DAV
- Bulgaria / BDA
- China / CFDA
- Nigeria / NAFDAC
- Russia / SID&GP
- Uganda / NDA
- Zimbabwe / MCAZ
1. Pre-accession procedure

- As some of the new applicants may have notable differences or are not familiar to PIC/S standards, a new “period” offers a “softer” approach and more time to adjust.
- It is a kind of pre-assessment and gap analysis of the Applicant Authority to the PIC/S requirements and a possible on site visit of an “auditor” appointed by the Committee.
- Time frame up to 2 years.
- Then, time to decide for the application. Is the Applicant ready? The Committee will decide on the next steps (invitation to apply or further delay to prepare.)

An option for New Applicant
2. Membership Accession procedure

Steps to Accession

- General interest & commitment, eg. attend Seminars
- Written application to Secretary + supporting documents
- PIC/S Committee appoints Rapporteur to evaluate
- Applicant invited to Committee meeting to answer questions of Rapporteur and Committee
- PIC/S delegation undertakes assessment visit (Inspectorate’s procedures; observe 3 or 4 inspections)
- Delegation report issued (to applicant & Committee)
- Committee decides on membership.

Full Membership Application
Benefits of PIC/S Membership (1/2)
(For NDRA, National Drug Regulatory Authorities)

- Training opportunities (seminars, Joint Inspections, etc.)
- International GMP harmonisation (Involvement with developing international GMPs)
- Networking with other Inspectors (for calibration of GMP expectations and facilitate information sharing)
- High standards (Accession forced improvements – i.e. discipline)
- Exchange / Sharing of information
- Rapid Alert System
- Facilitate the conclusion of other Agreements (Facilitate Government to Government MRA: E.g. Australia/TGA MRA, ASEAN MRA)
Benefits of PIC/S Membership (2/2)
For Industry

- Reduced duplication of inspections
- Cost saving
- Export facilitation
- Enhanced market access
How PIC/S operates?

- PIC/S Committee
- Secretariat
- Executive Bureau: Chair, Deputy Chair, immediate past Chair, seven Chairs of Sub-Committees
- Small Budget
- Good relationship and co-operation
- Training opportunities
- Exchange of information, rapid alerts
- Development of GMP guidelines
New PIC/S Organisational Sub-Committee Structure

To reply to PIC/S’s growing membership, a new Sub-Committee structure has been developed and come in force on 1st January 2014, in order to:

- Favour the participation of all PIC/S Participating Authorities
- Establish a more participative and efficient organisation of PIC/S, where each Sub-Committee will be responsible for its respective core areas and will take the lead in developing policies.
PIC/S new structure as of 1 January 2014

Most competences of the PIC/S Committee are delegated to Sub-Committees, which report back to the Committee.

PIC/S Committee

- Election of office holders & SC Members, Treaty power
- Acceptance of new PA
- Adoption of budget Etc.

Plenary Meeting: operates PIC Scheme and takes decisions

- Sub-Committee on Compliance
  - Plans & reviews both assessments & reassessments
- Sub-Committee on Strategic Development
  - Reviews PIC/S strategy & policies
- Sub-Committee on Harmonisation of GM&DP
  - Harmonises GM&DP & establishes Best Practice
- Sub-Committee on Communication
  - Defines communication strategy
- Sub-Committee on Budget, Risk & Audit
  - Assesses all risks, reviews audits; prepares budget
- Sub-Committee on Expert Circles
  - Reviews activities of Expert Circles
- Sub-Committee on Training
  - Plans & reviews GMP Training
Virtually identical to EC GMP Guide
(main difference = “Qualified Person” vs. “authorised person”)

Basic GMP Guide (Part I)

GMP Guide for APIs (Part II)

Plus Annexes, covering:
- Sterile Medicinal Products
- Sampling of Starting Materials & Packaging Materials
- Pressurised Metered Dose Aerosols
- Liquids, Creams & Ointments
- Computerised Systems
- Radiopharmaceuticals
PIC/S GMP Guide (22)

Plus Annexes, covering:

