Leading the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products

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May 2018

Press release: PIC/S Meetings in Geneva (Switzerland)

From 16 to 18 April 2018, the following meetings took place in Geneva (Switzerland): PIC/S Committee and PIC/S Executive Bureau.

HEADLINES

- **NEW PIC/S GUIDANCE ON GMP INSPECTION RELIANCE BASED ON DRAFT BY ICMRA WITH AIM TO MAXIMISE INSPECTION RESOURCES FOR GMP COMPLIANCE OF OVERSEAS FACILITIES.**
- **REVISION OF PIC/S GMP GUIDE (PE 009). CHAPTERS 3, 5 AND 8 OF THE PIC/S GMP GUIDE HAVE BEEN REVISED AND WILL ENTER INTO FORCE ON 1 JULY 2018; ALONG WITH ADOPTION OF TRANSPOSITION FOR PIC/S PURPOSES OF EU GUIDANCES ON GMP EXICIPENT RISK ASSESSMENT, EXPOSURE LIMITS AND GDP FOR API.**
- **NEW PIC/S WORKING GROUP ESTABLISHED WITH W.H.O. TO REVISE ANNEX 2 ON BIOLOGICALS AND ATMP.**
- **FOCUSED STAKEHOLDER CONSULTATION FOR DRAFT PIC/S GUIDANCE ON DATA INTEGRITY.**
- **NEW PIC/S AIDE-MEMOIRE ON CROSS-CONTAMINATION IN SHARED FACILITIES.**
- **NEW PIC/S PRE-ACCESSION APPLICATION RECEIVED FROM PAKISTAN / DRAP.**
- **NEW PIC/S WORKING GROUPS TO BE ESTABLISHED ON WHISTLE-BLOWERS/CONFIDENTIAL INFORMANTS; QUALITY DEFECTS PROCEDURES; AS WELL AS PIC/S ASSESSMENT AND RE-ASSESSMENT PROCEDURES.**
- **PIC/S 2018 SEMINAR TO BE HOSTED BY US FDA IN CHICAGO AND OTHER NEWS IN THE FIELD OF TRAINING FOR GM(D)P INSPECTORS.**

PIC/S COMMITTEE MEETING

PIC/S Chairman
Mr Boon Meow Hoe
(Singapore / HSA)

The PIC/S Committee met on 17-18 April 2018, under the chairmanship of Mr Boon Meow Hoe (Singapore Health Sciences Authority / HSA). The Chairman said that it was a particular honour for Asia to chair PIC/S for the first time in history. The meeting was attended by 45 out of 52 PIC/S Participating Authorities (PA) as well as by a number of Applicants, Pre-Applicants, Associated Partners and Guests.

PIC/S Committee meeting in Geneva

NEW PIC/S GUIDANCE ON GMP INSPECTION RELIANCE TO MAXIMISE RESOURCES FOR GMP COMPLIANCE OF OVERSEAS FACILITIES

The PIC/S Committee adopted a new guidance on GMP inspection reliance based on a draft by the International Coalition of Medicines Regulatory Authorities (ICMRA) GMP Inspection Reliance Framework.

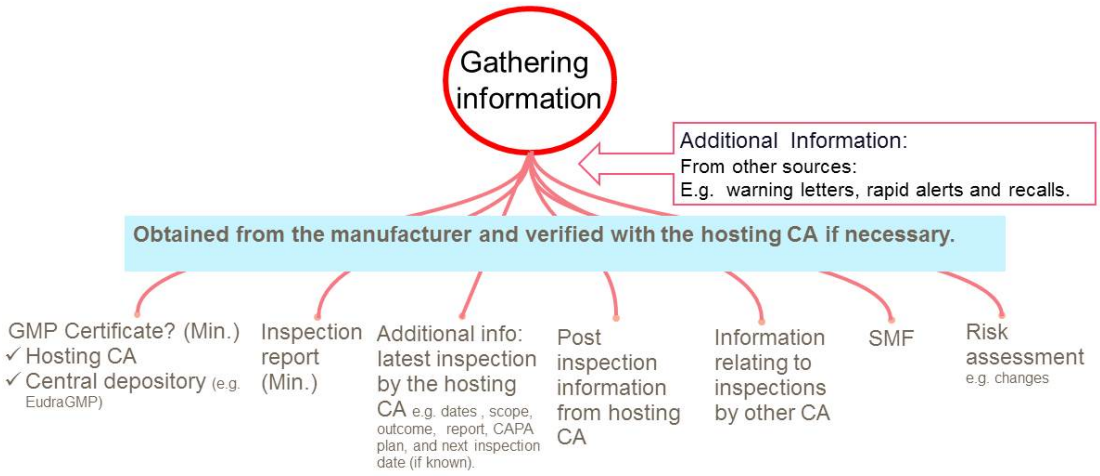
This guidance provides a tool and framework which aims to help Competent Authorities (CA) prioritise resources for GMP inspections for human and veterinary medicines. The demand for inspecting pharmaceutical manufacturing facilities far exceeds what any one CA can accomplish and this framework will assist regulators in managing product quality risks posed by the increasingly complex pharmaceuticals global supply chain.

