# 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 |
| [ ]  | [ ]  | [ ]  | [ ]  | [x]  |

# 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.

1. **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?**

[x]  I agree with this understanding

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

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1. **Email Address**

EFPIA and IFPMA

1. **Organisation that you represent**

# 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](https://picscheme.org/en/activites-gmdp-harmonisation)" and "[Publications](https://picscheme.org/en/publications)");
* Training Competent Authorities, in particular GMP Inspectors (see "[Training](https://picscheme.org/en/activites-training)");
* Assessing (and re-assessing) GMP Inspectorates (see "[Accession](https://picscheme.org/en/accessions)" and "[Compliance](https://picscheme.org/en/activites-compliance)");
* Facilitating co-operation and networking for Competent Authorities and International Organisations (see "[International Co-operation](https://picscheme.org/en/about-international-co-operation)")
1. **What do you see as important strategic considerations in relation to the PIC/S mission?** (Maximum of 3000 characters)

Industry supports PIC/S mission to lead the international development, implementation, interpretation and maintenance of harmonised Good Manufacturing Practice (GMP) and related quality systems including for inspectorates in the field of medicinal products.

The following additions may be considered also:

* Facilitate co-operation and networking for Competent Authorities and International Organisations with the goal to facilitate reliance on knowledge gained by member inspectorates (see "[International Co-operation](https://picscheme.org/en/about-international-co-operation)") including for pre-approval inspections, where applicable, and life cycle activities. This can link to ICMRA supporting their goals on ‘[Global Pharmaceutical Quality Knowledge Management by enhancing Regulatory Reliance and Agility](http://www.icmra.info/drupal/strategicinitatives/pqkms/statement)’;
* Support joint inspectorate-industry training (more rounded, holistic approach), developed/executed with industry involvement / engagement where possible;
* Engage with industry (e.g., organising stakeholder forums including industry) on a routine basis covering topics such as new technologies, GMPs/GDPs, reliance, etc. and to help identify potential efficiencies that may be gained amongst PIC/S members;
* Increase the understanding of the PIC/S “joint assessment program qualification” for inspectors as it is equivalent to the EU / WHO requirements in this regard for the purpose to be recognised in 3rd countries;
* Expand PIC/S scope to include devices and drug-device combination products.

# 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.
1. **What do you see as important strategic considerations in relation to the PIC/S vision and values?** (Maximum of 3000 characters)
* Industry supports PIC/S values and proposes its mission is further enhanced as described under item 6.

# Current PIC/S Strategic Roadmap

The [current Roadmap](https://picscheme.org/docview/2473) 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)](https://picscheme.org/en/pia-home) 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
1. **Do you support PIC/S's continued prioritisation of these priorities?**

[x]  Yes

[ ]  No

[x] Other

1. **If you selected other, can you tell us why?**

(Maximum of 3000 characters)

* Industry supports the above especially to strengthen PIC/S' governance and resources, and to review and assess PIC/S' outputs. In that respect, we recommend prioritising the assessment and communication of PIC/S outputs, including e.g. in the field of reliance.
* An additional priority is to ensure inspectorates continuous understanding of evolving manufacturing solutions (e.g., [agile manufacturing](file:///C%3A%5CUsers%5Csroennin%5CDocuments%5CMust%20backup%5C_SR%5C_SR%20EFPIA%5C_MQEG%20GMP%20Sub%20team%5C2107%20PICS%20stakeholder%20consultation%20for%20PICS%202022-2026%20Strategic%20Plan%5CMQEG%20RP%20Mobile%20Manufacturing_Final23Mar2021%20%28efpia.eu%29), [digitalisation](file:///C%3A%5CUsers%5Csroennin%5CDocuments%5CMust%20backup%5C_SR%5C_SR%20EFPIA%5C_MQEG%20GMP%20Sub%20team%5C2107%20PICS%20stakeholder%20consultation%20for%20PICS%202022-2026%20Strategic%20Plan%5CEFPIA%20MQEG%20Digitalization%20Discussion%20Paper), Annex 1), including through e.g., organising a joint inspectors / industry workshop at least annually.

