Consultation on the PIC/S Strategic Plan 2022-26

June 2021

Who are we and what do we do?

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a Swiss Association that has a worldwide membership of 54 participating medicines authorities which includes over 2000 inspectors. PIC/S is a scientific and technical organisation in the field of Good Manufacturing Practice (GMP) for medicinal products.

1. **How would you rate your awareness of PIC/S as an organisation that leads the international development, implementation and maintenance of harmonised GMP standards and quality systems of Inspectorates in the field of medicinal products?**

   (1 not familiar and 5 very familiar) - boxes can be ticked by clicking on them ☒.

1	2	3	4	5
☐	☐	☐	☒	☐

Your Contact Information and Disclosure

PIC/S welcomes you to share some information about yourself. This information does not need to be disclosed to complete the survey.

PIC/S will not publish your name or contact information. Your feedback in this survey and contact information will be collected by PIC/S and may be shared with PIC/S Participating Authorities. This information will remain subject to confidentiality requirements under the PIC/S Scheme. There are currently 54 PIC/S Participating Authorities representing international regulatory agencies in the field of GMP.

2. **Do you agree with the understanding that your feedback and contact information (if provided) can be shared within PIC/S and PIC/S Participating Authorities?**

   ☒ I agree with this understanding

3. **Name** (First and Last)

4. **Email Address**

5. **Organisation that you represent** — International Society for Pharmaceutical Engineering (ISPE)

PIC/S Mission

The PIC/S mission is to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products.

PIC/S' mission is to be achieved by:

- Developing and promoting harmonised GMP standards and guidance documents (see "GMDP Harmonisation" and "Publications");
- Training Competent Authorities, in particular GMP Inspectors (see "Training");
- Assessing (and re-assessing) GMP Inspectorates (see "Accession" and "Compliance");
- Facilitating co-operation and networking for Competent Authorities and International Organisations (see "International Co-operation")

6. **What do you see as important strategic considerations in relation to the PIC/S mission?** (Maximum of 3000 characters)

Drive Global Mutual Reliance of GXP regulation by promoting harmonisation and mutual acceptance of basic requirements for technical standards, e.g. Aseptic facilities, Data Management, others. We suggest adding another bullet to the PIC/S Mission:

• Promote mutual reliance amongst member authorities and associated organisations

The mission may benefit from more granularity in the following areas of:
- mutual acceptance of regulatory flexibilities applied, for example, to Advanced Therapy Medicinal Products (ATMPs)
- supporting accelerated regulatory pathways
- supporting agile supply chains to help mitigate drug shortages
- facilitating increased digitalization

PIC/S Vision and Values

PIC/S' successful development has been possible due to the common sharing of the following shared vision and principles:

- A technical expert's organisation: PIC/S has always taken great pride in featuring itself as a purely technical organisation in the field of regulatory GMP. Not becoming politically involved or discriminating against e.g. religion or race has always been PIC/S' firm belief. Moreover, PIC/S is a major "think-tank" in the GMP field, the place where new ideas related to GMP are debated by highly competent experts.

- Based on consensus and mutual trust: Consensus in PIC/S has been based on the understanding that all Members have equal rights and obligations and that no Member is more "equal" (larger, richer...) than others. Despite the difficulty of having to negotiate compromises acceptable to all Members, PIC/S has always found a way forward without isolating a Member, which finds itself alone against the vast majority. Mutual trust is a key value in PIC/S and largely relies on the concept of voluntary co-operation (there is no legal obligation under PIC/S) and each Member being assessed for equivalence before being admitted.
- As all PIC/S Members are supposed to be equivalent, Members find it easier to exchange information on GMP on a voluntary basis.
- Driven by Members: PIC/S is an organisation which is mainly driven by Participating Regulatory Authorities and where the Secretariat has remained flexible and productive. As a result, PIC/S is a flexible and dynamic organisation, which is neither bureaucratic nor expensive. This also implies that Participating Authorities are expected to contribute to either PIC/S events (e.g. by hosting training events) or to PIC/S functioning (e.g. by allowing Members to carry out official duties for PIC/S such as chairing PIC/S meetings or representing PIC/S during conferences).
- Cemented by strong professional and personal links: PIC/S' strength relies on its informal character, networking and the strong personal links between individual Members or Inspectors which have created a forum for brain storming, discussing new ideas and sharing information. It is not a coincidence that the first draft of the ICH Q7A Guide was initiated by PIC/S.

7. **What do you see as important strategic considerations in relation to the PIC/S vision and values?** (Maximum of 3000 characters)

Continue to build a strong level of trust between member authorities using established and new approaches and technologies to support the mission.

