



ANNUAL REPORT 2002

Summary of Activities

1. The PIC/S Joint Committee met in Geneva (Switzerland) on 23-24 April 2002 and Montebello (Canada) on 8 October 2002 under the chairmanship of Ms. Lilian Hamilton of Sweden's Medical Products Agency (MPA). A Strategy Meeting was also held in London (UK) on 4-5 February 2002 to discuss PIC/S' future.
2. On 1 January 2002 Greece's National Organization for Medicines (NOM) and Malaysia's National Pharmaceutical Control Bureau (NPCB) officially joined PIC/S. In the course of the year, the Committee reviewed the membership applications of Poland, Latvia, Estonia, Chinese Taipei and the Czech Veterinary Agency. It also started with the reevaluation of Romania and Sweden under the Joint Reassessment Programme.
3. A PIC/S Executive Bureau was created to steer the organisation in-between meetings. The following goal was adopted for PIC/S: "to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products."
4. A revised concept of the IMI, the International Medicinal Inspectorates Database, was endorsed by the Committee. PIC/S also decided to support the WHO Global Alliance for the Quality of Medicines, of which it will be one of the partners.
5. The annual PIC/S seminar was organised by Canada's Health Products and Food Branch Inspectorate (HPFBI). It took place in Montebello (Canada) on 9-11 October 2002 and dealt with "The Interface Between Good Clinical Practice (GCP) and GMP in the Manufacture and Audit of Clinical Trial Products".
6. The other main activities during the year 2002 were:
 - * The PIC/S visit to Chinese Taipei aiming at assessing the local GMP inspection system;
 - * The annual meeting of the Working Group on the Training of Inspectors (Montebello, 7 October 2002);
 - * The 9th meeting of the Expert Circle on Human Tissue in Paris; the 1st meeting of the Expert Circle on Computerised Systems in London; the 5th and 6th meetings of the Expert Circle on Hospital Pharmacy in Reykjavík and London, respectively; and the 1st meeting of the Working Group on Biotechnology in Copenhagen.
 - * Last but not least: the entry into force of the Aide-Memoire on the Inspection of Utilities; the Standard Operating Procedures on Rapid Alert System and PIC/S Inspection Report Format; and the revised Explanatory Notes for Industry on the Preparation of a Site Master File.

Strategy Meeting in London

7. A Strategy Group of the PIC/S Committee held a meeting in London on 4 and 5 February 2002 to discuss the future direction of PIC/S. The Group came out with a number of important recommendations (e.g. the creation of an Executive Bureau, the adoption of goals, etc.), which were all endorsed by the PIC/S Joint Committee during the meeting in Geneva (Switzerland) on 23 and 24 April 2002. The Committee met also later in the year in Montebello (Canada) on 8 October 2002. Both meetings were chaired by Ms. Lilian Hamilton (Sweden / Medical Products Agency). Mr. Hans Smallegenbroek (Netherlands / Inspectorate of Health Care) acted as First Deputy Chairman and Ms. France Dansereau (Canada / Health Products and Food Branch Inspectorate) as Second Deputy Chairperson.

Pharmaceutical Inspection Co-operation Scheme

The Pharmaceutical Inspection Co-operation Scheme (PIC Scheme), which entered into force in November 1995, is an informal and flexible arrangement between the inspectorates of the PIC Contracting States. It is run in parallel with the Pharmaceutical Inspection Convention (see Annex II). It is open to the participation of the inspectorates of other countries.

The Scheme retains and improves the Convention's main features, i.e. the networking and confidence building between the national inspection authorities, the development of quality systems, the training of inspectors and other related experts and its work towards global harmonisation of GMP.

The Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme are run concurrently by one joint Committee and one Secretariat. The common logo for both is PIC/S.

To ensure greater public security with regard to pharmaceutical products marketed in the PIC/S countries, the Scheme provides that if a participating authority learns of particular circumstances due to which a pharmaceutical product could be of imminent and serious danger, its findings have to be communicated to the other competent authorities under the Scheme.

Greece and Malaysia accede to the Scheme as from 1 January 2002

8. The National Organization for Medicines (NOM) of Greece and the National Pharmaceutical Control Bureau (NPCB) of Malaysia jointly acceded to PIC/S on 1 January 2002 following a successful accession procedure.