# 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.

1. **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)
* Reflect the trend towards more diverse type of modalities, e.g., personalised medicines, ATMPs, and evolving technologies towards more agile, mobile and point of care manufacturing, while maintaining ability to rely on each other’s inspections and promoting the relevance of current GMP requirements;
* Drive the use of reliance on local inspections performed by their members for both Pre-Approval Inspections, where applicable, and routine inspections;
* Facilitate the understanding of all inspection tools including for virtual inspection and how they can work effectively together.
1. **What do you see as important strategic considerations of PIC/S in support for innovation?** (Maximum of 3000 characters)
* Demonstrate that innovative technologies do not need a complete new set of GMPs, but can be covered by appropriate interpretation and enhancement of current requirements rather than detailed requirements and tools;
* Engage PIC/S participating authorities to continue support for the principles outlined in the PIC/S Recommendation Paper on “*How to Evaluate/Demonstrate the Effectiveness of a Pharmaceutical Quality System in relation to Risk-based Change Management*” to encourage industry and reviewers to respectively apply and recognise science and risk-based strategies to manage post approval changes within a mature/effective PQS.

# 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.

1. **What do you see as important strategic considerations in the PIC/S contribution to the network of competent authorities internationally?** (Maximum of 3000 characters)
* PIC/S plays a key role in developing and issuing harmonised standards for inspectorates and industry;
* We further recommend that PIC/S strengthens its interaction with existing bodies like ICMRA, ICH, WHO-ICDRA, and APEC-Regulatory Harmonisation Steering Committee as we understand the management level of regulators within these organizations can decide on implementing PIC/S; recommendations within their local agencies. These interactions are critical for driving an effective communication between assessors and inspectors, which is key to successfully facilitate regulatory oversight of product lifecycle management;
* In accordance with WHO Good Reliance Practices, Reliance can be applied in various regulatory procedures incl. Import testing, thus PIC/S should continue its efforts to ensure that reliance is anchored in National Regulatory Authorities (NRA) strategies;
* PIC/S can demonstrate with practical examples that inspection reliance and use of virtual tools can ensure continuous oversight of the manufacturing sites, while preserving patients’ safety, these will contribute to preparedness for future pandemics.

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# 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.

1. **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)
* To maintain global distribution models and ensure a consistent supply of medicines to patients, PIC/S should continue to promote the use of reliance including the acceptance of test results (incl. registration testing, import testing) by national control laboratories or companies, if applicable.
1. **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)
* PIC/S implementation and maintenance of GMP Standards, can support reliance on domestic inspections and therefore decrease the number of redundant inspections of a same facility overseas. This will ensure resources are better distributed across all manufacturing sites globally. Reliance may be further driven through developing a common planning tool to manage inspections globally;
* Sharing of inspection findings and outcomes to allow reduced on-site presence by other regulators to drive harmonization across the globe, subjected to confidentiality agreements;
* We value the PIC/S Inspectorates’ Academy (PIA) to foster harmonisation among member inspectorates. Industry is open to support that with SMEs upon request.
1. **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)
* Exchange illustrative cases of compliance with legal requirements through implementing alternative approaches;
* Facilitate mutual understanding between inspectors and assessors on the risk based approach to inspections, e.g., a site is capable to manufacture a new product / implement a variation with the goal to speed regulatory product approvals, when there is a very limited or no risk for patients due to the new/additional operation.

# Global Best Practices

1. **Are there best practices have you seen elsewhere that you think PIC/S should consider for strategic priorities?**(Maximum of 3000 characters)
* There is complementary work done in APEC on Good Reliance Practices;
* We see an opportunity to increase collaboration by exchanging best practices on related disciplines such as GCP and GPvP inspections;
* We encourage a more collaborative approach with industry to promote sharing of best practices and learnings across the pharmaceutical industry.
1. **Do you have other feedback for PIC/S to consider in developing a strategic plan?**(Maximum of 3000 characters)
* Provide a platform, to facilitate the knowledge interface between inspectors on GMP/GDP requirements/realisation and reviewers to understand the capability of a manufacturing site and role of the PQS in the management of products life cycle;
* Make available to the Industry relevant training material from PIC/S if considered to be helpful, to enhance industry’s understanding of regulators’ thinking and expectations;
* Share experience on virtual inspections (remote / distant assessment) and combination of inspections tools incl. reliance;
* Encourage PIC/S to routinely share documents directly with industry for comments;
* Facilitate reliance and acceptance of test results by industry or governmental laboratories to enable global distribution models ensuring a consistent supply of medicines to patients;
* Consider PIC/S future role in public health emergencies.