The main feature of this new guidance is that it outlines a process for **desk-top assessment** of GMP compliance of overseas facilities to identify instances where an acceptable level of GMP compliance can be confirmed and assured from the activities of another CA or CAs without the need for an on-site inspection.

It is a **non-binding** (i.e. applicable on a voluntary basis) **high-level** guidance for ICMRA and PIC/S Participating Authorities (PA) alike, whose purpose is to facilitate this assessment process. It does not supersede country / regional guidance, procedures or legislation where they exist. It is compatible with the PIC Scheme, which already provides for sharing of GMP-related information between PIC/S PA, on a voluntary basis, subject to national law, supranational law and other legally binding agreements such as Mutual Recognition Agreements (MRA).

The details of the process will vary as CAs are invited to use this framework to establish their own procedures, at national level, containing details of the assessment process. The procedure should include the information that is needed to make an informed regulatory decision about site compliance, triggers and risk factors that would result in an inspection being required, and how the assessment and outcome should be recorded.

Assessment of site compliance



The aim in assessing the gathered information is to gain assurance that GMP compliance has been established by the hosting CA and that there are no other new evidence that would warrant an on-site inspection by the requesting CA.

The adoption by PIC/S of this new guidance highlights efforts undertaken by PIC/S in improving sharing of information between authorities. These efforts include the PIC/S list of foreign inspections, which for 2018 contains more than 900 scheduled foreign inspections so far. For any possibly duplicate inspections, PIC/S PA are encouraged to either perform a joint inspection or rely on the inspection report from a PIC/S PA (or Partner Organisation). The new guidance on GMP reliance, supplemented by national procedures detailing local processes, can hopefully further enhance these efforts as well as help Inspectorates to make optimal use of inspection resources.

Essential to its success and implementation will be the political will and support of ICMRA Heads of Agencies and other concerned networks of Heads of Agencies (such as the EU/EEA HMA). A survey on acceptance of same scope inspections conducted in 2016 with all PIC/S PA showed that most PA do not rely on available GMP information unless it is in the framework of a MRA or equivalent (e.g. EU Member States). Also crucial will be the support of industry as it will be up to companies to proactively share reports if they wish to avoid duplicate inspections.

REVISION OF PIC/S GMP GUIDE (PE 009)

The PIC/S Committee adopted the following Chapters of the PIC/S GMP Guide, which have been revised:

Chapter 3 on “Premises and Equipment”;
Chapter 5 on “Production”;
Chapter 8 on “Complaints and Product Recall”.

The revised Chapters 3, 5 & 8 of the PIC/S GMP Guide are based on the equivalent Chapters of the EU GMP Guide with some minor differences in terms of language. These Chapters of the PIC/S GMP Guide have now been aligned with principles of

Quality Risk Management. Chapter 3 and 5 have been revised to include requirements to prevent cross-contamination. A change in the qualification of suppliers has also been introduced by revised Chapter 5. Expectations with regard to quality management system for the evaluation of quality defects in relation to product recalls have been expanded in Chapter 8, which has been entirely revised.

The revision has been successfully completed by the PIC/S Sub-Committee on the Harmonisation of GM(D)P, led by Paul Gustafson (Canada / RORB). The revised GMP Guide (PE 009-14) will **enter into force on 1 July 2018**. All non-EU/EEA Participating Authorities of PIC/S (and Applicants) have been invited to transpose the revised Chapters of the PIC/S GMP Guide into their own GMP Guides.

The revised GMP Guide (PE 009) will be published on the page "Publications" prior to its entry into force.

