2023-2027 Strategic Plan

PHARMACEUTICAL INSPECTION CONVENTION

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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

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PS/W 15/2022
Annex
28 September 2022

2023-2027
Strategic Plan

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970 (see Annex). PIC/S is a legally non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. On 31 December 2021, PIC/S comprised 54 Participating Authorities (PAs) from all continents.

PIC/S strives to improve public health by leading development and implementation of inspection frameworks for human and veterinary medicines through harmonisation of standards and offering world class training to regulatory inspectors around the globe. This is achieved by harmonising inspection procedures worldwide, by developing common standards in the field of GMP, by providing training opportunities to inspectors and by facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing confidence, inspection reliance and avoiding duplication of efforts as well as wasting of resources.

A Committee of the Participating Authority representatives (the PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by (i) various Sub-Committees; (ii) an Executive Bureau, which steers the Organisation in-between meetings; and (iii) a Secretariat, which supports PIC/S bodies in their duties.

This is the PIC/S 2023-2027 Strategic Plan.

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Vision

Our vision is to enable one inspection per site that is fit for all regulatory authorities in the benefit of public health.

Mission

PIC/S will strive to improve public health by leading development and implementation of inspection frameworks for human and veterinary medicines through harmonisation of standards and offering world class training to regulatory inspectors around the globe.

1. Executive summary

In 2021, PIC/S achieved an operational milestone with 50 years since the 1971 coming into force of the Pharmaceutical Inspection Convention (PIC) of 1970. During this period, many achievements have been reached including establishment of the Pharmaceutical Inspection Co-operation Scheme on 2 November 1995. PIC and the PIC Scheme, which operate together in parallel, are jointly referred to as PIC/S. This strategic plan is intended to provide a foundation for the five years (2023-2027) ending December 31, 2027 following celebration of the 50th anniversary milestone on October 4, 2022.

The strategic plan was developed with careful consideration to valued feedback from a 2021 consultation involving:

- PIC/S participating authority heads of agencies
- PIC/S partner organisations
- PIC/S sub-committees
- key industry associations
- other related non-governmental organisations
- inspectors around the world

The resulting strategic priorities are outlined in Figure 1.

Figure 1: PIC/S 2023-2027 Strategic Priorities

This strategic plan is a non-binding policy paper highlighting the possible future strategic orientations of PIC/S over the next five years. Subject to the consent of all Participating Authorities, the strategic objectives and goals will have to be

implemented through measures, which will be discussed and – if agreed upon – unanimously endorsed by Members of the PIC/S Committee. A business case (project plan) must be presented for any measure, which requires additional human or financial resources in order to be implemented, whether from Participating Authorities or from the PIC/S Secretariat.

The Committee is the highest decision-making body in PIC/S where all Participating Authorities are represented.

These strategic goals and objectives have been agreed by consensus. Nothing in this strategic plan should be understood as having a binding effect or constituting an obligation for any Participating Authority.

This strategic plan does not intend to deviate from or replace the PIC Scheme, which is PIC/S constitution and those amendment requires the unanimous consent of all Participating Authorities.

2. Inspection reliance

Over the next 5 years, the efforts and successes of PIC/S and the PIC/S Working Group on Inspection Reliance will be paramount to deliver on strategic priorities related to inspection reliance (e.g. mutual reliance):

1. **Promote** greater use of the PIC/S inspection reliance initiative among PIC/S Participating Authorities
2. **Provide** a forum to continuously monitor and improve upon the implementation of inspection reliance

PIC/S and other international partners have long recognized the importance of inspection reliance to regulatory authorities, pharmaceutical industry, and patients. With the complexity of global supply chains, the demand for inspecting pharmaceutical manufacturing facilities far exceeds what any one regulatory authority can accomplish and a framework is required to assist regulators in managing product quality risks posed by the increasingly complex pharmaceutical global supply chains. Additionally,

added regulatory burdens are realized by pharmaceutical manufacturing sites that supply the globe in the hosting of inspections from multiple regulatory authorities. Tools, which enable increased inspection reliance, offer opportunities to better allocate resources, expedite access to medicinal products, and reduce costs all to the benefit of patients around the world.