The Participating Authorities of the PIC/S (Convention and Scheme taken together)

By the end of 2002, PIC/S comprised 26 inspectorates from Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, **Greece**, Hungary, Iceland, Ireland, Italy, Liechtenstein, **Malaysia**, Netherlands, Norway, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom (see also Annex I).

Estonia, Latvia, the European Agency for the Evaluation of Medicinal Products (EMA) and the World Health Organisation (WHO) enjoy an observer status with PIC/S.

Evaluation of membership applications

9. The Latvian State Pharmaceutical Inspection continued to report on progresses in the implementation of PIC/S recommendations, thus making it possible for the Committee to decide on a follow-up visit in March 2003. No progress was, however, reported from the Estonian State Agency of Medicines, thus leading to the postponement of the scheduled follow-up visit in autumn 2002.

10. A PIC/S Delegation visited the National Laboratories for Foods and Drugs (NLFD) of Chinese Taipei from 29 April to 3 May 2002 in order to assess the local GMP inspection and licensing system. On the basis of the Delegation's recommendations, the NLFD pledged to amend the Pharmaceutical Affairs Law, adopt the PIC/S GMP Guide and intensify the training of inspectors.

11. Progress was also achieved in the evaluation of the application made by the Main Pharmaceutical Inspectorate of Poland, where the pharmaceutical law was amended.

12. A Rapporteur and a Co-Rapporteur were appointed to assess the membership application by the Czech Institute for State Control of Veterinary Biologicals and Medicaments. The Czech Institute is the first veterinary agency to apply for PIC/S membership (the Czech State Institute for Drug Control, responsible for medicines for human use, is already a PIC/S Member).

13. The Committee welcomed the decision by the South Africa's Medicines Regulatory Authority (Inspectorate and Law Enforcement) to update its membership application.

Reevaluation of Members under a Joint Reassessment Programme

14. The pilot phase of the PIC/S Joint Reassessment Programme (JRP) was launched with the reevaluation of the Inspectorates from Romania and Sweden during

the second half of 2002 (to be followed by Australia and Greece in first half of 2003). The Committee established a Compliance Group in charge of monitoring the JRP. The reassessment aims to ensure that all current Members fulfil their obligations under the Scheme.

Creation of a PIC/S Executive Bureau

15. To alleviate the burden on the Chair, the Committee decided to create an Executive Bureau consisting of the Chairperson, the First and Second Deputy Chairpersons as well as two Bureau Members. The Executive Bureau will meet in-between Committee meetings.

16. At its meeting in Montebello, the Committee elected Mr. Jacques Morénas (France / AFSSAPS) and Dr. Martin Valchár (Czech Republic / SUKL) as new Members of the Executive Bureau. Mr. Morénas will be the new PIC/S-EU Liaison Officer (also in charge of relations with WHO) and Dr. Valchár will be responsible for monitoring the processing of the growing number of membership applications.

Adoption of PIC/S goal

17. The Committee adopted a goal for PIC/S, which reads as follows:

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.

18. This goal is to be achieved by:

- Developing and promoting harmonised GMP standards and guidance documents;
- Training competent authorities, in particular inspectors;
- Assessing (and reassessing) inspectorates;
- Facilitating the co-operation and networking for competent authorities and international organisations.

International Medicinal Inspectorates Database

19. The Committee endorsed the revised concept of an International Medicinal Inspectorate (IMI) covering the inspection of manufacturers located in non-PIC/S countries, which was presented by Mr. Jean Lambert of Canada (Health Products and Food Branch Inspectorate). In the revised concept a distinction is made between the

long-term objective of the IMI (an international inspectorate responsible for the conduct of GMP inspections) and the short-term goal of creating database containing standardised inspection reports from PIC/S Participating Authorities. The latter will be able to use these reports to process requests for manufacturing authorisations (or establishment licensing). Manufactures interested to have the inspection report of their facility on the database will be charged an additional fee.

WHO Global Alliance for the Quality of Medicines

20. The Committee decided to fully support the WHO Global Alliance for the Quality of Medicines, which aims at ensuring the quality, safety and efficacy of pharmaceuticals worldwide through partnership and international co-operation. PIC/S will be one of the strategic partners of the Global Alliance.

