# *Pharmaceutical Inspection Co-operation Scheme (PIC/S)*


## *2015 PDA-PIC/S Training Course on GMPs for APIs*

***September 14-15 - Hyderabad, India***
***September 17-18 - Ahmedabad, India***

**Mrs. Helena Paula Baião**
**PIC/S Former Chairperson**
**helena.baiao@infarmed.pt**
**http://www.infarmed.pt/**

***Bom dia***
***Good Morning***

# Overview

- About **PIC/S Role** & **Goals**
- **PIC/S Quality Systems & Guides & Recommendations**
- **Pre-Accession + Accession procedure**
- **Quality System** requirements for Pharmaceuticals Inspectorates
- **Harmonization & Good Inspection Practices & GM(D)P**
- **PIC/S Recent developments**
- **PIC/S Future & Philosophy & Final Remarks**
- Acknowledgement

# PIC/S Mission

"To lead the international development, implementation and maintenance of **harmonised GMP standards and quality systems of inspectorates** in the field of medicinal products".

# History

**PIC = Pharmaceutical Inspection Convention**

- Founded by The European Free Trade Association (EFTA) in October 1970
- PIC is a legal Treaty between countries
- Initially only 10 member countries: Austria, Denmark, Finland, Iceland, Liechtenstein, Norway, Portugal, Sweden, Switzerland and UK.

# History

| | |
|---|---|
| PIC | Pharmaceutical Inspection Convention |
| PIC Scheme | Pharmaceutical Inspection Cooperation Scheme |

Both operate in parallel under the logo/abbreviation

PIC/S

# PIC versus PIC/S

## PIC

- Convention
- Between countries
- A formal treaty
- Has legal status
- Focus on inspection
- Mutual recognition of inspections

## PIC/S

- Scheme
- Between agencies
- An informal arrangement
- Has no legal status
- Focus on training & Developing guidelines
- Exchange of information

# Original Goals

- ✓ **Harmonised** GMP requirements (*)
- ✓ **Mutual recognition** of inspections
- ✓ **Uniform** inspection systems
- ✓ **Training** of Inspectors
- ✓ **Mutual confidence (Trust)**

**(*) The difference is not so much in different GMP standards being used around the world but in the interpretation of standards**

# Reason for creating the PIC Scheme

- After 1993, no new members of PIC possible
- Reasons:
  - Under EU law, only European Commission authorised to sign agreements with other countries
  - Expansion of PIC not possible unless European Commission became a member of PIC
  - Amendment of Convention difficult & lengthy
  - Inspectorates (& industry) favoured maintaining the principles of PIC
- Consequently, the PIC Scheme was developed & implemented.

# Main features of PIC Scheme

- Commenced operating on 2 Nov. 1995
- An informal arrangement between Agencies
- Networking and confidence building
- Exchange of information and experience on GMP
- Development of Quality Systems for Inspectorates
- Training of inspectors
- International harmonisation of GMP
- No obligation to accept inspection reports
- PIC & PIC/S operate in parallel - jointly referred to as **“PIC/S”**