PIC/S was identified as a preferred forum to promote, implement, and monitor a guide, drafted by the International Coalition of Medicines Regulatory Authorities (ICMRA), which provides a GMP inspection reliance framework. In 2018 this guide was adopted as the PIC/S Guidance on GMP Inspection Reliance (PI 048) and monitoring of the implementation began. It has since been realized that work is needed to facilitate increased inspection reliance to promote benefits and help reduce barriers that exist in enabling reliance.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, PIC/S Sub-committees (Compliance, Strategic Development, Training, Harmonisation of GM(D)P, Budget, Communication, and Expert Circles) and the many PIC/S working groups — in particular the PIC/S Working Group on Inspection Reliance — will be essential to ensure that PIC/S can succeed in its goals to improve inspection reliance. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

2.1 Overview of Goals and Objectives

Goal	Objectives
Promote greater use of reliance initiatives among PIC/S Participating Authorities.	➢ enable well rounded understanding of the barriers that impact in the implementation of inspection reliance ➢ provide solutions to encourage broader implementation of inspection reliance
Provide a forum to continuously monitor and improve upon the implementation of inspection reliance.	➢ enable monitoring and continuous improvement in the implementation of inspection reliance ➢ support greater communication and information sharing among PIC/S Participating Authorities

3. Preferred forum for GxP harmonisation

Over the last 50 years, PIC/S has established itself to be a preferred forum for harmonisation of GMP among global regulatory authorities. It has also enabled opportunities for them to come together in other GxP inspection activities including Good Distribution Practices (GDP), Good Vigilance Practices (GVP) and Good Clinical Practices (GCP). GDP activities are already well established within the PIC/S framework and continue through the PIC/S Expert Circle on GDP. Additionally, a GVP and GCP Working Group has been active in bringing GVP and GCP inspectors together in various approaches including Joint Visits Programs. In 2022 this working group was restructured into two separate PIC/S Expert Circles on GCP and GVP to support training of GCP and GVP inspectors.

Over the next 5 years, subject to the availability of additional human resources, PIC/S will be committed to support training and encourage expansion of its offering in GxP elements. In doing so, PIC/S will prioritize resources to core GM(D)P elements while welcoming PIC/S Participating Authorities to take leadership roles in supporting PIC/S's development of other GxP priorities.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, PIC/S Sub-committees (in particular sub-committees on Compliance, Strategic Development, Training, Harmonisation of GM(D)P, and Expert Circles) along with the many PIC/S working groups will be essential to ensure that PIC/S can succeed in its goals to improve inspection reliance in these other fields. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

3.1 Overview of Goals and Objectives

Goal	Objectives
Fortify PIC/S as the leading international forum for development,	➢ ensure PIC/S continues with the successes in leading the international development, implementation and maintenance of