NEW PIC/S WORKING GROUP ESTABLISHED WITH W.H.O. TO REVISE ANNEX 2 ON BIOLOGICALS AND ATMP

PIC/S has established with WHO (World Health Organization) a new Working Group led by Australia / TGA on a **revision of Annex 2** (biologicals) of the PIC/S GMP Guide in order to review the European Commission's (EC) Guidelines on Good Manufacturing Practice (GMP) specific to Advanced Therapy Medicinal Products (ATMP) in order to identify:

- strengths and weaknesses;
- legitimate concerns by industry and regulators with respect to ATMP;
- areas of GMP applicable to ATMP that may benefit from modernisation to reflect the current status of the manufacturing processes and manufacturing settings.

The objective is to advance a recommendation to the PIC/S Committee on a strategy to harmonise where possible with the EC guidelines while addressing the perceived concerns raised by PIC/S Participating Authorities which have led to international divergence in this field (see News of 2 March and 25 April 2017).

FOCUSED STAKEHOLDER CONSULTATION FOR PIC/S GUIDANCE ON DATA INTEGRITY

The PIC/S Working Group on Data Integrity, co-led by Australia / TGA and UK / MHRA, has revised the **Draft PIC/S Guidance on Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments**. The purpose of the guidance is to serve to outline the position an inspector would adopt during the inspection of GDP/GMP facilities and is designed to facilitate a harmonised approach to the inspection, including reporting in regards to data management and integrity.

A first draft (PI 041-1 (Draft 2)) was published by PIC/S on a trial basis in August 2016. Following feedback received from PIC/S Participating Authorities during its 6-month implementation trial-period, the draft of this guidance has been updated and expanded by the Working Group.

The Committee agreed to a **focused stakeholder consultation** seeking substantive comments from trade and professional associations, during which the new draft will be applied by PIC/S Participating Authorities on a **trial basis for a new implementation trial period**.

Other PIC/S-internal data integrity tools have also been developed by this Working Group which is currently developing training material as well as assessing other external guidances which could be made available to PIC/S inspectors via the PIC/S Inspectorates Academy in order to assist inspectors in understanding both strengths and limitations of these documents, thereby facilitating more targeted and risk-based data integrity inspections.

Interview of the Co-Chairs of the Working Group, Matt Davis (Australia / TGA) and David Churchward (UK / MHRA)

Q. Why has this new revised draft been published on a further trial basis?
A. *In light of the widespread interest from industry to the first PIC/S draft guidance published in August 2016, the PIC/S Sub-Committee on Harmonisation has supported a proposal for a focused external stakeholder consultation on the updated version. In order for this new version to be available to PIC/S Participating Authorities without unnecessary delay, agreement of the PIC/S Committee was sought to publish this revised draft on a further trial basis, while the external consultation is held in parallel. A final version will be prepared following review of any consultation comments received through the focused stakeholder consultation, and submitted to the PIC/S Committee for formal adoption.*

Q. What are the other PIC/S-internal data integrity tools under development?
A. *The Working Group has developed an Aide Memoire - which provides a useful reference for inspectors, including key questions to ask, expectations and references to both the PIC/S guidance on data integrity and GMP/GDP clauses – as well as a flow-chart to assist inspectors in prioritising which systems should be reviewed for good data management practices during an inspection and system-specific guidance. The Working Group is also developing training materials for Inspectorates to improve understanding and assist in harmonisation of Inspectorates' approaches to Data Management and Integrity. Due to the nature of their content, these documents are not intended for wider dissemination outside PIC/S Inspectorates.*

NEW PIC/S AIDE-MEMOIRE ON CROSS-CONTAMINATION IN SHARED FACILITIES

The PIC/S Committee adopted an **Aide-Memoire on Cross-Contamination in Shared Facilities** developed by the PIC/S Working Group on Controlling Cross-Contamination in Shared Facilities (CCCISF), led by UK / MHRA.

The purpose of this Aide-Memoire is to assist GMP inspectors in the assessment of the risks to the product from cross-contamination in shared facilities. This document, which will **enter into force on 1 July 2018**, provides guidance for GMP inspectors to use in preparation for, and performance of, inspections.

The Aide-Memoire promotes a **risk-based approach** and should guide the inspector to make both the optimal use of the inspection time and the optimal evaluation of GMP compliance. It addresses many facets from:

- cross-contamination hazard assessment and risk management
- technical measures for equipment, premises and their design
- general organisational controls such as campaign organisation, equipment cleaning and inspection, cleaning validation and verification, and personnel.