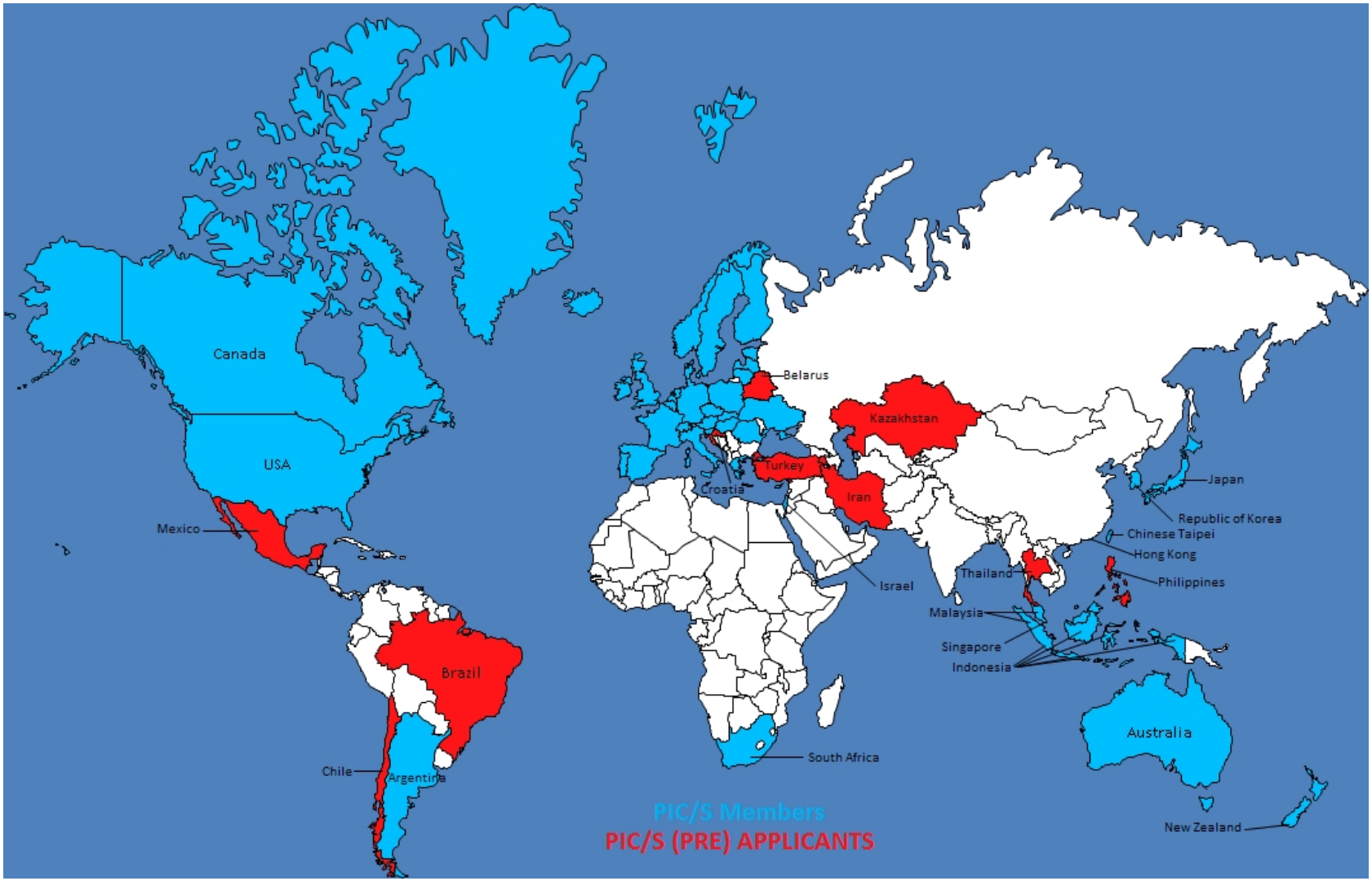
# Achievement of PIC/S Goals

PIC/S **goals to be achieved** by:

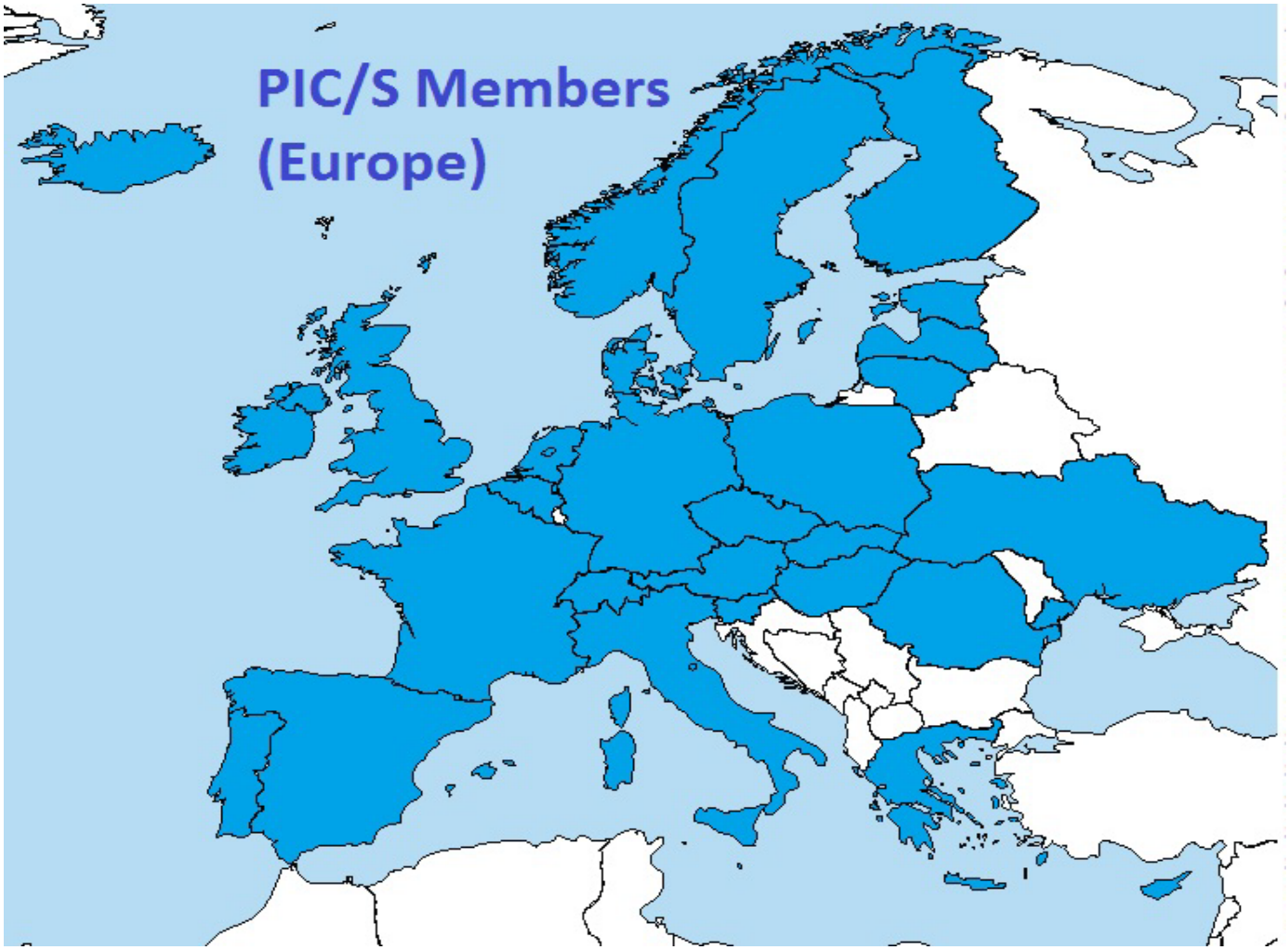
- ✓ Developing and promoting **harmonised GMP standards and guidance documents**
- ✓ **Assessing (and reassessing)** GMP Inspectorates
- ✓ **Training** competent authorities, in particular GMP inspectors
- ✓ **Facilitating the co-operation and networking for competent authorities and international organisations**