- Biologicals
- Herbals
- Medicinal gases
- Use of Ionising Radiation
- Investigational Medicinal Products
- Products Derived from Human Blood & Plasma
- Qualification and Validation
- Parametric release
- Reference and Retention Samples
The training of GMP inspectors has been one of PIC/S’ main features since the very beginning. Training Competent Authorities, in particular inspectors, is an integral and key activity of PIC/S in achieving its mission.
Training - A Key Feature of PIC/S (2/4)

Harmonising GMP requirements through the PIC/S GMP Guide is not sufficient to ensure a uniform interpretation and application of GMP. The training of GMP inspectors is an essential tool to achieve this goal. This is why the training of GMP inspectors is a key activity of PIC/S. Recently, PIC/S has also opened its training tools to inspectors active in other areas such as Good Distribution (GDP) and Good Clinical Practices (GCP).
The various PIC/S training tools have been put in place progressively. At the beginning, there was only one annual Seminar. Then, a Joint Visits Programme (JVP) was added to train inspectors and harmonise both GMP standards and inspection procedures. In the 1990s, Expert Circles in specialised areas were established. New Inspector Training Courses and Train the Trainer Courses were developed as from 2011 and 2014 respectively. The PIC/S Inspectorates' Academy (PIA) was established in 2014 and officially launched in 2016.
Currently PIC/S boasts various training and harmonisation tools, which have proved to be effective and are constantly being further developed and improved. These include:

- Seminars
- Expert Circles
- Joint Visits Programme
- Coached Inspections Programme
- Training Courses for New Inspectors
- Train the Trainer Courses
- Training for Auditors
- API International Training Programme
- Other Non-PIC/S Training Events & Tools

More information about all PIC/S training activities and tools is available at the PIC/S Inspectorates' Academy.
Development of GMP Guidance Documents

- Usually initiated at end of PIC/S Seminars
- PIC/S Working Group formed
- Author prepares draft
- Comments from Working Group
- Comments from PIC/S Inspectorates
- Comments from Industry
- Endorsed by PIC/S Committee for general distribution
- Simultaneous distribution by EMA (& vice versa)
PIC/S Seminars (1/5)

- Packaging & Labelling: Switzerland, 1971
- Contamination: Sweden, 1972
- Quality: France, 1972
- Sampling & Analytical Control: UK, 1973
- Contract Manufacture & QC: Switzerland, 1974
- QC Department: Denmark, 1975
- Stability: Austria, 1976
- Isolation/ID/Quantification of Drugs: Sweden, 1977
- Tablet Manufacture: UK, 1978
- Large Volume Parenterals: Norway, 1978
- PIC Basic GMP Guide: Finland, 1979
- (Need for Revision?): Denmark, 1980
- Tablet Manufacture: Switzerland, 1980
- Manufacture of Active Ingredients: Switzerland, 1980
- Inspection & Testing in Relation to the Marketing Authorisation: Belgium, 1993
PIC/S Seminars (2/5)

- Control Laboratory  Hungary, 1981
- Validation  Ireland, 1982
- Packaging  Portugal, 1983
- Production of Biological Products  Germany, 1984
- Premises  Norway, 1985
- Plastics  Sweden, 1986
- Inspection  UK, 1987
- Water  Switzerland, 1988
- Contamination Risk in the Manufacture of Parenterals  Austria, 1989
- Blood & Blood Products  Denmark, 1990
- Audit - Pharmaceutical Inspection  Hungary, 1991
- Products Derived from Biotechnology  Italy, 1992
- Qualification & Validation  Ireland, 1994
- Manufacture of Sterile Products  Iceland, 1995
PIC/S Seminars (3/5)

- Computer Systems
- GMP Standards for APIs
- Manufacture & Inspection of APIs
- Quality Systems for Inspectorates
- Non-technical Aspects of Inspection
- Biotechnology
- Inspection of Utilities
- Interface between GCP and GMP
- Inspection of QC laboratories
- Inspection of APIs
- Primary packaging, labelling and prevention of mix-up
- Risk Management
- Solid Dosage Form Manufacturers
- Good Distribution Practices