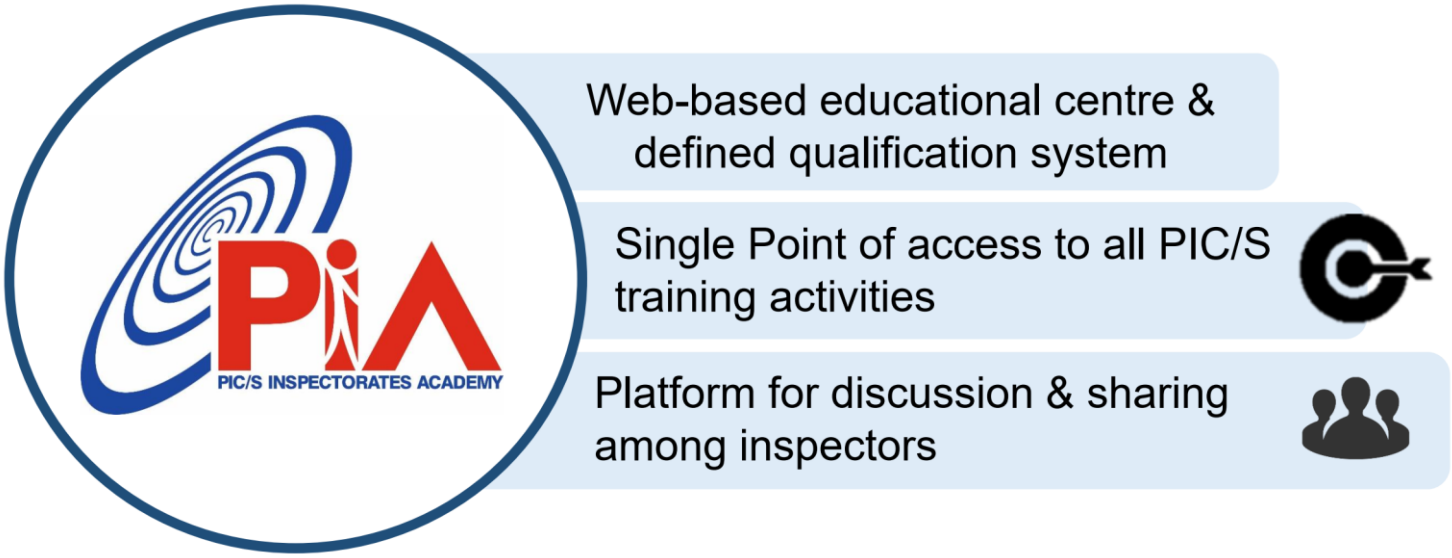
implementation, and maintenance of harmonised GxP standards for human and veterinary medicine.	harmonised Good Manufacturing Practice (GMP) standards ➢ enable PIC/S to remain the preferred forum to continue opportunities for expansion in leading international development, implementation, and maintenance of other GxP standards for good distribution practices, good clinical practices, and good vigilance practices ➢ monitor new technologies and trends in scientific advancements to ensure GxP standards remain relevant and current ➢ liaising with other international organisations in the development, implementation, and maintenance of harmonised GxP standards
Empower PIC/S to lead international development, implementation, and maintenance of quality systems of inspectorates and inspection best practices.	➢ seek continuous improvement opportunities for the conduct of harmonised approaches to GxP inspection practices ➢ implement opportunities and learnings experienced in managing inspections through the COVID-19 pandemic to deliver upon GxP inspection excellence ➢ advance harmonisation and adoption of a common inspection report format template that can enable machine learning opportunities and international co-operation in the development of a pharmaceutical quality knowledge management system (PQ KMS) ➢ advance globally harmonized approaches for the unique identification of facilities engaged in GxP activities to support international co-operation in the development of a pharmaceutical quality knowledge management system (PQ KMS)
Establish best in class networking and co-operation opportunities on GxP harmonisation priorities.	➢ enable new technologies to support international co-operation in development of GxP standards and inspection best practices ➢ improve co-operation and engagement of PIC/S Participating Authorities in development of GxP standards and inspection best practices ➢ assess and evaluate GxP priorities and advancing with due consideration to available resourcing

4. Centre of excellence in training of regulatory inspectors

With the PIC/S 50th anniversary milestone, PIC/S can reflect upon and celebrate the decades of success it has in training of inspectors. Training is one of the key fundamental elements that PIC/S is focusing upon to support other strategic priorities. PIC/S also recognizes the importance well trained inspectors can have to help build confidence in the GxP inspections conducted by international partners and how this influences and underpins inspection reliance. To this end, PIC/S aims to continue advancing its success in training the global GxP inspection community with the long-term goal to succeed in advancing improved inspection reliance.

Today, PIC/S recognizes the rapidly evolving world where people work and learn in new ways through advancements in digital technologies. As the world transitions in stages of the COVID-19 pandemic, PIC/S will seek to provide optimal approaches to enable inspector training building upon new training approaches implemented during the pandemic.

