The Pharmaceutical Inspection Co-operation Scheme (PIC/S) Inspectorates' Academy

Inspection Excellence Through Harmonised Training

https://www.picscheme.org/en/pia-home

A Global Capacity Building and Training Initiative developed by PIC/S Participating Authorities aiming at delivering inspection excellence through harmonized training in the field of Good Manufacturing Practices (GMP) to ensure that high quality standards for medicinal products are met worldwide in the interest of public health.

- Training to improve inspection expertise in the manufacturing of medicines and of their distribution
- for regulators by regulators, developed on the basis of PIC/S recognised GMP training experience and expertise since 1971
- supported by more than 50 PIC/S Participating Authorities from all continents
- for approx. 2,000 inspectors worldwide
- offering currently more than 500 training materials and 250 training videos
- Webinars, on-line learning tools, forum in development
- Library of relevant GMP references
- Much more…

Who are PIC/S Members

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding co-operative arrangement between Medicines 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. PIC/S presently comprises more than **50 Participating Authorities** (Members) coming from all over the world.

> For more information on PIC/S Members: https://www.picscheme.org/en/members

In addition to its Members and (Pre-) Applicant Authorities, PIC/S has associate partnerships with the European Directorate for the Quality of Medicines & HealthCare (**EDQM**), the European Medicines Agency (**EMA**), the United Nations International Children's Emergency Fund (**UNICEF**) and the World Health Organization (**WHO**).

Since its establishment in 1971, the Pharmaceutical Inspection Convention (PIC), extended in 1995 by the Pharmaceutical Inspection Cooperation Scheme (PIC/S), has become a global leader in helping to ensure the quality of medicines for human or veterinary use. It aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

This is reflected in PIC/S' mission which is
to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.

The importance, role and impact of PIC/S has grown significantly in the last few years against the backdrop of globalization. PIC/S role is recognised not only by its Members and Associated Partners but also by a number of international organisations such as the Organisation for Economic Co-operation and Development (**OECD**), the Heads of EEA Medicines Agencies (**HMA**), the European Commission (**EC**), the International Coalition of Medicines Regulatory Authorities (**ICMRA**), among others.

PIC/S is organised as a not-for-profit association under Swiss law, based in Geneva (Switzerland).

> For more information on PIC/S: https://www.picscheme.org/en/about

What is GMP

GMP is defined as follows in the PIC/S GMP Guide: “Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification.”

Put in other words: GMP ensures that the production of medicines meets the required quality standards.

Why is GMP training by PIC/S so important

In order to ensure that in the interest of public health medicinal products are produced according to internationally recognised quality standards, GMP requirements need to be harmonised and implemented worldwide.

PIC/S plays a key role in issuing harmonised GMP guidance documents as well as harmonising GMP requirements through its PIC/S GMP Guide. More than 50 Medicines Regulatory Authorities around the world use the PIC/S GMP Guide or a guide which is equivalent. PIC/S has developed a number of guidance documents related in the field of GMP.

> For more information on the PIC/S GMP Guide and other publications: https://www.picscheme.org/en/publications?tri=gmp

Harmonising GMP requirements through the PIC/S GMP Guide ensures uniform interpretation and application of GMP. However, focused training of GMP Inspectors is essential to achieve this goal since inspectors are responsible for the assessment of compliance of manufacturers with GMP. PIC/S current Participating Authorities and Partners together have approx. 2,000 inspectors. Thousands of GMP inspections are carried out each year by PIC/S Members, domestically and internationally.

For this reason, training of GMP Inspectors is a key priority and activity of PIC/S. Recently, the PIC/S training tools, available to Inspectors, have been expanded and activated in areas such as Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP). GDP aims at ensuring control of distribution chains and consequently maintaining the quality and the integrity of medicinal products. GCP is a quality standard for clinical trials which serves to protect the safety and rights of trial subjects and the integrity of the data, whereas GPvP is the monitoring of pharmacovigilance, which aims to ensure that the benefit-risk of medicines remains acceptable.

The training of GMP Inspectors has been one of PIC/S’ main focal points since its very beginning in 1971. The training of inspectors ensures that the qualification of inspectors and the quality of their inspections will be based on common standards. PIC/S is able to achieve its mission through this emphasis on training, which will continue to be developed, strengthened and expanded in order to respond to training needs globally, through its Academy.

What is the PIC/S Inspectorates' Academy

The PIC/S Inspectorates' Academy (PIA) is a PIC/S Training Initiative to set up a web-based educational centre under the PIC/S umbrella which aims at harmonising and standardising GMP training at an international level through a recognised qualification system. PIA delivers not only general or advanced training but also serves as a platform for discussion and sharing among regulators. It offers a single point of access to all PIC/S training activities and is in the course of being implemented in various stages.