# 47 PIC/S Members (as of 1 January 2016)

## 10 PIC/S Applicants & Pre-Applicants



# PIC/S Members (Europe)




AUSTRIA
BELGIUM
CZECH REP. (Human & Vet)
CYPRUS
DENMARK
ESTONIA
FINLAND
FRANCE (Human & Vet)
GERMANY
GREECE
HUNGARY
ICELAND
IRELAND
ITALY
LATVIA
LIECHTENSTEIN
LITHUANIA
MALTA
NETHERLANDS
NORWAY
POLAND
PORTUGAL
ROMANIA
SLOVAK REPUBLIC
SLOVENIA
SPAIN
SWEDEN
SWITZERLAND
UKRAINE
UNITED KINGDOM (Human & Vet)

# Benefits of PIC/S Membership

- ✓ Accession forced improvements – i.e. discipline
- ✓ Cost saving – import control mechanism
- ✓ Facilitated exports of medicines
- ✓ Training (seminars, Joint Inspections, etc.)
- ✓ Involvement with developing international GMPs
- ✓ Facilitated MRA with EC
- ✓ Networking & personal contacts

# Quality system requirements for pharmaceuticals inspectorates

## based on proper inspection standards

Reference document : **PI 002-3**

Purpose : adopt a common standard for **quality system requirements** in order to achieve **consistency in inspection standards** between National Pharmaceutical Inspectorates and thus to **facilitate the equivalence of Inspectorates**

# Quality system requirements for pharmaceuticals inspectorates

## Reference document : **PI 002-3**

- based on various ISO standards:
  - ISO 17020, ISO 17021, ISO 9001, ISO 19011 etc.
- Some inspectorates are accredited or certified, others are not
- **ISO Certification or Accreditation is NOT mandatory.**

# Quality system requirements for pharmaceuticals inspectorates

## Main topics

- Quality Manual
- Administrative Structure
- Organisation and Management
- Documentation and Change Control
- Records
- Inspection Procedures
- Inspection Resources
- Internal Audit

# Quality system requirements for pharmaceuticals inspectorates

## Main topics

- Quality Improvement and Corrective / Preventive Action
- Complaints
- Issue and Withdrawal of Licences and GMP certificates
- Handling Suspected Quality Defects and Rapid Alert System
- Liaison with OMCL
- Sub-Contracting and Assessing
- Publications