The Aide-Memoire (PI 043-1) will be published on the page "Publications" prior to its entry into force.

The new PIC/S Expert Circle on Controlling Cross-Contamination in Shared Facilities, led by UK / MHRA, is also developing a PIC/S training programme in this field for which a first PIC/S Expert Circle meeting and training event is planned for summer 2019 in Taipei, to be hosted by Chinese Taipei / TFDA.

TRANSPOSITION FOR PIC/S PURPOSES OF EC GUIDANCES

The PIC/S Committee adopted the **transposition for PIC/S purposes** of the following European Commission (EC) guidance documents:

- Guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use (PI 045-1);
- Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (PI 046-1);
- Guidelines on the principles of Good Distribution Practice for active substances for medicinal products for human use (PI 047-1).

Transposition of these Guidelines further strengthens harmonisation between PIC/S and the EU and are in essence equivalent with some minor editorial differences. The Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities is also closely linked to revised Chapter 5 of the PIC/S GMP Guide.

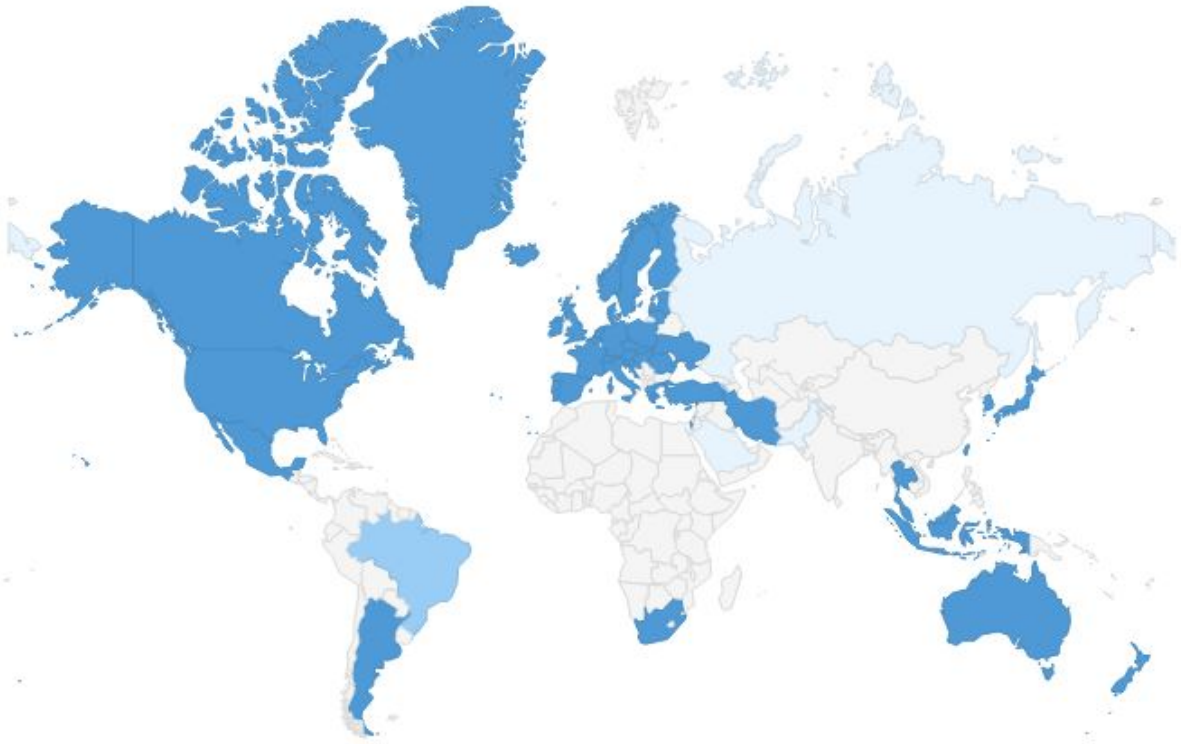
These Guidelines will **enter into force on 1 July 2018**, on a voluntary basis for non-EU/EEA PIC/S Participating Authorities.

The Guidelines (PI 045-1; 046-1; 047-1) will be published on the page "Publications" prior to their entry force.

PAKISTAN / DRAP APPLIES FOR PRE-ACCESSION

The **Drug Regulatory Authority of Pakistan (DRAP)** applied for PIC/S pre-accession on 18 September 2017. A Rapporteur is to be appointed by the Committee.