Current PIC/S Strategic Roadmap

The current Roadmap covers the years 2018 to 2020 and is based on the following three high-level goals, each of which has a number of objectives and activities which guide our annual business planning and reporting.

1. Training Inspectors: Enhancing and implementing the PIC/S Inspectorates' Academy (PIA) to provide training to all inspectors.
2. Sharing Information: Facilitating the exchange of GMP information by mutual confidence based on the equivalence of PIC/S Participating Authorities (i.e. Members)
3. Strengthening the Organisation: Identifying and addressing emerging organisational challenges, notably by;
    - Improving communication (both internally and externally);
    - Enhancing PIC/S' Sub-Committee (SC) structure;

- Strengthening the PIC/S Secretariat and implementing an effective human resourcing strategy; and
- Identifying new income streams, which will yield the required funding necessary to finance PIC/S' projects.

Achieving these goals is in line with long-term strategic objectives of PIC/S, notably:

- To further promote the international harmonisation and interpretation of GMP standards as well as the harmonisation of inspection procedures;
- To ensure the continued compliance of Acceding and Participating Authorities with PIC/S' requirements;
- To strengthen PIC/S' governance and resources; and
- To review and assess PIC/S' outputs
- To further promote the international harmonisation and interpretation of GMP standards as well as the harmonisation of inspection procedures;
- To ensure the continued compliance of Acceding and Participating Authorities with PIC/S' requirements;
- To strengthen PIC/S' governance and resources; and
- To review and assess PIC/S' outputs

8. Do you support PIC/S's continued prioritisation of these priorities?

☐ Yes
☐ No
☒Other

9. If you selected other, can you tell us why?

(Maximum of 3000 characters)

• Build stronger relationships with ICH to facilitate introduction of new ICH guidelines critical to promoting early and continued (obviating drug shortages) access of patients to medicines, e.g., Q12 and Q9 Revision.

• Consider taking a greater coordination and leadership role when any member authority is developing new or revising major existing guidances/regulations. An example is the emerging topic of Business Continuity Plans (BCPs) to help prevent drug shortages, particularly after the pandemic. Availability of such plans is becoming an inspection activity in some member authorities. PIC/S could assist member authorities and industry with, for example:
- Facilitating a unified approach to drug shortage prevention, including harmonised definitions of "drug shortage" and "essential medicine"
- Developing best practice templates for BCPs
- Directionally influence emerging regulation towards global harmonisation

• Continue the PIC/S activity to deliver tools and harmonised processes for distant assessments/remote inspections to support mutual reliance between member authorities of the outcomes of this type or part of an inspection.

• There should be a stronger focus on keeping PIC/S guidance's and aid memoirs current and up to date. Many are old and need to be updated--- to give direction to inspectorates' guidance is needed in Training, Aide memoire and formal guidance documents that are available to the industry. This causes confusion because many countries adopt PIC/S guidances which can result in different inspection standards. For example, Chapter 4 Documentation EU vs PICS: these are essentially aligned but with a few notable differences.

• PIC/S inspectors could participate in industry association technical committees, such as ISPE's Communities of Practice, to assist in the development of Guidance documents for industry.

Innovation

Scientific and technological innovation has accelerated dramatically in recent years with advances in personalised medicines, convergence of health products with digital information and novel manufacturing technologies. Increasingly complex products have the ability to greatly improve patient outcomes but may pose challenges to the current regulatory system as well as create demands for appropriate supports. Inspections may need to be adapted for effective regulation, new tools and approaches developed, and regulators themselves will need upskilling and access to additional expertise.

10. **What do you see as important strategic considerations in how the industry / sectors we inspect will develop over the next 5 to 10 years?**
    (Maximum of 3000 characters)

• Digitization, artificial intelligence, self-learning machines, autonomous decision-making processes
• Digitization: use of data as an aid to process science, data analytics
• Digitization: use of new communication technologies
• Blockchain
• New therapeutic modalities
• Flexible production
• Precision medicines
• Sustainability and carbon dioxide reduction targets will drive introduction of new technologies and change in supply chains for new and existing products. Potential for new government regulation.

11. **What do you see as important strategic considerations of PIC/S in support for innovation?**
    (Maximum of 3000 characters)

• Drive understanding and improved regulatory Quality Control and Quality Assurance Strategies to support paperless documentation, computer-based decision making, computer-controlled batch release. For example, PIC/S may be able to take a lead role in driving principles and approaches

towards a more standardised pharmaceutical quality system implemented in industry and assessed by inspectors (e.g., more standardised approaches to and assessment of CAPA procedures).