PIC/S has long realized the importance of investing in new training initiatives. The PIC/S Inspectorates Academy (PIA) was established long before the pandemic at the Paris 2014 PIC/S Committee meeting. The vision of the PIA is to be an online learning management system (LMS) for global GMP inspectors. The ultimate goal is to harmonise and standardise GMP training at an international level through a recognised qualification system. Such a system should ensure that inspectors apply GMP consistently so that high quality standards for medicinal products are met worldwide in the interest of public health.



In the next five years, PIC/S will continue to actively seek PIA funding to advance the project. The project is now in a 2nd of a three-stage development plan with focus on:

- identification of training needs
- development of e-learning modules
- development of a recognition and certification process

The PIC/S Secretariat's resource allocation for development of the PIA over the next five years will prioritize GM(D)P inspector training. PIC/S will, however, maintain a vision to the future ensuring that the platform design can incorporate future training modules for other GxP inspection activities. At any time during this plan's lifecycle, PIC/S will enable PIA to be leveraged by any PIC/S Participating Authorities that may wish to lead a PIC/S working group in development and resourcing of any GxP PIA training module where Secretariat resource impacts are minimized.

PIA in combination with other PIC/S trainings through Annual Seminars, Expert Circles, and other training events will help PIC/S ensure it continues having a leading global role in the training of GxP inspectors.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, PIC/S Sub-committees (in particular Training, Expert Circles, Budget, Harmonisation of GM(D)P, and Compliance) along with the many PIC/S working groups will be essential to ensure that PIC/S can succeed in its goals to be a centre of excellence in training of regulatory inspectors. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

4.1 Overview of Goals and Objectives

Goal	Objectives
Revolutionize approaches for globally harmonised inspector training and qualification through PIC/S' Inspectorates Academy (PIA) - critical for allowing and maintaining "inspection reliance".	➢ provide a global forum for harmonized training and qualification of GxP inspectors that enables development of all GxP inspectors including those of Competent Authorities in developing countries and partner organisations ➢ develop, implement, and enable curricula defining harmonised minimum requirements and e-learning modules, forum and other tools and resources to succeed in the implementation of PIA ➢ transform traditional PIC/S training approaches to best integrate new technologies and approaches applied through the COVID-19 pandemic ➢ develop and assess metrics to measure and improve PIC/S trainings
Promote continued opportunities within PIC/S to enhancing learning opportunities in GxP inspection.	➢ enhance the participation in the PIC/S joint visits program (e.g. by opening scope to all GxP fields) to enable agencies to learn best practices and review inspection approaches ➢ re-energize and strengthen networking, co-operation, and learning opportunities through PIC/S expert circles and working groups
Facilitate the development and training of auditors that can support inspection reliance in assessing Inspectorates.	➢ establish a pool of qualified auditors to enable the assessment of PIC/S applicants and re-assessment of PIC/S Participating Authorities
Collaborate in training with global partners.	➢ identify new opportunities for co-operation with key partners in the delivery of training on GxP priorities (including engaging with industry representative bodies e.g. in joint events against a fee or financial return)

5. Preparing inspectorates for the future

This is a very important time for people around the world to recognize and respond to the many crises that lie ahead including:

- global climate change
- antimicrobial resistance
- emerging viral outbreaks
- complexity of global supply chains in an unstable world

Within the field of GxPs for medicinal products PIC/S knows that it is ever more important to ensure that regulations are designed in consideration to sustainability. Additionally, PIC/S will work to promote approaches, which enable PIC/S Participating Authorities to operate in manners that reflect sustainability with an objective to minimize climate change impacts.

There are also other crises that humanity is facing in relation to antimicrobial resistance where PIC/S knows that Participating Authorities can play an important role while inspecting medicinal product manufacturers or through data analytics on the global medicinal product supply chain.

As we learn lessons from the COVID-19 pandemic, PIC/S will be working toward a focus on the future where advanced manufacturing techniques and new approach to biotechnology can help enable responding to future viral outbreak while also helping usher in new more effective treatments for many other diseases.