Annual Meeting of the Working Group on the Training of Inspectors

21. The Working Group on the Training of Inspectors met in Montebello (Canada) on 7 October 2002 under the chairmanship of Mr. Hans Smallegenbroek (Netherlands / Inspectorate of Health Care). The Working Group reviewed the operation of the PIC/S joint visits programme (see para. 26) and supervised the activities of the various Expert Circles (see para. 27 – 30). It also monitored the preparations to the 2002 and 2003 PIC/S Seminars (see para. 22 – 25).

2002 PIC/S seminar in Canada

22. For the first time in its history, an Annual Seminar was organised in America. The Seminar on “The Interface Between Good Clinical Practice (GCP) and GMP in the Manufacture and Audit of Clinical Trial Products” took place in Montebello (Canada) on 9-11 October 2002. It was organised by the Canada’s Health Products and Food Branch Inspectorate (HPFBI).

23. The PIC/S Seminar was attended by 96 participants from 33 Inspectorates, 4 agencies and 6 non-regulatory authorities. This number also includes invited inspectors and speakers from a number of non PIC/S countries or agencies such as Brazil, Chinese Taipei, EMEA, FDA, Latvia, New Zealand, Poland, South Africa, UNICEF, and WHO.

24. The Seminar concentrated on differences and analogies between GMP and GCP in the manufacture and inspection of clinical trial products. It will be followed up by the drafting of two Aide-Memoires: the first on GMP particularities in the manufacture of products used in clinical trials and the second on GCP issues specific to the inspection of clinical trial products.

Seminars in 2003 and 2004 in the Slovak Republic and Spain, respectively

25. The Committee took note of the preparations for the 2003 seminar on the Inspection of Quality Control Laboratories (Bratislava, 4-6 June 2003) organised by the Slovak State Institute for Drug Control (SIDC). It also reviewed the preliminary

programme presented by the Spanish “Agencia Española del Medicamento” (AEM) on the 2004 seminar on the Inspection of Active Pharmaceutical Ingredients (El Vendrell, Tarragona, Cataluña) on 16-18 June 2004.

25 PIC/S Joint Visits groups are operational

26. At its annual meeting in Montebello, the Working Group on the Training of Inspectors set up five new groups and modified the composition of four other groups. In 2002 there are 25 groups participating in the programme representing 75 inspectors from 25 different nationalities.

PIC/S Joint Visit Groups

Another means of training inspectors of the PIC/S countries has been devised in the form of joint visits to manufacturers by inspectors of different countries. Groups of three inspectors are set up on the basis of applications sent to the PIC/S Secretariat. Each inspector is assigned within his/her group to act in turn as host for one year and guest for the other two years.

Visits are carried out in English or in a language commonly agreed by inspectors. Joint reports are drafted after each visit and sent to the Committee for evaluation.

The organisation of the joint visits has proved an excellent means for the further training of inspectors through mutual exchange of experience and a useful contribution to the maintenance of mutual confidence between competent authorities. Participants have also the possibility to discuss and compare their inspection methods and their interpretation of GMP rules.

Five Expert Circles / Working Groups meetings in 2002

Expert Circle on Human Blood and Tissue

27. The 9th meeting of the “Expert Circle on Human Blood and Tissue”, organised by the French Agency for the Safety of Health Products French (AFSSAPS), took place in St. Denis (France) from 19 to 21 June 2002. It was attended by 37 participants from 23 different countries and was devoted to questions related to the inspection of human tissues.

Expert Circle on Hospital Pharmacy

28. Two meetings were organised under the auspices of the Expert Circle on Hospital Pharmacy: the first took place in Reykjavik (Iceland) on 15 April 2002. It was organised by the Icelandic Medicines Control Agency (IMCA) and attended by 17 countries; the second meeting was held in London (United Kingdom) on 21-22 October 2002 and organised by the Medicines Control Agency (MCA).

Expert Circle on Computerised Systems

29. The first meeting of the Expert Circle on Computerised Systems, organised by the United Kingdom's MCA, was held on 12-13 June 2002 and attended by 30 inspectors from 19 countries.

Working Group on Biotechnology

30. The first meeting of the Working Group on Biotechnology took place in the premises of the Danish Medicines Agency (DMA) on 26 September 2002. It was attended by 10 experts, who started with the drafting of an Aide-Memoire on the Inspection of biotech products.

Why Expert Circles?