Australia, 1996
Australia, 1996
Finland, 1997
Holland, 1998
UK, 1999
France, 2000
Czech Rep, 2001
Canada, 2002
Slovak Rep, 2003
Spain, 2004
Romania, 2005
Germany, 2006
Singapore, 2007
Poland, 2008
PIC/S Seminars (4/5)

- Sterile Aseptic Manufacturing, Sweden, 2009
- Herbal / Traditional Medicines, Malaysia, 2010
- Good Inspection Practices, South Africa, 2011
- Qualification and Validation, Ukraine, 2012
- Global Supply Chains and GMP compliance, Canada, 2013
- Dedicated Facilities or Not, France, 2014
- Biopharmaceuticals (biotechnology and biologicals): how to inspect, Indonesia, 2015
- Inspectorates of the Future 2016, UK/Manchester
Future PIC/S Seminar (5/5)

- QC Laboratory: How to inspect Chinese Taipei 2017

- PIC/S Annual Seminar 2018 US/FDA

- PIC/S Annual Seminar 2019: Japan/PMDA? Korea/MFDS? Thailand/FDA? Hong Kong SAR/PPBHK?
Organised by the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA) in Manchester (UK) on 6-8 July 2016.
The topic of the Seminar was “Inspectorates of the Future”.
Attended by more than 180 participants from 53 countries.
PIC/S Joint Visits programme (JVP)

- Started in 1987
- Around 25 groups of 3 inspectors from 3 countries
- 1 inspection per 6 months per country
- for training purposes
- for uniform GMP interpretation
- for uniform inspection procedures
- for mutual confidence
Typical PIC/S Inspection of a Medicine Manufacturer

Before the inspection (Pre-inspection activities):

- Lead inspector assigned.
- Inspection team selected.
  - Technical specialist sometimes included on team
- Company notified.
  - Company requested to provide Site Master File (SMF)
- Inspection team reviews documentation.
  - SMF, complaints, recalls, testing failures, marketing authorisations.
- Lead inspector prepares inspection plan & sends to company.
- Inspection conducted. (On-site-inspection activities):
Typical PIC/S Inspection of a Medicine Manufacturer (cont’d)

**After the inspection** *(Post-inspection activities)*:

- Caucus of inspection team.
- Interim inspection report prepared (deficiencies only).
- Exit interview with company:
  - Attendance sheet completed.
  - Interim inspection report provided (discussion encouraged).
  - Written response requested within 4 weeks.
- Objective evidence assessed by lead inspector.
- If response judged OK, inspection closed out.
- Final inspection report sent to company
- If response **not** OK, refer to Independent Committee for appropriate action.
PIC/S Inspection Report

• Identical to the EU Inspection Report format

• SOP for PIC/S Inspection Report format is available on PIC/S web site (document PI 013-3)

• This format used by PIC/S and EU Inspectorates to prepare GMP inspection reports

• Uniform system of classifying GMP deficiencies
  – “critical”, “major” & “other”
Quality system requirements for pharmaceuticals inspectorates

- Reference document: PI 002-3

- Purpose: adopting a common standard for quality system requirements in order to achieve consistency in inspection standards between National Pharmaceutical Inspectorates and thus to facilitate mutual recognition of those Inspectorates
Joint Reassessment programme (JRP)

Goals

- To verify that PIC/S member authorities maintain compliance with the requirements of the Scheme (as described in paragraph 8 of the Scheme [PIC/S 1/95 modified]).
- To verify the implementation of quality system requirements for pharmaceutical inspectorates.
- To help maintain consistency among PIC/S member authorities

For all existing members
PIC/S Blueprint

- PIC/S Blueprint for the period 2006-2015 (A 10-year master plan adopted in Dec 2005) have been successfully implemented and even surpassed in some cases. E.g. membership anticipation.