# How PIC/S operates

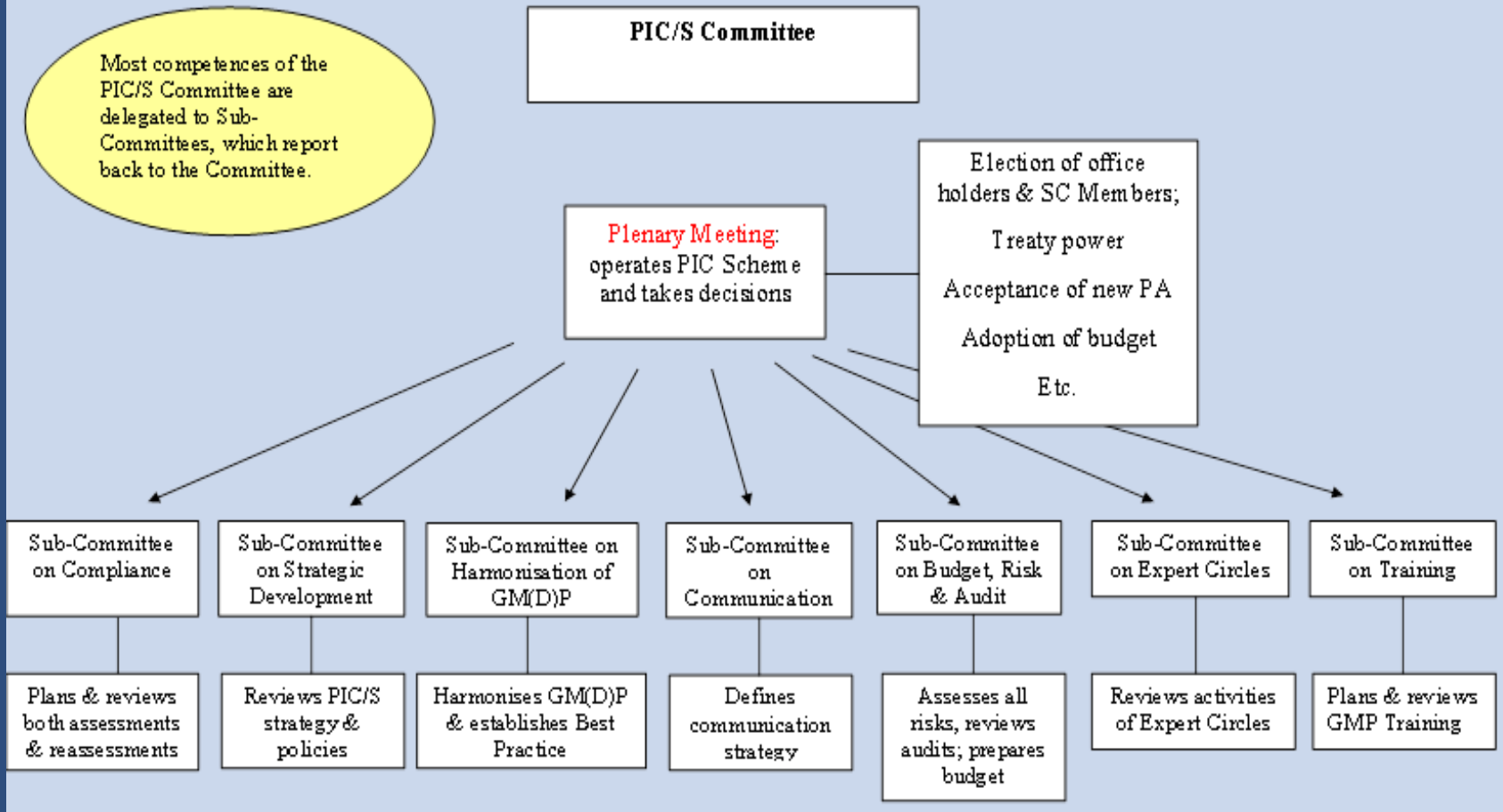
- PIC/S Committee
- Secretariat
- Executive Bureau: Chair, Deputy Chair, past Chair, seven Chairs of Sub-Committees
- Small Budget
- Good relationship and co-operation
- Training opportunities
- Exchange of information, rapid alerts
- Development of GMP guidelines

# 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 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



# Accession dates (1)

| | Accession to PIC | Accession to PIC/S |
|---|---|---|
| Austria | May 1971 | Nov 1999 |
| Denmark | May 1971 | Nov 1995 |
| Finland | May 1971 | Jan 1996 |
| Iceland | May 1971 | Nov 1995 |
| Liechtenstein | May 1971 | Nov 1995 |
| Norway | May 1971 | Nov 1995 |
| Portugal | May 1971 | Jan 1999 |
| Sweden | May 1971 | Feb 1996 |
| Switzerland | May 1971 | Feb 1996 |
| UK | May 1971 | Jun 1999 |
| Hungary | Aug 1976 | Dec 1995 |
| Ireland | Dec 1977 | Feb 1996 |
| Romania | May 1982 | Nov 1995 |
| Germany | Sep 1983 | Dec 2000 |
| Italy | Aug 1990 | Feb 2000 |
| Belgium | Sep 1991 | Feb 1997 |
| France | Dec 1992 | Feb 1997 |
| Australia | Jan 1993 | Nov 1995 |
| Netherlands | - | Nov 1995 |
| Czech Republic | - | Jan 1997 |
| Slovak Republic | - | Jan 1997 |