Today the world is experiencing geopolitical events that were previously unthinkable. These events require us to reflect on sensitivities that exist in global relations and what might develop in the next five years and beyond. PIC/S knows that it will be ever more important in the coming years for regulatory authorities to continue to maintain good dialogue, build relations, and co-operate in preparing to respond to global supply chains where geopolitical events unfold.

The science around us is evolving at a rapid pace that will help address climate change and advance new technologies in the manufacture of medicinal products. This will

require GxP regulatory frameworks and inspectors to keep pace with PIC/S leading the path forward. This is important to ensure that regulatory frameworks help promote scientific advancements and avoid becoming impediments. At the same time, it will be important for inspectors to maintain skillsets to prepare them in the inspection of manufacturing processes that embrace these scientific advancements.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, PIC/S Sub-committees (Compliance, Strategic Development, Training, Harmonisation of GM(D)P, Budget, Communication, and Expert Circles) and the many PIC/S working groups will be essential to ensure that PIC/S can succeed in preparing inspectorate for the future. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

5.1 Overview of Goals and Objectives

Goal	Objectives
Establish opportunities for GxP regulation of medicinal products to integrate with other global priorities.	➢ seek opportunities for GxP regulatory frameworks to address sustainability and respond to climate change (2016 Paris Agreement) ➢ seek opportunities for GxP regulatory frameworks to support responding to antimicrobial resistance (June 2021 UK G7 priority) ➢ seek opportunities that facilitate dialogue on global supply chain security
Invest in and Encourage opportunities for implementation of new technologies that support inspection reliance.	➢ collaborate with partners to implement a pharmaceutical quality knowledge management system, which can support machine learning and artificial intelligence that includes GMP compliance information ➢ seek opportunities to enable secured sharing of information and enabling security of information
Ensure that GxP standard guidance is not an obstacle to the development of new technologies providing new possibilities of treatment to patients.	➢ lead and harmonise the development of GMP requirements & guidance documents on new technologies / novel approaches ➢ monitor and respond to developments in emerging fields such as ATMP, biotechnology, and artificial intelligence

Equip inspectors with the skills, training and relevant tools to inspect and assess new technologies.	➢ provide continuous training programmes on new technologies, notably through PIA
Adapt the means to determine compliance with innovation & technological development.	➢ facilitate the use of hybrid and remote inspections and the development of related best practices ➢ seek opportunities for possibility of PIC/S Participating Authorities to participate remotely to on-site inspections of others

6. Partnership and stakeholder co-operation

PIC/S has succeeded in that last 50 years through active co-operation with strategic partners. Over the next five years, PIC/S will work to continue this successful practice by:

- seeking opportunities to better engage with other international organisations
- attracting PIC/S membership applications and pre-applications from non-member inspectorates
- strengthening PIC/S communications and engagement

There are many avenues that PIC/S can consider in partnership and stakeholder co-operation. This is the case of PIC/S partner organisations with which PIC/S has established a strong co-operation under memoranda of understanding and confidentiality agreements, including:

- European Commission (EC)
- European Directorate for the Quality of Medicines & HealthCare (EDQM),

- European Medicines Agency (EMA),
- World Organisation for Animal Health (OIE),
- United Nations International Children's Emergency Fund (UNICEF), and
- World Health Organization (WHO).

Additionally, there are other partners with strong regulatory memberships such as International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or International Coalition of Medicines Regulatory Authorities (ICMRA), where PIC/S is well positioned to engage in co-operation on activities related to GxP inspections. The forum that PIC/S provides in GxP inspection roles is one that can be leveraged by international bodies such as these in the benefit of public health.

PIC/S also recognizes the importance of industry associations and non-regulatory bodies. This enables leading international experts to share positions, scientific information, and other ideas for the consideration of regulatory partners in developing PIC/S GMP guides and other science-based PIC/S documents. It is engagements such as these that enable affirmation of good practices and enables consideration toward alternative positions that help us advance in continued improvements in regulatory frameworks.

