



International Geneva
Directory of Global Health Actors

Pharmaceutical Inspection Co-operation Scheme | PIC/S

<https://picscheme.org/>

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BACKGROUND AND MISSION

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970. The Pharmaceutical Inspection Co-operation Scheme is a non-binding, informal 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. PIC/S presently comprises 52 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia). PIC/S 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.

AREAS OF INTEREST

- Coordination and standardisation
- Training and teaching activities
- Good manufacturing practices
- Access to medicines

HEALTH-RELATED ACTIVITIES

To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products, PIC/S is developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates and facilitating the co-operation and networking for competent authorities and international organisations.

GOVERNANCE AND STAFF

Membership to PIC/S is restricted to Regulatory Authorities. Individuals cannot join our organisation. The same is valid for companies. A Committee of the Participating Authorities' representatives (PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by 7 Sub-Committees (e.g. on the training of inspectors, on GMDP harmonisation, etc.), by an Executive Bureau, which steers the Organisation in-between meetings, and by a small Secretariat, which mainly assists the Committee, the Sub-Committees, the Bureau and Participating Authorities in their duties.

FUNDING SOURCES AND BUDGET

The PIC/S budget is funded by two main revenue streams: around two-third of the income, necessary to finance the Secretariat, is provided by PIC/S Membership annual contributions while the rest comes from the sub-contracting of secretariat services to other organisations such as the Convention on the Control and Marking of Articles of Precious Metals (Hallmarking Convention). PIC/S Participating Authorities contribute to the cost of the Secretariat in equal parts. The contribution amounts to CHF 8,100 a year. In 2005, the Secretariat had two permanent staff members and a budget of CHF 390,000. In 2016, it had 2.5 permanent staff members and a budget of CHF 620,000.

PUBLICATIONS

Since its creation, PIC/S has been active in the development and promotion of harmonised GMP standards and guidance documents. All the relevant documents are available at <https://picscheme.org/en/publications>

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