- A new PIC/S Blueprint: PIC/S ROAD-MAP FOR 2017-2019 (next 3 years) includes an action plan has been drafted (Status: under finalisation and to be adopted)

  The objectives are to:
  - enhance PIC/S’ Sub. Comm. structure and full implementation of PIA;
  - identify PIC/S’ next challenges and possible solutions;
  - strengthen the PIC/S Secretariat; and
  - identify new income revenues to support / finance PIC/S’ projects.
Where is PIC/S now?
International Harmonisation: 1970: PIC/S Original Goals

- Harmonised GMP requirements
- Mutual recognition of inspections
- Uniform inspection systems
- Training of Inspectors
- Mutual confidence
• 47 years on, Goals remain the same, in the ever changing field of pharmaceuticals.

• PIC/S has had to adapt and change to meet many challenges since its inception in 1970.

• Is PIC/S relevant today?
Drug Regulatory Authorities appear to think so:

- 49 Participating Authorities;
- 5 Applicants;
- 1 Pre-Applicant;
- Preliminary enquiries from a number of Authorities.
International Harmonisation

How does PIC/S achieve international harmonisation of inspections and GMP?

- PIC/S GMP Guide
- Guidance documents and Q&As
- Expert Circles
- Working Groups

Annual Seminars and other tools for training of inspectors:
- Joint visits programme (JVP),
- coached inspections programme (CIP),
- training for new inspectors & train the trainer, training for auditors, API international training programme (all under PIA)
International Harmonisation

- Joint Reassessment Programme (JRP) harmonised with EMA Joint Audit Programme (JAP)
- Exchange of information on planned foreign inspections
- SOP for informing foreign regulatory authorities for inspections to be conducted in their territory
- Single Point of Contact (SPOC) with 49 Participating Authorities (Committee member)
International co-operation with Partners and other Organisations

**Abbreviations:**
- ASEAN – Association of South East Asian Nations
- EDQM - European Directorate for the Quality of Medicines & HealthCare
- EMA - European Medicines Agency
- EC - European Commission (DG Health & Food Safety)
- HMA - Heads of Medicines Agencies
- ICDRA – International Conference of Drug Regulatory Authorities
- ICMRA - International Coalition of Medicines Regulatory Authorities
- ICH – International Council for Harmonisation
- IFPMA - International Federation of Pharmaceutical Manufacturers & Associations
- ISPE – International Society for Pharmaceutical Engineering
- OECD – Organisation for Economic Co-operation and Development
- PDA – Parenteral Drug Association
- UNICEF - United Nations Children's Fund
- WHO – World Health Organisation
International Harmonisation
PIC/S Expert Circles (EC)

5 Expert Circles

Abbreviations:
API – Active Pharmaceutical Ingredients
ATMP – Advanced Therapy Medicinal Products
QRM – Quality Risk Management
GDP - Good Distribution Practice
Compu. System: Computerised System
International Harmonisation
PIC/S Working Groups (WG)

Abbreviations:
- API – Active Pharmaceutical Ingredients
- ATMP – Advanced Therapy Medicinal Products
- GCP – Good Clinical Practice
- GPvP – Good Pharmacovigilance Practice
- PIA PMSC – PIC/S Inspectorate’s Academy Project Management Steering Committee
- SMF – Site Master File
- UFI – Unique Facility Identifiers
- VMP – Validation Master Plan

12 WG

- Data Integrity
- Classification Deficiencies
- Controlling Cross-contamination in shared facility
- Joint EMA-PIC/S Revision to Annex 1
- Rec – VMP, IQ, OQ, Non-sterile PV, and CV
- Travel Safety
- Veterinary Medicinal Products
- GCP and GPvP
- API Q&A
- PIA PMSC
- UFI
- ATMP

 Amend SMF  
EMA’s WG
WG on Harmonisation of Classification of Deficiencies

- A guidance drafted to harmonise risk classification of GMP deficiencies
- “Calibration” among PIC/S PAs to facilitate consistency

Status:
- Integrating (i) input from the PIC/S Seminar 2016 and (ii) comments received from the PIC/S QRM Expert Circle and the WG on DI.
- 2nd Internal consultation will follow… (Q2 or Q3 / 2017)
WG on Advanced Therapy Medicinal Products (ATMPs)

- To draft an Aide-Memoire to support the inspection of ATMPs.
- Status: on hold while awaiting the outcome of discussions on ATMPs in the EU.