PIC/S knows that there is also much more work to do in advancing GxP related initiatives globally to better support public health. To this end, the importance to continually advance PIC/S' global membership and outreach can extend tremendous benefit to public health by furthering local GxP inspection oversight that will enable better quality medicinal products.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, all PIC/S Sub-committees (Communication, Compliance, Harmonisation of GM(D)P, Strategic Development, Training, Budget, and Expert Circles) along with the many PIC/S working groups will be essential to ensure that PIC/S can succeed in its goals to address aspects related to partnerships and stakeholder co-operation. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

6.1 Overview of Goals and Objectives

Goal	Objectives
Seek opportunities to better engage with other international organisations.	➢ strengthen international co-operation and encourage team work between organisations ➢ increase the engagement of PIC/S Participating Authorities and Partners in opportunities for co-operation (including PIA) ➢ advance relationships and co-operation with other key international organisations

	➢ evaluate and implement opportunities for increased engagement on key priorities including reliance ➢ ensure PIC/S representatives have the ability to identify issues and position in the regulatory network to take the lead on relevant topics
Enlarge PIC/S membership.	➢ work toward bringing all global Competent Authorities within the PIC/S Community ➢ invite discussion and opportunities for submission of PIC/S membership and pre-accession applications
Strengthen PIC/S communications and engagement.	➢ seek new opportunities for communication strategies and engagement through social media and the PIC/S website ➢ determine if a WG on international co-operation is required

7. PIC/S operational capacity

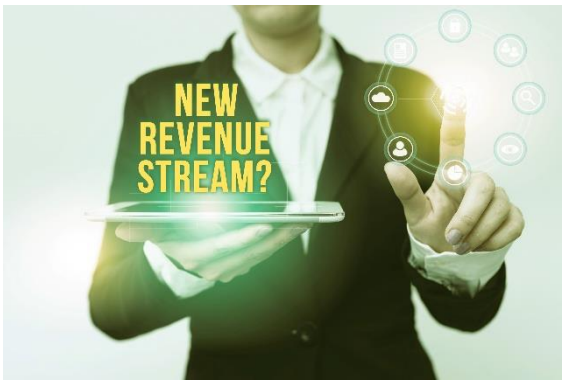
The operational capacity of PIC/S is key to the successful implementation of this strategic plan. During the period of this strategic plan the following goals will be a key priority:

1. **Secure** new revenue streams to advance operational excellence
2. **Build** operational capacity with the PIC/S Secretariat
3. **Implement** fiscally sound and sustainable financial plans
4. **Increase** transparency to PIC/S community, including through new communication & information channels as well as adequate

tools to support the management of PIC/S increasing portfolio of projects

The PIC/S Secretariat is not only essential to support PIC/S in all its activities; it is also the "memory" of PIC/S and the only body, which has an historical overview on past activities. The success of PIC/S and implementation of this strategic plan lie with a strong and effective PIC/S Secretariat, which can only be achieved through improved resourcing.

This strategic plan highlights opportunities for the growth and development of PIC/S over the next five years. This will ensure solid funding bases are established to support PIC/S operational priorities.



During this period and subject to the availability of additional human resources, PIC/S will prioritize exploring and securing of new long term revenue streams through co-operations within the PIC/S Sub-committee on Budget and PIC/S Working Group on Third Party Funding. Enabling the success of these teams will realize opportunities for PIC/S to obtaining revenue streams through varied avenues such as:

- ongoing review of membership fee structure
- evaluation of third-party funding sources
- exploration of new funding models such as developing small or modular projects/deliverables that can be used to target directed contract opportunities among PIC/S Participating Authorities or in part with third party funding

When assessed against other comparable organisations, the PIC/S Secretariat is a small agile team. Over the decades, the PIC/S Secretariat has had a notable increase in the number of activities for which it prepares or implements. This is as a result of the new operational structure and outcome of the PIC/S Heads of Agencies' survey on "future projects", in particular the PIC/S Inspectorates' Academy (PIA). This in turn has led to a

considerable increase of the workload while the number of staff units has remained relatively stable over past periods. To maintain the current level of activities, there is an urgent need to increase the Secretariat's capacity. Additionally, many of the strategic goals and objectives outline in this strategic plan can only be successful with a PIC/S Secretariat that is sufficiently resourced.