• Consider PIC/S supporting a more agile, global clinical trial network, e.g., by using technology to obviate the need for expiry dates on clinical supply containers

• It would be beneficial for PIC/S to keep inspectorates updated on the latest emerging technologies – see above. This could include advanced manufacturing technologies and continuous manufacturing. It is important that inspectors understand these technologies prior to performing an inspection.

• Small and medium SME academic and public organizations play a major part in innovation. It would be beneficial for PIC/S to take a role alongside leading industry members to explore how can this be supported within the remit of the PIC/S mission.

Partnerships and Inspection Reliance

The COVID pandemic has had a very significant impact on PIC/S' and its members.

Adversities come with opportunities and the organisation has adapted to overcome the restrictions by moving to digital platforms for training and meetings and supporting members adapt their inspection processes. PIC/S can make the best possible use of its network in order to share GMP relevant information including the use of each other's inspection reports, when foreign inspections cannot be carried out.

Leveraging the work of other authorities strengthens our systems of reliance and builds a network of trusted experts that can help us regulate more effectively. The future of medicines regulation will be found in functional regulatory networks of agencies, with increasing specialisation and reliance on each other's work, in parallel with decreasing duplicative efforts. More systematically engagement with other international medicines organisations, who benefit from PIC/S' expert feedback, is key to enhancing our participation.

12. **What do you see as important strategic considerations in the PIC/S contribution to the network of competent authorities internationally?** (Maximum of 3000 characters)

• Building trust between members
• Building trust in application of new technologies such as use of digital platforms for assessments and training, for example by considering cultural factors.
• Sharing best practices
• Build knowledge, for example of new and existing Guidances
• Training
• Proactively and deliberately support mutual reliance, e.g., harmonisation where appropriate
• Share data with industry associations on duplicate, same-scope GMP inspections.
• Take meaningful action to reduce duplicative inspections and related data requests.

Public Trust and Confidence

We are living in a time in which public demand for information is increasing and numerous, sometimes unreliable, information sources exist.

Conflicting information and multiple channels of communication can undermine the critical importance of the work we do. Therefore PIC/S, as other actors in the system, must maintain a focus on its own trustworthiness and on demonstrating that to the outside world. This means being transparent around decision-making, communicating via appropriate channels in a timely manner and having robust internal processes.

13. **Patient Impact: What do you see as most important PIC/S activities or deliverables that has had the greatest impact on patients, and why?**
    (Maximum of 3000 characters)

PIC/S member authorities, through their GMP inspection activities, help ensure that patients receive medicines of consistently reliable quality, safety and efficacy.

14. **Industry Impact: What do you see as most important PIC/S activities or deliverables that has had the greatest impact on the industry/sector we regulate, and why?**
    (Maximum of 3000 characters)

During the pandemic there has been significant use of mutual reliance and regulatory flexibilities, according to comments made by regulators at recent ISPE Summits and Conferences. This has been in large part due to PIC/S groundwork. The industry would benefit by PIC/S expanding its role in these areas.

15. **Regulator Impact: What do you see as most important PIC/S activities or deliverables that has had the greatest impact on regulators, and why?**
    (Maximum of 3000 characters)

Activities which build trust leading to increased mutual reliance such as use of:
- Guidance's. PIC/S Guidance documents that help ensure a uniform approach to GMP inspections
- Aide Memoires, which are very useful tool for trainee inspectors
- Training. The training of GMP inspectors to help ensure a consistent approach to GMP inspections

- Sharing best practices
- Build comfort of regulators with digitization and use of digital platforms

For example, using a digital platform to provide a forum for regulators to come together and share perspectives and best practices around inspection methodologies. This has a positive impact of allowing the regulators to become comfortable with the other health authorities. It makes the world a smaller place. It does help regulators to focus on what the greatest challenges are during their inspections (as they are reinforced by other inspectorates in their thinking).

Global Best Practices

16. Are there best practices have you seen elsewhere that you think PIC/S should consider for strategic priorities?
(Maximum of 3000 characters)

Currently PIC/s engages directly with the regulatory agencies, and this is a 'safe haven'. More direct interaction with the professional societies or industry groups might help PIC/S to move more dynamically.

PIC/S frequently supports industry conferences; however, PIC/S could consider methods that would gain faster and more direct input from industry on points of interest.

As an example, PIC/s could look at the best data integrity inspections and model some best practices around such inspections. The data integrity focus of inspections should be a strategic priority. They could look at regulatory actions and find common themes around data integrity. Subsequently, there could be an Expert Circle with some of the inspectors that performed the noteworthy inspections. There also could be a guide built around this.

17. Do you have other feedback for PIC/S to consider in developing a strategic plan?
(Maximum of 3000 characters)

The industry and the patients that it serves would benefit from complementary strategic themes between PIC/S and industry associations. ISPE welcomes the opportunity to engage further in this space.