Geneva (Feb 2017) Committee Meeting:
Unanimous concern at the EC’s proposed stand-alone ATMP GMP Guidelines

- Lower GMP standards for ATMP at the risk of patients safety
- Lead to an international non-harmonised approach to the implementation of GMP for ATMP. (Loss of harmonisation, lack of integration, risk of confusion, double-standards, impact ATMP availability and regulatory burden and etc.)
- EC’s proposal will also trigger a revision of EU GMP Guide Annex 2 (Biologics) and the repeal and replacement of Annex 13 (IMP), these actions will also result in the PIC/S GMP Guide and the EU GMP Guide no longer being equivalent.
WG on Advanced Therapy Medicinal Products (ATMPs)

Since the launch of the EU stakeholder consultation back in 2015, PIC/S has repeatedly tried to engage with the EC to draw attention on the potential detrimental effects of this initiative.

The EC ignored all PIC/S’s voicing / requests for co-operation, including a proposal by PIC/S to form a joint working party with the EMA IWG.

The PIC/S Committee reviewed various options and concluded that all PIC/S can do is to draw the EC’s attention on its responsibilities. A letter to this effect dated 24 Feb 2017 has been addressed to the Director General for Health and Food Security of the EC. The letter is also published on the PIC/S website for reasons of transparency.
With regard to allegations that some PIC/S Participating Authorities have enacted lower GMP requirements for ATMP, as mentioned in your letter, we believe that there may have been a misunderstanding on the European Commission’s part. Some Participating Authorities have introduced non-binding guidelines regarding ATMPs. However, these guidelines do not override GMP requirements, as enshrined in the national GMP Guide. Moreover, where ever there is a slight difference in terms of requirements for ATMP, PIC/S Participating Authorities have expressed their will to align and harmonise their requirements with those of PIC/S. The international harmonisation of GMP standards is a never-ending process, which PIC/S aims to facilitate. PIC/S Participating Authorities are disappointed in the decision made by the European Commission to enact its standalone Guidelines on ATMPs, which will add barriers in the field of GMP and make harmonisation efforts more difficult.

We have tried our best to draw your attention to the risks that lower ATMP standards may have on the patients’ health. Patient health aside, PIC/S would like to remind the European Commission of liabilities to which it may be exposed.

For the sake of transparency and the rights of patients, this letter will be published on the PIC/S website.

Yours sincerely,

Paul Hargreaves
PIC/S Chairman
United Kingdom / MHRA

Boon Mew Hoe
PIC/S Deputy Chairman
Singapore / HSA
WG on Data Integrity (DI)

Status:

- Completed draft guidance document on “PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments”.
- Will review the PIC/S-internal comments to the draft (6 months trial ended 28 Feb 2017)
- Will also review guidance documents issued by other organisations on DI in order to make the PIC/S guidance as complete as possible.
- Will then develop an Aide Memoire and Q&A.
WG on Controlling Cross-Contamination in Shared Facilities (CCCISF)

Status:

- An Aide Memoire has been drafted. Focusing on harmonising terminology used in relation with the control of cross-contamination in shared facilities and relevant inspection questions in connection to risk management.
- Under internal consultation within PIC/S (deadline: 21 Apr 2017)
- Committee Meeting (Geneva Feb 2017) agrees to turn the WG on CCCISF into an Expert Circle.
WG on Veterinary Medicinal Products

- Aims to better take into account the needs and specificities of Veterinary Agencies within PIC/S
PIC/S Working Groups (WG) 6/12

WG on Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP)

- Primary purpose is to facilitate technical co-operation and harmonisation of practices (including the development of guidance and training material), capacity building and information sharing.

- Very active WG using the PIC/S Joint Visits Programme (JVP).