As PIC/S implements and advances this strategic plan, it will be essential to plan, manage and increase the resourcing capacity within the PIC/S Secretariat in line with available funding and project needs. This strategic plan is intended to highlight the needs for the PIC/S Secretary, Deputy Secretary, and PIC/S Executive Bureau to advance operational excellence in building capacity within the PIC/S Secretariat by:

- implementation of effective organisational and management structures
- establishing solid expectations in distribution of roles and responsibilities
- recruiting new staff to support new projects throughout the duration of the strategic plan (and beyond)

Resourcing considerations for the Secretariat are forecasted to include:

- managing new projects
- fundraising (contacting potential donors and donor organisations, submitting projects to be funded, reporting back to donors, etc.)
- communication & web site design (managing the external communication of PIC/S, in particular updating the website, issuing press releases, newsletters, etc.)

As PIC/S advances this strategic plan over the next five years, steady growth in PIC/S' revenue streams is anticipated to support key projects, which will enable better serving the needs PIC/S Inspectorates. This will elevate the need for PIC/S to effectively:

- demonstrate stewardship of resources and accountability
- manage financial risks
- promote long term financial sustainability throughout project lifecycles

To this end, and subject to available human resources, PIC/S commits to implement fiscally sound financial project plans that will enable the long-term sustainability and development of PIC/S. Subject to available human resources, PIC/S will also work to continuously improve processes and services to help advance excellence in management. Careful attention to long term sustainability will be applied to all projects with long term lifecycles.

PIC/S reaffirms its commitment to principles of transparency and accountability on finances and budget which will become ever more important as PIC/S considers third party funding. PIC/S plays a significant role in establishing globally harmonised GxP

standards and inspection frameworks. The success of PIC/S in implementing these standards and frameworks has in part been through effective values and ethics that have maintained PIC/S as an independent body free from undue influence from the pharma industry.

The Organisation for Economic Co-operation and Development (OECD) has highlighted the importance of protecting independence against perceptions of undue influence as an important aspect in the governance of regulators. As such PIC/S remains committed to ensuring its future development in line with PIC/S' well recognized international standing to operate with independence.

Additionally, with new project management tools, PIC/S believes that it will be better positioned to demonstrate that project funding sources have been well managed, ensure strong and tangible added-value, and enhance the opportunity to engage with partners in future project funding initiatives.

Co-operative efforts of the PIC/S Committee, PIC/S Executive Bureau, PIC/S Sub-committees (in particular Budget, Communication, and Training), and PIC/S Secretariat will be important to define and implement the tools to establish increased project management efficiency to strengthen capacity within PIC/S, its activities and projects. Corresponding action will be undertaken to address implementation of these goals in consideration to capacity and resourcing.

7.1 Overview of Goals and Objectives

Goal	Objectives
Secure new revenue streams to enable operational excellence.	➢ ensure solid funding bases are established to support PIC/S operational priorities
Implement fiscally sound and sustainable financial plans.	➢ enable short and long term success in building operational capacity and delivering on PIC/S operational priorities
Build operational capacity with the PIC/S Secretariat.	➢ enable capacity in the resourcing for PIC/S to deliver on operational priorities ➢ establish clear and transparent organisational structure and management systems and related tools for the Secretariat
Increase transparency to the PIC/S community.	➢ define and implement tools to establish increased transparency, including financial transparency