ONGOING PIC/S MEMBERSHIP APPLICATIONS



Overview of PIC/S 52 Members as of 1 January 2018 (dark blue); 3 Applicants (medium blue) and 3 (Pre-) Applicants (pale blue)

Applicants (3)	Pre-Applicants (3)
Armenia / SCDMTE	Pakistan / DRAP
Brazil / ANVISA	Russian Federation / Minpromtorg Russia and FSI "SID&GP"
Italy (Vet) / DGSAF	Saudi Arabia / SFDA

(in alphabetical order, starting with Applicants and then Pre-Applicants).

- A Rapporteur, Co-Rapporteur and Audit Team were appointed by the Committee for the assessment of the membership application of **Armenia / SCDMTE**;
- A 1-year clock-stop was granted to **Brazil / ANVISA** instead of the re-lodging of their application, due to the major re-organisation ANVISA has undergone. The on-site visit is scheduled for before end 2019;
- The Committee was updated on next steps in the membership application of **Italy (Vet) / DGSAF**, which will be facilitated by a partial assessment, taking into account the audit performed within the EMA Joint Audit Programme, in line with the PIC/S-EEA HMA Letter of Agreement;
- The Committee was updated on progress in the assessment by the Rapporteur of the pre-accession applications of the **Russian Federation / Minpromtorg Russia and FSI "SID&GP"**, lodged on 28 August 2017 and of **Saudi Arabia / SFDA**, lodged on 31 July 2017.

NEW DEVELOPMENTS IN THE FIELD OF GMP FOR VETERINARY MEDICINAL PRODUCTS (VMP)

The Committee was updated on the outcome of a survey carried out by France / ANSES-ANMV and UK / VMD with regard to the need to maintain and implement a **PIC/S Working Group on Veterinary Medicinal Products (VMP)**. The purpose of this Working Group is to take better into account the needs and questions related to GMP for VMPs and aims to address the specific needs of veterinary Agencies (currently 3 PIC/S PA) as well as veterinary departments of Agencies with mixed competencies (currently more than 20 PIC/S PA).

The **World Organisation for Animal Health (OIE)**, which also deals with GMP for VMPs, was invited to attend as special Guest this Committee meeting in the perspective of potential future co-operation between PIC/S and OIE.

NEW PIC/S WORKING GROUPS

The Committee agreed in principle on the establishment of a number of new PIC/S Working Groups.

A dedicated PIC/S Working Group will be established in connection with the revision of the EU Procedures for **Handling of Rapid Alerts Arising from Quality Defects & Managing Reports of Suspected Quality Defects** and of their possible transposition by PIC/S.

A **Working Group on Whistle-Blowers / Confidential Informants** will be created under the co-leadership of US FDA and UK / MHRA with a view to respond to the need for guidance on how to handle information provided by such sources, as identified during the PIC/S 2016 Seminar on “Inspectorates of the Future” hosted by UK / MHRA.

In order to develop further guidance and updates to the **PIC/S assessment and re-assessement procedures**, which ensure equivalency between all PIC/S Participating Authorities, as well as to improve the **PIC/S pre-accession process**, two new Working Groups internal to the PIC/S Sub-Committee on Compliance will be established.

OTHER NEWS

The PIC/S Committee:

- adopted the PIC/S **2017 Annual Report**, which will be published under “Publications”;
- adopted a **summarised public version of the PIC/S Road Map for 2018-2020**, drafted by an ad-hoc Working Group, led by US FDA. The public summary which provides an overview and description of road map priorities will be published under “Publications”;

- was updated on the outcome of discussions within the **PIC/S Executive Bureau** meeting on 16-17 April 2018, which preceded the Committee meeting, in particular on relations with China Food and Drug Administration (CFDA) further to a bilateral meeting between PIC/S and CFDA in December 2017. It was also informed of the restructuring of CFDA further to a recent re-organisation;

PIC/S Executive Bureau 2018-2019 (from left to right): Jacques Morénas (France / ANSM); Mark Birse (UK / MHRA); Susan Laska (US FDA); Paul Gustafson (Canada / RORB); Boon Meow Hoe, PIC/S Chairman (Singapore / HSA); Andreas Krassnigg (Austria / AGES); Anne Hayes, PIC/S Deputy Chairperson (Ireland / HPRA); Ger Jan van Ringen (Netherlands / IGJ); Paul Hargreaves (UK / MHRA).