# Accessions dates (2)

| Accession to PIC | | Accession to PIC/S |
|---|---|---|
| Spain | - | Jan 1998 |
| Canada | - | Jan 1999 |
| Singapore | - | Jan 2000 |
| Greece | - | Jan 2002 |
| Malaysia | - | Jan 2002 |
| Latvia | - | Jan 2003 |
| Czech Rep (Vet) | - | Jul 2005 |
| Poland | - | Jan 2006 |
| Estonia | - | Jan 2007 |
| South Africa | - | Jul 2007 |
| Argentina | - | Jan 2008 |
| Malta | - | Jan 2008 |
| Cyprus | - | Jul 2008 |
| France (Vet) | - | Jan 2009 |
| Israel | - | Jan 2009 |
| Lithuania | - | Jul 2009 |
| USA | - | Jan 2011 |
| Ukraine | - | Jan 2011 |
| Slovenia | - | Jan 2012 |
| Indonesia | - | Jul 2012 |

# Accessions dates (3)

| Accession to PIC | | Accession to PIC/S |
|---|---|---|
| New Zealand | - | Jan 2013 |
| Chinese Taipei | - | Jan 2013 |
| United Kingdom (Vet) | - | Jan 2014 |
| Japan | - | Jul 2014 |
| Korea (Republic of) | - | Jul 2014 |
| Hong Kong SAR | - | Jan 2016 |

# Current situation of candidates to PIC/S July 2015

## Applicants

**Up to 6 years**

1. Brazil
2. Philippines
3. Iran
4. Turkey
5. Croatia
6. Mexico
7. Thailand

## Pre – Applicants

**Up to 2 years**

1. Armenia*
2. Belarus
3. Uganda*
4. Kazakhstan
5. Chile

*pre-accession application complete

## Interested to apply

1. Nigeria
2. China CFDA
3. Bulgaria
4. Hungary (vet)
5. Saudi Arabia
6. Russia
7. Bhutan

Europe | Asia | Africa | America

# Why should an Agency apply to PIC/S?

- To strengthen the GMP Inspectorate and regulatory standards.
- To participate in the development of new and improved ways to inspect the industry.
- To improve its own quality system through the assessment and re-assessment procedure
- To cooperate and find common solutions in the GMPs along with more than **46** authorities in 5 continents
- **Because we are not alone on this planet!**

# Pre-accession + Accession procedure

**Useful Documents**

- Pharmaceutical Inspection Cooperation Scheme(**PIC/S 1/95**)

- Guidelines for Accession to PIC/S (**PS/W 14/2011**)
- Questionnaire for Competent Authorities (**PS/W 1/2011**)
- Audit Checklist **(PS/W 1/2005)**

- **Recommendations on quality system requirements pharmaceutical inspectorates (PI 002-3)**

# 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)

# 2. 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.

# Obligations as a PIC/S Member

**PIC/S Member's active participation and contribution is the only way forward**

(1) Payment of annual membership fee

(2) To attend PIC/S Committee Meetings – twice a year – one in Geneva and the other one in a member country (together with the annual seminar)

**(3) To host or participate in the annual PIC/S Seminar**

**(4) To host or participate in PIC/S Expert Circles & JVP & JRP**

**(5) To participate in PIC/S Sub-Committees (SC).**

# PIC/S Guides & Recommendations
## PIC/S GMP Guide

**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

**The PIC/S GMP Guide – PE 009-11**

**(latest revision entered into force on 1st March 2014)**

# PIC/S GMP Guide (2)

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

# PIC/S Guides & Recommendations

## 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 Works on Validation

- 1994 PIC Seminar in Ireland on Validation identified need to develop guidance document
- PIC/S Recommendations prepared covering:
  - Validation Master Plan
  - Installation & Operational Qualification (IQ & OQ)
  - Non-sterile Process Validation
  - Cleaning Validation
- PIC/S entry into force on 1st March 1999
- Adopted by the EU and PIC/S as Annex 15
- Jointly revised with the EU (published April 2015 with entry into force in October 2015)

# PIC/S Involvement in the ICH GMP Guide on APIs

- PIC/S Conference in Canberra 1996:
  - consensus obtained to prepare international GMP.
- PIC/S draft document prepared during '97 & '98.
- ICH Q7 took over the work of PIC/S mid-1998 to enable industry to become involved:
  - ICH involves 3 regions (USA, Europe & Japan).
- ICH GMP Guide finalised in November 2000 after extensive public consultation.
- Most countries have adopted ICH document as a GMP requirement for APIs by 1st April 2001 (EU).
- ICH document became Part II of PIC/S GMP Guide in 2007

# PIC/S Guides & Recommendations

- ✓ **PIC/S GMP Guide (similar to EU GMP Guide)**
- ✓ PIC/S GMP Guide for **Blood Establishments**
- ✓ PIC/S Guide to Good Practices for the **Preparation of Medicinal Products in Healthcare Establishments**
- ✓ **Validation** (master plan, IQ/OQ, process, cleaning)
- ✓ Validation of **Aseptic Processes**
- ✓ Inspection of **Isolator Technology**
- ✓ **Quality Systems for Inspectorates**
- ✓ Validation of Computerised Systems
- ➔ **PIC/S Aide –Memoire ON ASSESSMENT OF QRM IMPLEMENTATION PI 038-1**
- ➔ **PIC/S RECOMMENDATION ON RISK-BASED INSPECTION PLANNING PI 037-1**