8. Summary

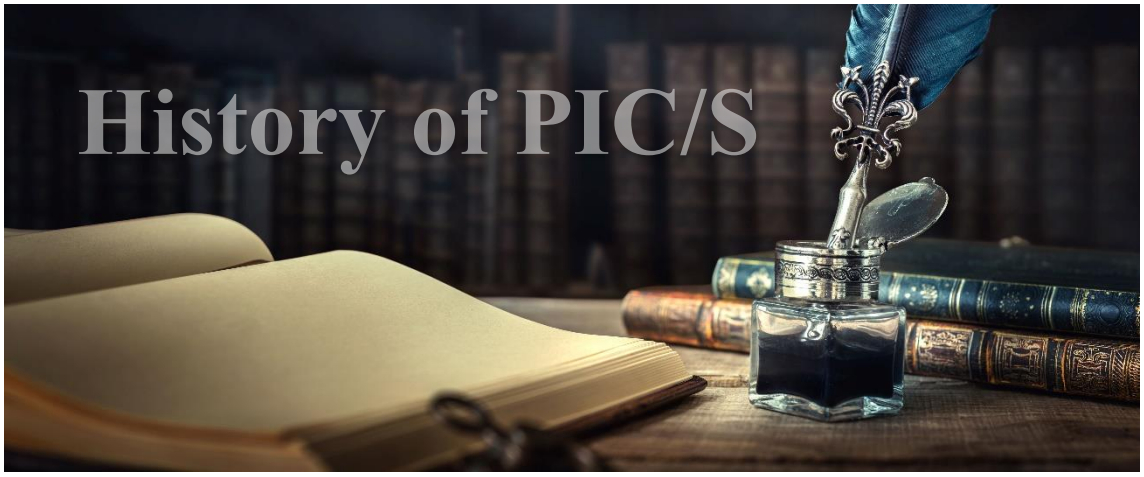
Over the last 50 years PIC/S has been a model of success in contributing to safe, effective and quality medicinal products around the world through harmonized GMP standards and inspections. The next 5 years will realize new and significant contributions as we prepare PIC/S for the next fifty years.

Over the next five years, the PIC/S Secretariat, Executive Bureau, Committee, Sub-Committees, Working Groups, and Expert Circles will apply this strategic plan as a framework to implementing action through annual work plans and other initiatives, which will contribute to the continued success of PIC/S.

All these parties within PIC/S along with other interested parties and partners will need to continue in the spirit of co-operation in order for us to excel in the achieving this PIC/S strategic plan that focuses on:

- inspection reliance
- preferred forum for GxP harmonisation
- centre of excellence for training and qualifying Regulatory Inspectorates for inspections as well as for auditing new applicants and PIC/S PA
- preparing inspectorates for the future
- partnership and stakeholder co-operation
- PIC/S operational capacity

This focus will enable PIC/S to continue with the successes realized from its long-standing history and position PIC/S to excel into the future.



9. Annex – History of PIC/S

PIC/S was established in 1995 as an extension to PIC (Pharmaceutical Inspection Convention), which was founded in October 1970 by EFTA (European Free Trade Association) under the title of "The Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products".

The initial Members of PIC comprised the 10 Member countries of EFTA at that time (i.e. Austria, Denmark, Finland, Iceland, Liechtenstein, Norway, Portugal, Sweden, Switzerland and United Kingdom). Membership of PIC was subsequently expanded to include Hungary, Ireland, Romania, Germany, Italy, Belgium, France and Australia.

When the Maastricht Treaty came into force and established the European Union an incompatibility between the Convention and European law was identified. It was no longer possible for EU member states to sign the Convention and thereby become members of PIC. Consequently, the PIC Scheme was formed on 2 November 1995. PIC and the PIC Scheme operate together in parallel and are jointly referred to as PIC/S.

The original goals of PIC were:

- mutual recognition of inspections
- harmonisation of GMP requirements
- uniform inspection systems
- training of Inspectors
- exchange of information
- mutual confidence

These goals have also been adopted by the PIC Scheme as revised in 2019 and expanded to include additional goals. The PIC Convention, dated October 1970, is available on the PIC/S website.