PIC/S Expert Circles have been set up by the PIC/S Joint Committee to facilitate the discussions and the exchange of information among inspectors specialised in a specific area of GMP such as blood, medicinal gases, hospital pharmacy and computerised systems. Expert Circles meet regularly to develop draft guidance, recommendations, etc. and offer training in their respective fields of specialisation.

PIC/S guidance documents

31. The following PIC/S internal documents entered into force:

On 1 July 2002:

- Recommendation on Isolators Used for Aseptic Processing and Sterility Testing (PI 014-1);
- Aide-Memoire on the Inspection of Utilities (PI 009-1);
- Standard Operating Procedure on Rapid Alert System (PI 010-1);
- Guidelines on the Acceptance and Status of Observers to the PIC/S Committee (PS/W 3/2002);

On 1 November 2002:

- Standard Operating Procedure on the PIC/S Inspection Report Format (and classification of deficiencies) (PI 013-1);
- (Revised) Explanatory Notes for Industry on the Preparation of a Site Master File (PE 008-1);
- Recommendation on Sterility Testing (PI 012-1).

32. Furthermore, the PIC/S Joint Committee discussed the following draft documents:

- Annexes 1 and 13 to the PIC/S GMP Guide (revision in parallel with the EU);
- Annex 16 of the EU GMP Guide on “Certification of a Qualified Person and Batch Release” (the Committee decided not to adopt this EU specific Annex, which is applicable to EU/EEA Members States only);
- Draft Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (PI 008-1 (Draft));
- Standard Operating Procedures on requirements for PIC/S inspectors, on a PIC/S code of conduct, on PIC/S inspections and on the handling of quality defects and complaints (PI 016-1 (Draft), PI 017-1 (Draft), PI 015-1 (Draft), PI 018-1 (Draft)).

33. The list of PIC/S publications is attached at Annex III.

PIC/S on line

34. The Web Site Editorial Committee, which met in Montebello on 7 October 2002, reviewed the password protected “bulletin board” for inspectors, which was launched on a trial basis and which is linked to the PIC/S web site (<http://www.picscheme.org>). During its meeting in Montebello, the Committee also decided to establish a Working Group, which would look into the possibility of drafting a “Questions & Answers” document with regard to the interpretation of the PIC/S GMP Guide (to be posted on the web site).

**LIST OF PIC/S
PARTICIPATING AUTHORITIES**
(in 2002)

AUSTRALIA	GMP Audit and Licensing Section Therapeutic Goods Administration Department of Health and Ageing GPO Box 100 AU-Woden Act 2606
AUSTRIA	Federal Ministry for Social Security and Generations Radetzkystrasse 2 AT-1030 Vienna
BELGIUM	Ministère des Affaires sociales, Santé publique et Environnement Inspection Générale Pharmacie Cité Administrative de l'Etat Quartier Vésale BE-1010 Bruxelles
CANADA	Health Products and Food Branch Inspectorate (HPFBI) Health Canada 11, Holland Ave., 2 nd Floor Holland Cross, Locator 3002C CA-Ottawa, Ontario K1A OK9
CZECH REPUBLIC	State Institute for Drug Control Srobárova 48 CZ-100 41 Prague 10
DENMARK	Danish Medicines Agency 378 Frederikssundsvej DK-2700 Brønshøj
FINLAND	National Agency for Medicines Mannerheimintie 166 P.O. Box 55 FI-00301 Helsinki
FRANCE	French Agency for the Safety of Health Products (AFSSAPS) 143-145 Boulevard Anatole France FR-93285 Saint Denis

GERMANY	Federal Ministry for Health and Social Security Am Probsthof 78a DE-53121 Bonn
GREECE	National Organization for Medicines (NOM) Hellenic Republic Messoghion Ave. 284 GR-Holargos 155 62
HUNGARY	National Institute of Pharmacy P.O. Box 450 HU-1372 Budapest 5
ICELAND	The Icelandic Medicines Control Agency (IMCA) Eiðistorg 13-15 P.O. Box 180 IS-170 Seltjarnarnes
IRELAND	Irish Medicines Board Block A Earlsfort Centre - Earlsfort Terrace IE-Dublin 2
ITALY	Ministero della Sanità Dipartimento per la Valutazione dei Medicinali e la Farmacovigilanza Viale della Civiltà Romana 7 IT-00144 Rome
LIECHTENSTEIN	ALKVW / Kontrollstelle für Arzneimittel Postplatz 2 FL-9494 Schaan
MALAYSIA	National Pharmaceutical Control Bureau Ministry of Health Malaysia Jalan Universiti P.O. Box 319 MY-46730 Petaling Jaya, Selangor
NETHERLANDS	Inspectorate of Health Care P.O. Box 16119 NL-2500 BC Den Haag
NORWAY	Inspection Services Norwegian Medicines Agency Sven Oftedals Vei, 6 NO-0950 Oslo