# PIC/S Training for GMP Inspectors

- ✓ Annual Training Seminars
- ✓ Training Courses for New Inspectors
- ✓ Expert Circles
- ✓ Joint Visits Programme (JVP) and Coached Inspections Programme (CIP)
- ✓ **PIC/S - Industry Workshops**

# PIC/S Seminars (1)

| | |
|---|---|
| - 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 (Need for Revision?) | Finland, 1979 |
| - Tablet Manufacture | Denmark, 1980 |
| - Manufacture of Active Ingredients | Switzerland, 1980 |

# PIC/S Seminars (2)

| | |
|---|---|
| - 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 |

# PIC/S Seminars (3)

| | |
|---|---|
| - Inspection & Testing in Relation to the Marketing Authorisation | Belgium, 1993 |
| - Qualification & Validation | Ireland, 1994 |
| - Manufacture of Sterile Products | Iceland, 1995 |
| - Computer Systems | Australia, 1996 |
| - GMP Standards for APIs | Australia, 1996 |
| - Manufacture & Inspection of APIs | Finland, 1997 |
| - Quality Systems for Inspectorates | Holland, 1998 |
| - Non-technical Aspects of Inspection | UK, 1999 |
| - Biotechnology | France, 2000 |
| - Inspection of Utilities | Czech Rep, 2001 |
| - Interface between GCP and GMP | Canada, 2002 |

# PIC/S Seminars (4)

| | |
|---|---|
| - Inspection of QC laboratories | Slovak Rep, 2003 |
| - Inspection of APIs | Spain, 2004 |
| - Primary packaging, labelling and prevention of mix-up | Romania, 2005 |
| - Risk Management | Germany, 2006 |
| - Solid Dosage Form Manufacturers | Singapore, 2007 |
| - Good Distribution Practices | Poland, 2008 |
| - 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**

# Expert Circles

- ✓ APIs
- ✓ Computerised Systems
- ✓ Human Blood, Tissues and Cells
- ✓ Quality Risk Management
- ✓ Good Distribution Practices

**Aim: Develop draft guidance documents**
**Training in specialised field**

# Working Groups

- ✓ Revision of Annex 1 (joint WG with EU)
- ✓ ATMPs
- ✓ Harmonisation of Classification of Deficiencies
- ✓ GCP & GVP
- ✓ Data Integrity
- ✓ Veterinary Medicinal Products
- ✓ Controlling Cross-Contamination in Shared Facilities

# PIC/S Joint Visits

Idea was highlighted already in 1974 and **started in 1987** with a trial phase

- Around **19** groups of 3 inspectors from 3 countries
- 3 inspections (one per country) to be completed ideally within 18 months

- **for training purposes**
- **for uniform GMP interpretation**
- **for uniform inspection procedures**
- **for mutual confidence**


- The current groups are inspecting **Gas (1), Vet (1), GMP (2), Sterile GMP (3), APIs (1), GDP (1), GCP (5) and GVP (5)**

# Joint Reassessment programme

## 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**

# Harmonization of Good Inspection Practices and GM(D)P Practices & Standards

**Through encouraging risk-based inspections** and introducing a QRM tool for inspectorates; can be used for other activities such as e.g. “the audit of suppliers” (services)

Through a PIC/S aide-memoire for API inspections in order to harmonize practices & interpretation & approach

Through developing an International API Training Programme to harmonize interpretation and application

Through a notification procedure for quality defects and falsification for PIC/S members

# 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"**
- **Working Group created to harmonize interpretation & classification of deficiencies**

# Typical PIC/S Inspection of a Medicine Manufacturer

*Before the inspection:*

- 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.