- Status: Contemplating to convert WG to an Expert Circle.
International Harmonisation: PIC/S PIC/S Working Groups (WG) 7/12

EMA – PIC/S Joint Drafting Group on the revision of Annex 1 (sterile manufacturing) of the PIC/S-EU GMP Guide

Status:

- A joint public consultation will be launched with the EMA after approval of the final draft by the PIC/S Committee and the EMA.
- The Committee Meeting (Geneva, Feb 2017) also agreed to involve WHO in the joint publication of this document, as well as in several other future PIC/S guidance documents (E.g. DI, Deficiency classification and etc.).
PIC/S Project Management Steering Committee (PMSC) in charge of the PIC/S Inspectorates’ Academy (PIA)

- Development of web-based platform.
- Aim: To harmonise and calibrate the training of inspectors by offering a common training platform to PIC/S inspectors, thus ensuring a greater consistency in the interpretation of GMP. It also aims at making training materials more readily accessible to current 1,800 PIC/S inspectors.

- Status: Stage 1: Completed
  
  Stage 2: Current stage
  
  Stage 3: Will commence after end of Stage 2

- Will be illustrated more in later slides on PIA
International Harmonisation: PIC/S
PIC/S Working Groups (WG) 9/12

WG on the revision of PIC/S Recommendations on Validation Master Plan; Installation and Operational Qualification; Non-Sterile Process Validation; and Cleaning Validation (PI-006-3)

- In connection with the transposition and adoption by PIC/S of the EMA Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.

- Status: Created at Manchester Meeting (July 2017)
WG on the API Q&A developed by PIC/S

- Q&A developed by PIC/S, which were not transferred to ICH, for the development of training material part of the PIC/S API International Training Programme.

- Status: Created WG at Manchester Meeting (July 2016)
Established a new Working Group on inspector travel safety with the objective of developing guidance for inspectors on managing travel risks;

- Status: A new WG -- newly created at Geneva Feb 2017 Meeting
WG on Unique Facility Identifiers (UFI)

Last Committee meeting (Geneva, Feb 2017) established a new WG on Unique Facility Identifiers (UFI), to respond to the need for an internationally recognized UFI to be selected for use by international regulators;

- Status: A new WG
Participation of PIC/S in:

- EMA Drafting Group to amend Site Master File re: mitigation of drug shortages

- Status: WIP
Expert Circle on Active Pharmaceutical Ingredients (API)

Leads PIC/S API International Training Programme:

- ICH Q7 Training for inspectors and industry, co-organised with PDA;
- Advanced API Training for inspectors only (e.g. counterfeits, data integrity, etc.)
- API Q&A, including PIC/S contribution to ICH Q&A document on Q7 published in June 2015
International Harmonisation: PIC/S
PIC/S Expert Circles (EC) 1/5 continue…

Expert Circle on Active Pharmaceutical Ingredients (API)

- PIC/S - PDA ICH Q7 trainings:
  - 2012 in China and Portugal;
  - 2014 in USA, South Africa and Belgium;
  - 2015 in South Korea, Brazil, India and China, with the support of the European Commission;
  - 2016 in Puerto Rico
Expert Circle on Active Pharmaceutical Ingredients (API)

- PIC/S Expert Circle on APIs meeting and Advanced Training, in Melbourne (Australia), hosted by Australia / TGA, 5 - 7 April 2017.
Expert Circle on **Quality Risk Management**

- Advanced training for inspectors:
  - 2014 hosted by PMDA Japan
  - 2015 hosted by FDA USA
  - 2016 hosted by the EMA in London (United Kingdom), 26 – 28 September 2016
Expert Circle on Human Blood, Tissues, Cells and ATMPs

- 21\textsuperscript{st} EC Meeting in Rome (Italy), 26–30 Oct 2015 hosted by AIFA/Italy. 120 inspectors from 36 countries attended.

- 22\textsuperscript{nd} EC Meeting - hosted by Hong Kong SAR / PPBHK in Hong Kong SAR, 24-28 Oct 2016

- 23\textsuperscript{rd} EC Meeting - To be hosted by Korea (Republic of) / MFDS on 26-28 June 2017 in Seoul (Republic of Korea)
After a very busy and active few years this EC has now been turned into a Working Group focusing on:

- Revision of the PIC/S Guidance Document on Good practices for Computerised Systems in regulated GxP environments.
Expert Circle on Good Distribution Practice (GDP)

- The 4th meeting was hosted by South Africa / MCC on 12-14 April 2016 in Pretoria.