Efforts to harmonise, improve and strengthen regulatory capabilities through training are of paramount importance, in particular the possibility to provide a pragmatic approach to "calibrate" GMP inspectors and to uphold consistency in the interpretation of GMP, the classification of GMP deficiencies, inspection methodology, inspection skills and inspectors' qualification. Training also allows inspectors to keep abreast of the most recent best practices and standards as well as improve these. PIC/S training often results in the development or revision of existing GMP guidance.

What are the key features and benefits of the Academy

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 Academy. These include:

PIC/S Annual Training Seminars
Seminars are the main annual training event by PIC/S and are hosted each year by a different Member. Each Seminar focuses on a specific hot GMP-related topic. For a full list since 1971: https://www.picscheme.org/en/pia-pic-s-training-seminars

PIC/S Expert Circles
Expert Circles are groups formed with the aim to enable inspectors to discuss and exchange information on specific technical areas of GMP; develop draft guidance documents and provide for training opportunities in their field of expertise. Expert Circles exist in the field of Cross-Contamination in Shared Facilities; Good Distribution Practice (GDP); Human, Blood, Tissues, Cells and Advanced Therapy Medicinal Products (ATMPs), Quality Risk Management (QRM) and Active Pharmaceutical Ingredients (APIs). The Expert Circle on API also manages the PIC/S International Training Programme on APIs.

PIC/S Joint Visits Programme and Coached Inspection Programme
The Joint Visits Programme allows 3 inspectors from 3 different countries to team up to observe GM(D)P inspections in each country with a view to comparing inspection procedures and techniques and to harmonise GM(D)P interpretation. The Coached Inspection Programme allows a junior inspector to team up with an experimented inspector during a routine inspection.

PIC/S New Inspector Training Course and Train the Trainer Course
New Inspector Training Courses are designed for new Inspectors who have already observed or participated in GMP inspections and who would like to develop inspection skills necessary to assess compliance of manufacturers against the PIC/S GMP Guide. These courses, have also been held alongside Train the Trainer courses, whose aim are to give participants the skills to assist the training of new inspectors within their respective Agencies, worldwide.

Auditors Training
The training for Auditors has been developed by PIC/S and the EMA (European Medicines Agency) for Auditors operating in the frameworks of the PIC/S Joint Re-assessment Programme (JRP) and the EEA Joint Audit Programme (JAP). These programmes regularly audit the Quality Systems of GMP Inspectorates from PIC/S Participating Authorities, respectively EEA Authorities.

Non-PIC/S Training
The Academy also provides cross-references to GMP training events and tools by PIC/S Partners such as the Prequalification Programme of the World Health Organization (WHO) or by Professional Associations with which PIC/S liaises such as the International Society of Pharmaceutical Engineers (ISPE) and the Parenteral Drug Association (PDA) which both propose training sessions and events all over the year and around the world, which are open to participants from Regulatory Authorities.

The Academy offers a **single point of access** to all these PIC/S training activities. Moreover, its webportal provides:

- **Information** on all PIC/S training activites and tools;
- A **Calendar** of upcoming PIC/S training events;
- Available **Video Recordings** of PIC/S training events;
- A **Database** compiling all PIC/S training materials available;
- A **Library** collecting guidance documents related to GM(D)P inspection;
- A **Forum** for discussion and sharing among regulators.