# Typical PIC/S Inspection of a Medicine Manufacturer (cont'd)

*After the inspection:*

- 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 activities in 2015

| Date | Place | Activity | Organised by |
|---|---|---|---|
| 22-23 January | Seoul (KR) | PIC/S - PDA ICH API (Q7) Training | PIC/S and PDA in co-operation with MFDS |
| 10-12 February | Brasilia (BR) | PIC/S - PDA ICH API (Q7) Training | PIC/S and PDA in co-operation with ANVISA |
| 23-26 March | Taipei (TW) | PIC/S Expert Circle on Good Distribution Practices (GDP) | TFDA (Chinese Taipei) |
| 11 May (morning) | Geneva (CH) | PIC/S Executive Bureau: Preparatory Meeting | PIC/S Secretariat |
| 11-12 May | Geneva (CH) | PIC/S Committee (starting at 2 pm on the first day) | PIC/S Secretariat |
| 13 May | Geneva (CH) | PIC/S Executive Bureau - China / CFDA bilateral meeting | PIC/S Secretariat |
| 14-15 September | Hyderabad (IN) | PIC/S - PDA ICH API (Q7) Training | PIC/S and PDA in co-operation with DIA |
| 17-18 September | Ahmedabad (IN) | PIC/S - PDA ICH API (Q7) Training | PIC/S and PDA in co-operation with DIA |
| 5 October | Nusa Dua (ID) | PIC/S Executive Bureau: Preparatory Meeting | PIC/S Secretariat |
| 5-6 October | Nusa Dua (ID) | PIC/S Committee (starting at 2 pm on the first day) | PIC/S Secretariat |
| 7-9 October | Nusa Dua (ID) | PIC/S Seminar on “Biopharmaceuticals (Biologicals and Biotech): How to inspect” | NADFC (Indonesia) |
| 5-7 October | Los Angeles (US) | PIC/S Advanced QRM Training Course | US FDA |
| 20-22 October | Strasbourg (FR) | PIC/S Expert Circle on APIs and Advanced Training on APIs | EDQM |
| 26-30 October | Rome (IT) | PIC/S Expert Circle on Blood, Tissue and Cells | AIFA (Italy) |

# Relationship with EMA
## (European Medicine Agency, EMA)

- EMA attends PIC/S Committee as a Associated Partner organisation
- **PIC/S-EU liaison officer attends Inspectors meetings at EMA as an observer**
- **A Harmonised Consultation Procedure**
- **Associated Partnership** negotiated in 2007 (renewed in 2010)

# Revision Procedure in EU and PIC/S
# Effort for parallel paths

EU

Initiative to Inspectors WG at EMA

**Concept paper** published and commented

Discussion of draft with other WGs like Qualiy, Safety, Biologics etc and approval to send to EU.

EU Commission approves and publishes the draft

Public consultation of draft for 3 to 6 months

**Comments are assessed by IWG. Possible discussions with other WGs and meetings with Industry**

**IWG agrees on new draft**

**European Commission performs final legal assessment**

**European Commission publishes the new Rule**

PIC/S

**Draft to PIC/S Committee**

**In parallel to IWG and EU discussions**

**Decision by PIC/S Committee**

# Comparing GMPs & GDPs in EU/EEA and PIC/S

## GMPs in EU

3 Parts and 19 Annexes

**PART I** Basic Requirements for MPs

**PART II** Basic Requirements for APIs

**PART III** GMP related guidance

& **19 Annexes of GMPs** (18 is blank)

**& GDPs in EU**

## GMPs in PIC/S

**(PE 009-11)**:

**PART I** Basic Requirements for MPs

**PART II** Basic Requirements for APIs

**No Part III**

**19 Annexes of GMPs** (16 and 18 blank)

**& GDPs in PIC/S**

# Liaison with other organisations

- ✓ The European Department for the Quality of Medicines (EDQM): Associated Partnership negotiated in 2007 (renewed in 2013),
- ✓ UNICEF: Associated Partnership negotiated in 2008,
- ✓ WHO: Co-operation Arrangement negotiated in May 2009
- ✓ ICH
- ✓ European Commission (DG Health & Consumers)
- ✓ ASEAN
- ✓ ICMRA

# PIC/S membership and positive impact for industry

Manufacturers are increasingly worried by the multiplication and duplication of inspections:

- which means not only more fees but also more staff immobilized;
- possibly a lower-than-usual production output during these inspections.

**Industry is generally favorable to PIC/S' expansion**

# PIC/S membership and positive impact for industry

It is **essential for PIC/S** to maintain good relations with industry as the manufacturer being at the heart of the GMP process

Reduced duplication of inspections *(cost savings)*

Export facilitation *(including to non-PIC/S countries)*

Enhanced market access

Reputation of industry enhanced

**Transparent inspection standards**

**Consistency of inspections**

**Reliable quality of medicines available locally and internationally**

# PIC/S membership
# Challenges Facing Regulators/Inspectors

**Regulating Products derived from Newer Technologies, e.g.:**

1. Nanomedicines from Nanotechnology;
2. Biopharmaceuticals from Biotechnology
3. Cell-Based Products from Tissue Engineering

**Migrating from Quality by Testing (QbT) to Quality by Design (QbD)**

**Assuring API Quality & Supply Chain Integrity**

# PIC/S membership
# Challenges Facing Regulators/Inspectors Assuring Supply Chain Integrity

**Many players in supply chain from manufacture of API to distribution of finished products to point of use**

- **Increased number of players in API/product supply chain**
- **Many potential points for interference of API/product**

**GMP/GDP Compliance can help :**

**Assure Quality of API/Finished Products - Manipulation by Unscrupulous Supply Chain Players - Detect Adulterated Products, Counterfeits & Falsified Medicines**

## International Efforts to Protect Supply Chain

# PIC/S membership
# Challenges Facing Regulators/Inspectors
# International Efforts on Supply Chain Integrity

Global Harmonization of GMP Standards for API by ICH, PIC/S & WHO

Specific International Collaborative Initiatives

***PIC/S Expert Circle on API (PIC/S API International Training Programme)***

Harmonization/Training of Inspectors *Exchange Reports & Avoid Duplication of Inspections*

- Q7 Training for Inspectors and Industry;
- Advanced API Training for Inspectors only;
- Q & A on API .