- was updated on progress made by the **Working Group on Harmonisation of Classification of Deficiencies**, led by Australia / TGA, on the status of the PIC/S Guidance on Classification of Deficiencies which is scheduled for adoption and publication later this year;
- noted that further to the public joint PIC/S – EMA – WHO targeted stakeholder consultation on revision of **Annex 1** (sterile manufacturing) of the PIC/S and EU GMP Guides, which ended on 20 March 2018, the joint Working Group on revision of Annex 1, chaired by UK / MHRA, has started on the review of comments;
- was updated on the planned revision by PIC/S of **Annex 13** (investigational medicinal products);
- was updated on progress in the adaption for PIC/S purposes of **Annex 16** of the EU GMP Guide (certification by a QP & batch release);
- was updated on the adoption of revised **Annex 17** (previously “parametric release” replaced by “real time release testing and parametric release“) of the PIC/S GMP Guide**,** which will be published once the EU revision of Annex 17 enters into force;
- noted that the PIC/S Working Group on the revision of the **PIC/S Guidances on Blood**, led by Switzerland / Swissmedic, has started work on the revision of PI 008-3 and of PE 005-3;
- discussed the possibility for PIC/S as ICH Observer to comment on the draft **ICH Q12 guideline** (technical and regulatory considerations for pharmaceutical product lifecycle management), under public consultation;
- was updated on the status of the PIC/S Working Group on the revision of the PIC/S guidance on Good Practices for **Computerised Systems** (PI 011-3);
- revised the **PIC/S annual fees** paid by PIC/S Members and (Pre-)Applicants;

- was updated on the future **PIC/S Working Group on Third-Party funding**, which aims at increasing PIC/S resources to respond to its growing expansion and development;
- was updated on progress by the **PIC/S Working Group on Unique Facility Identifiers (UFI)**, chaired by US FDA and on the **PIC/S Working Group on Inspector Travel Safety**, chaired by UK / MHRA;
- adopted a new mandate for the **PIC/S Expert Circle on Active Pharmaceutical Ingredients** (API), co-chaired on a rotating basis by EDQM, Switzerland / Swissmedic and Australia / TGA;
- was updated on current developments with regard to the implementation of the **EU – US Mutual Recognition Agreement (MRA)** and was updated on recent GMP-related developments by **EDQM, EMA, UNICEF** and **WHO** as PIC/S Associated Partner Organisations;
- was updated by the PIC/S – ASEAN Liaison Authority, Thailand / Thai FDA, on recent activities within **ASEAN**. The Committee discussed a first draft of an informal exchange of letters with ASEAN to allow for co-operation between PIC/S and the ASEAN Pharmaceutical Product Working Group (PPWG) in GMP matters;
- was updated by Japan / PMDA on activities of the **Asia Partnership Conference of Pharmaceutical Associations** (APAC) and of a new Site Master File specific to innovative medicines developed jointly by PMDA and APAC;
- welcomed the establishement of 8 new groups in the PIC/S Joint Visits Programme (JVP) by the **PIC/S Working Group on GCP & GVP** (Good Clinical Practices and Good Pharmacovigilance Practices), led by UK / MHRA. The JVP is a PIC/S training tool which allows 3 Inspectors from 3 different countries to team up to observe inspections in each country with a view to comparing inspection procedures and techniques and harmonising interpretation in their field of competence;
- discussed the planning of the **PIC/S re-assessments** of Canada / RORB and South Africa / SAHPRA (previously MCC) scheduled for 2019 and appointed PIC/S Re-Assessment Team members;
- noted the **PIC/S re-assessments** of Argentina / INAME, Switzerland / Swissmedic and Ukraine / SMDC which will be taking place in 2018;
- endorsed the **PIC/S re-assessment** reports of Australia / TGA and Singapore / HSA which both took place on 18-22 September 2017;
- was updated on the status of the **guideline and interpretation of the Audit Checklist** by the PIC/S Sub-Committee on Compliance, in co-operation with the EU Joint Audit Programme Compliance Group.

PIC/S SEMINAR 2018 AND OTHER NEWS IN THE FIELD OF TRAINING FOR GM(D)P INSPECTORS

Training Competent Authorities and in particular, training Inspectors, is an integral and key activity of PIC/S. The training of GMP Inspectors has been one of PIC/S' main focal points since the very beginning back in 1971. Through this emphasis on training, PIC/S is able to achieve its mission.