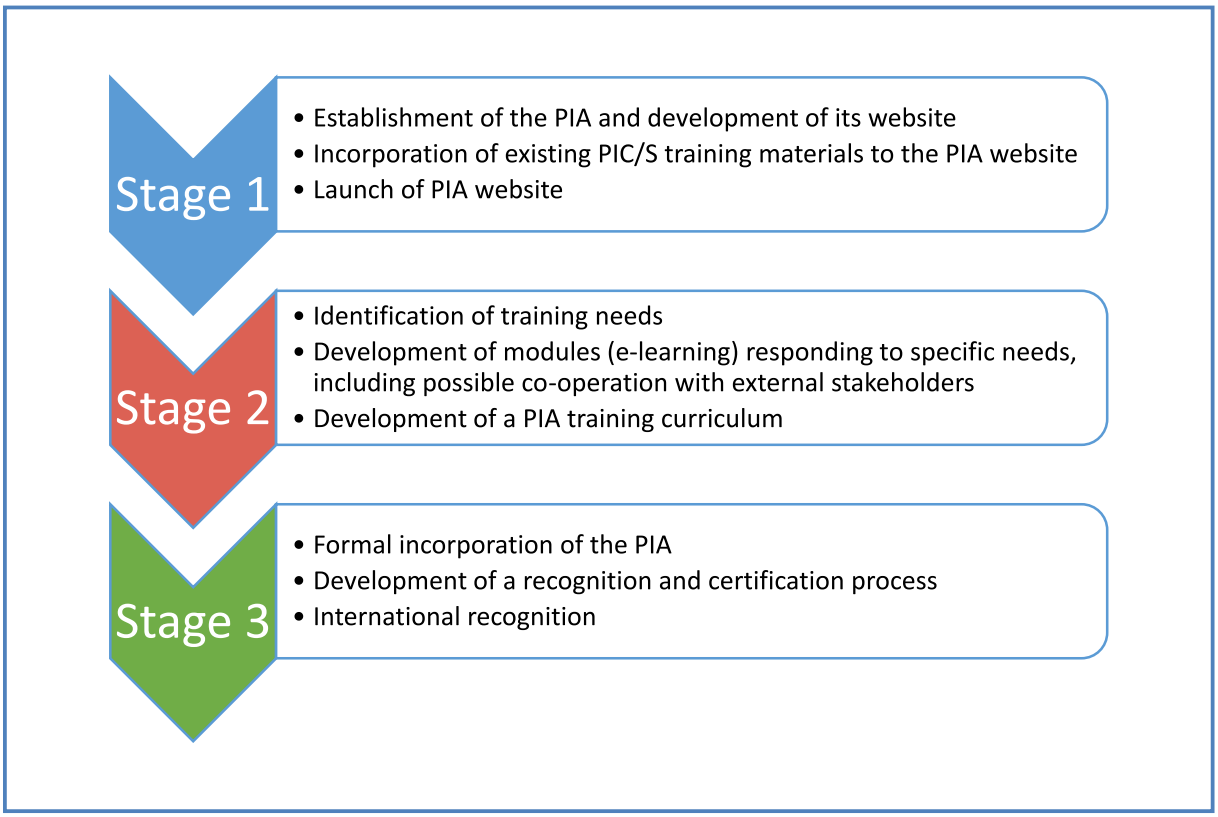
The PIC/S Inspectorates' Academy is for GM(D)P inspectors from PIC/S Members, Applicants, Pre-Applicants and Partners. It is a unique place for inspectors' to strengthen their knowledge, skills and capabilities by allowing them to mutually share, exchange and learn from each other.

A number of PIC/S training activities are also open to non-Member Medicines Regulatory Authorities, allowing them to benefit equally as well as helping contribute to efforts undertaken at a global level to heighten capacity building and share knowledge among regulators. The Academy is **not** open to Industry.

What are the next steps

The Academy is an ambitious project whose development will span several years. In 2016, stage 1 of the Academy was launched successfully with its website and since then the incorporation of all existing PIC/S training.

Stages 2 & 3 are in development and will encompass a fully integrated learning management system extending the current training resources, on the basis of a harmonized training curriculum. This will include basic, intermediate and advanced levels, consisting in a fine balance between **E-learning modules** and **Webinars** designed to needs and face-to-face training. Delivery and monitoring are to be optimized and the training curriculum steps to result in recognized certification.



Why do we need your support

At a time when resources are scarce and needs are ever more global, the sharing of knowledge and capacity building between regulators is all the more important, particularly in order to strengthen local regulatory capacities and continuously improve quality control systems, which in turn allow for increased safety in the global supply and access to quality medicines.

The Academy, as a global training initiative, is a project of high added-value which offers significant value for cost in this field.

The outreach and long term sustainability of the Academy very much depends on external support. PIC/S is a not-for-profit Association under Swiss law, which operates on a limited budget of approx. CHF 600,000 per year, financed largely by its membership annual contributions.

In this perspective, PIC/S needs funding for:

- **Maintaining and further developing the PIA website in line with training needs.**
- **Ensuring continuous development, review and selection of a broad range of training materials and keeping these up-to-date.**
- **Facilitating access to training materials, including support for Medicines Regulatory Authorities which have limited budgets to attend PIC/S face-to-face trainings.**
- **Designing and implementing new e-learning tools responding to specific needs such as webinars, e-learning modules and virtual reality training tools.**
- **Developing a fully integrated learning management system and a PIC/S training curriculum in view of its future certification.**

The Academy therefore relies heavily on voluntary and external funding. Contact us to find out how you can contribute!

Organisation

The PIC/S Academy is led by the PIC/S Sub-Committee on Training which reports to the PIC/S Committee, made up of representative of all PIC/S Participating Authorities. The Committee supervises all activities linked to the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by 7 Sub-Committees (Sub-Committee on Training is one of them), by an Executive Bureau, which steers the Organisation in-between meetings, and by a Secretariat.

Contact

PIC/S Secretariat
14, rue du Roveray CH
1207 Geneva
Switzerland
Tel: (+41) 22 738 92 16
Email: info@picscheme.org




PIC/S INSPECTORATES ACADEMY