- Attended by close to 60 inspectors from 23 countries allowed for the successful development of a draft PIC/S Aide-Memoire for GDP inspections as well as a draft Q&A document for GDP.

- Completed draft Aide Memoire for GDP Inspections and draft Q&A on GDP.
PIA = PIC/S Inspectorates’ Academy

Inspection Excellence Through Harmonised Training
What is PIA & What is PIA going to be?

Web-based educational centre & Accredited qualification system

Single Point of access to all PIC/S training activities

Platform for discussion & Sharing among inspectors

Inspection Excellence Through Harmonised Training
Background of PIA

2011
Idea of PIA was conceived during the 40th Anniversary Symposium

2012
Ad-hoc working group envisioned a cost-effective, primarily web-based training format

2013
Survey among PIC/S members and applicants to establish road-map

2014
PIC/S committee decided to establish the PIA

2016
Launch of PIA Website (Stage 1)
Stages of Development

Stage 1
- Establishment of the PIA and development of website
- Launch of PIA Website

Stage 2
- Identification of training needs
- Development of modules (e-learning) with possible co-operation with external stakeholders
- Seeking funding
- Establish recognition and certification process

Stage 3
- Formal incorporation of PIA
- Development of PIA training curriculum
- International recognition
The new (enhanced) PIC/S web site and PIA (the sub-site), rolled out on 18th July 2016.

The official launch marks end of Stage 1

It also marks commencement of Stage 2
Status: As at last PIC/S Committee meeting (Geneva Feb 2017):

- The PIC/S EB reviewed and discussed priorities in the implementation of the PIA.
- The EB decided on the need to prioritise the development of webinars over video recording of PIC/S training activities. This will allow for a more interactive and cost-effective delivery of e-learning training in the future.
- Such webinars are to be developed by PIC/S PA and may involve possible co-operation with external stakeholders, including Professional Associations (e.g. ISPE, PDA), other relevant Organisations (e.g. IFPMA) as well as consultants.
- Funding remains a key consideration.
NEW (Enhanced) PIC/S Webpage
www.picscheme.org

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

PIC/S Seminar 2016

6 - 8 July 2016

Participants attending the PIC/S 2016 Seminar on "Inspectorates of the Future" which took place in Manchester (UK) at the Museum of Science and Industry, on 6-8 July 2016, hosted by UK / MHRA.

› more
NEW PIA Webportal

PIC/S Inspectorates’ Academy

*Inspection Excellence Through Harmonised Training*

Login for PIC/S inspectors only

Email:

Password:

Login

Forgot your Password?

About

The PIC/S Inspectorates’ Academy (PIA) is a PIC/S initiative to set up a web-based educational centre under the PIC/S umbrella which aims at harmonising and standardising EMP training at an international level.

> More about PIA

Video Training

Recording of API Expert Circle meeting in Strasbourg (France)

Recording of PIC/S-EMA Auditors’ Training

Recording of API Expert Circle meeting in Russia (Moscow)

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Update on PIC/S GMP Guide

(If time permits to cover this section)
Revised PIC/S GMP Guide -
Main changes - If time permits

Chapter 1- Pharmaceutical Quality System (f.k.a. Quality Management)

Chapter 2 - Personnel

Chapter 6 - Quality Control

Chapter 7 - Outsourced Activities (f.k.a. Contract Manufacture and Analysis)

With effective from:
1 Jan 2017
Chapter 3- Premises and Equipment  
Chapter 5 - Production  
Chapter 8 – Complaint and Product Recall

Notes: The same applies to the following EMA guidance documents, which have been transposed for PIC/S purpose and reached Step 1 adoption process:

- Guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (PI 041-1 (Draft 1)).
- Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (PI 042-1 (Draft 1));
- Guidelines on the principles of Good Distribution Practices for actives substances for medicinal products for human use (PI 043-1 (Draft 1)).

Status: Under Stage 1 adoption process  
Deadline: Extended to 31 Jan 2017
The philosophy of PIC/S:

TRUST
+ COOPERATION
+ COLLABORATION
+ COMMUNICATION

HARMONISATION