Seminars are the main yearly PIC/S training event and are hosted each year by a different PIC/S Participating Authority. Each Seminar focuses on a particular aspect of GMP with the aim of providing training and harmonisation in the field covered.

The Committee was updated on the programme of the **2018 PIC/S Annual Seminar on** "**Management of Risk through the Product Life-Cycle**", which will be hosted by the US Food and Drug Administration (US FDA) in Chicago on **26-28 September 2018**.

Risk management is critical to ensuring product quality, safety, and efficacy. The Seminar will explore the best practices impacting risk assessments and share tools and techniques generated from experienced inspectors and assessors to enhance inspections. It will be an ideal opportunity for both novice and experienced inspectors to refine their inspection skills through knowledge sharing and discussion.

Registrations to the PIC/S Seminar 2018 **are now open here** (for Medicines Regulatory Authorities only).

The Committee also discussed preparations for the **2019 PIC/S Annual Seminar** which will be hosted by Japan / PMDA & MHLW in Toyama city (Japan) on 13-15 November 2019 on the topic of "**Quality Assurance of Sterile Medicinal Products - Annex 1**".

PIC/S training is unique as there is no other international training forum run jointly by regulators for regulators. Its high quality training has been developed progressively through a variety of training and harmonisation tools which have proved effective, presently regrouped under the **PIC/S Inspectorates' Academy.**

The PIC/S Committee discussed **future training priorities** for PIC/S in particular whether fields should be explored where PIC/S is the only Organisation with the appropriate expertise and added value (e.g. inspection methodology). These areas of focus should take precedence over purely technical topics for which other training offers exist by external stakeholders.

These priorities will guide the next stages of development of the PIC/S Inspectorates' Academy. The Academy presently offers about **500 training materials** and more than **200 videos** compiled from PIC/S training events. A number of e-learning modules such as webinars, on-line learning tools and modules, a training curriculum, forum and library of relevant GMP references are in development.

The Committee was updated on progress in these areas and – with regard to engagement with external stakeholders on more technical topics – agreed to a pilot on e-learning modules with ISPE. Possibilities of co-operation with other external stakeholders (e.g. PDA, IFPMA, ICH) will equally be pursued. The Committee also discussed strengthening co-operation in training activities with the European Medicines Agency (EMA).

The outcome of the **PIC/S – HPRA New Inspector Training Course** which was held in Dublin (Ireland) on 23-27 October 2017 hosted by Ireland / HPRA was reviewed. This was the 6th course run by HPRA since the new GMP inspectors course was initiated and developed in 2011, including this time also the support of UK / MHRA and US FDA.

This course has proved one of the most successful and sought after PIC/S training activities for new Inspectors. It offers them the opportunity to develop the inspection skills necessary to assess compliance of manufacturers against the PIC/S GMP Guide through presentations and case-studies. The programme comprises approx. 15 modules covering key GMP areas such as general inspection skills; inspection preparation; facility lay-out and design; supply chain; warehouse & dispensary; tablets, capsules & powders; liquids; creams & ointments; cleaning validation; utilities; autoclaves; garbing; asceptic manufacturing; microbiology laboratories; chemistry laboratories & QRM. 34 participants from 17 countries attended.

In light of the importance and capacity building dimension of this training for new inspectors, this course has been **institutionalised** under the PIC/S Inspectorates' Academy. It will be held at regular intervals; the next course has been scheduled by HPRA for April 2019 in Dublin.

COMING UP...

- 11-13 September 2018: **PIC/S Expert Circle meeting and Training Event on Quality Risk Management (QRM)**, in Taipei, hosted by Chinese Taipei / TFDA;
- 26-28 September 2018: **Annual PIC/S Seminar on "Management of Risk through the Product Life-Cycle"**, in Chicago, hosted by US FDA;
- 16-18 October 2018: **PIC/S Expert Circle on Good Distribution Practices (GDP) meeting**, in Madrid, hosted by Spain / AEMPS;
- 23-25 October 2018: **PIC/S Expert Circle on Blood, Tissues, Cells and ATMPs meeting**, in Warsaw, hosted by Poland / CPI;
- 26-30 November 2018: **Japan / PMDA - ATC GMP Inspection Seminar**, with the support of PIC/S, in Utsunomiya (Tochigi), Japan.

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