***WHO PQP on Essential Medicines including APIs*** *- Assist Developing Countries in Procurement of APIs/Finished Products*

International efforts going on, but more can be done:

**Benefiting Patients, Consumers & Public, Globally**

# PIC/S Membership and Impact at Regional Level

**Regional Institutions** have become increasingly important as they are actively involved **in the field of GMP whether in terms of:**

- **Harmonization;**
- **Standards;**
- **Training.**

**Co-operation, network and support are important to reduce the risk of unnecessary duplications and build confidence.**

# Benefits for all parties

PIC/S membership provides benefits not only to the **applicant regulatory authority**, but also to the medicine **manufacturing industry** and of course to the **consumers / patients** of the country involved.

**ALL will benefit by a proper Foreign Inspections cooperation**

**and ALL will save resources.**

# PIC/S Blueprint

- **PIC/S Blueprint** PS/W 8/2005
  **adopted by PIC/S Committee in December 2005**
  **Aim:**
  - To **review PIC/S' mission & goals** in a changing environment.
  - To set a number of **objectives and actions** for the next 10 years.
  - To raise PIC/S' visibility and explain the benefits of PIC/S membership.
  - To make PIC/S more of a **global organisation** rather than European focussed.

    ✓ PIC/S Blueprint is available at www.picscheme.org

# PIC/S Blueprint

- ✓ Most objectives have been or will be achieved in set time frame
- ✓ e.g. regarding the target of integrating 12 new Agencies by 2015
- ✓ **e.g. opening up PIC/S to GDP and GXP**

# Recent Developments

- Accession of Hong Kong SAR's PPBHK (as of January 2016)
- Revision of PIC/S GMP Guide (Annex 15) (enter into force on 1 October 2015)
- Establishment of PIC/S Inspectors' Academy (PIA) (October 2014)
- Accession of Japan's MHLW, PMDA & Prefectures and of Korea's MFDS (July 2014)
- New PIC/S GDP Guide, based on EU GDP Guide (June 2014)
- Revision of PIC/S GMP Guide (Part II of GMP Guide (Q7A), Annex 2 and 14) (March 2014)
- Revision of PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (new Annex 3 on radiopharmaceuticals) (March 2014)
- New PIC/S Organisational Sub-Committee Structure (Jan 2014)

# Final Remarks
# Conclusions

Increased emphasis on focused issues such as counterfeiting & pandemic & medicines shortage

**Requires the use of :**

- **science-based policies and standards**
- **risk-based orientation**
- ***integrated quality systems orientation***
- **international cooperation**

**To grant public health protection**

# Final Remarks
## Conclusions

"PIC/S is continuously exploring ways **to facilitate the harmonization of GM(D)P and to adapt** to a beautiful but constantly changing world"

**Reason for PIC/S' success: mandate & mission still valid today**

**Increasingly becoming and acting as a "global player"**

# Future of PIC/S & New Projects

- ✓ **Expansion** to cover Good Distribution Practices - GDP (new Expert Circle established); Good Clinical Practices - GCP and Good Pharmacovigilance Practices - GVP (new Working Group);

- ✓ **PIC/S Inspectorates Academy**

# PIC/S Executive Bureau

- **Joey Gouws (South Africa / MCC), PIC/S Chairperson;**

- **Paul Hargreaves (UK / MHRA**), PIC/S Deputy Chairman and Chair of the Sub-Committee on Budget, Risk and Audit (SCB);
- **Helena Baião (Portugal / INFARMED IP**), immediate former Chairperson;
- **Boon Meow Hoe (Singapore / HSA),** Chair of the Sub-Committee on Training (SCT);
- **Andreas Krassnigg (Austria / AGES**), Chair of the Sub-Committee on Expert Circles (SCEC);
- **Jacques Morénas (France / ANSM)**, Chair of the Sub-Committee on Strategic Development (SCSD);
- **Anne Hayes (Ireland / HPRA)**, Chair of the Sub-Committee on Compliance (SCC);
- **Paul Gustafson (Canada / HPFBI)**, Chair of the Sub-Committee on GM(D)P Harmonisation (SCH);
- **Tor Gråberg (Sweden / MPA),** Chair of the Sub-Committee on Communication (SC COM).


**PIC/S Secretariat**
**14 rue du Roveray**
**CH - 1207 GENEVA**
**Switzerland**

Tel: +41.22 738 92 16
Fax: +41.22 738 92 17

info@picscheme.org
www.picscheme.org

*The protection of public health and of the patient is our common goal*

*Thanks for your attention*