PORTUGAL	Instituto Nacional da Farmácia e do Medicamento (INFARMED) Avenida do Brasil, no 53 Pavilhão 21-A PT-1700 Lisbon
ROMANIA	National Medicines Agency Strada Maior Aviator Sanatescu 48 Sectorul I RO-Bucharest
SINGAPORE	Manufacturing and Quality Audit Division Centre for Pharmaceutical Administration Health Sciences Authority Singapore 2 Jalan Bukit Merah SG - Singapore 169547
SLOVAK REPUBLIC	State Institute for Drug Control Kvetná 11 SK-825 08 Bratislava 26
SPAIN	Agencia Española del Medicamento Subdirección General de Seguridade de Medicamentos Division de Inspección y Control Farmacéutico C/Huertas 75 ES-28014 Madrid
SWEDEN	Medical Products Agency Box 26 SE-751 25 Uppsala
SWITZERLAND	Swissmedic Swiss Agency for Therapeutic Products Erlachstrasse 8 CH-3000 Berne 9
UNITED KINGDOM	Medicines Control Agency Market Towers 1 Nine Elms Lane, Vauxhall GB-London SW8 5NQ

**From the Pharmaceutical Inspection Convention
to the Pharmaceutical Inspection Co-operation Scheme**

The Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products (Pharmaceutical Inspection Convention) entered into force in 1971.

The Convention applies to inspection of the manufacture of medicinal and related products intended for human use, which are subject to control under health legislation. It provides that the Contracting States will exchange, on the basis of inspections, such information as is necessary for the health authorities in an importing Contracting State to be able to recognise inspections carried out in the Contracting State of the manufacturer.

In 2000 the Convention was operating between eighteen countries, namely, Australia, Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Liechtenstein, Norway, Portugal, Romania, Sweden, Switzerland and the United Kingdom

Due to some incompatibility for the Member States of the European Union (and for the States parties to the European Economic Area) between their obligations under the Convention and under the EU, the conclusion of another type of agreement than the Convention was agreed upon. This is an arrangement between the inspectorates of the present Contracting States to the Convention but also open to the participation of the inspectorates of other countries. The new arrangement called "Pharmaceutical Inspection Co-operation Scheme" (or PIC Scheme) " was put into force in November 1995.

The Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme are run concurrently by one joint Committee and one Secretariat. The common logo for both is PIC/S.

LIST OF PIC/S GUIDES AND RECOMMENDATIONS

PIC/S Guides

- ➔ ☐ Guide to Good Manufacturing Practice for Medicinal Products (PH 1/97 (Rev.3))
 - Ann 1 ➤ Manufacture of sterile medicinal products
 - Ann 2 ➤ Manufacture of biological medicinal products for human use
 - Ann 3 ➤ Manufacture of radiopharmaceuticals
 - Ann 4 ➤ Manufacture of veterinary medicinal products other than immunologicals
 - Ann 5 ➤ Manufacture of immunological veterinary medicinal products
 - Ann 6 ➤ Manufacture of medicinal gases
 - Ann 7 ➤ Manufacture of herbal medicinal products
 - Ann 8 ➤ Sampling of starting and packaging materials
 - Ann 9 ➤ Manufacture of liquids, creams and ointments
 - Ann 10 ➤ Manufacture of pressurised metered dose Aerosol preparations for inhalation
 - Ann 11 ➤ Computerised systems
 - Ann 12 ➤ Use of ionising radiation in the manufacture of medicinal products
 - Ann 13 ➤ Manufacture of investigational medicinal products
 - Ann 14 ➤ Manufacture of products derived from human blood or human plasma
 - Ann 15 ➤ Qualification and validation
 - Ann 16 ➤ *Not adopted by PIC/S*
 - Ann 17 ➤ Parametric release
- ➔ ☐ GMP Guide for Blood Establishments (PE 005-1)
- ➔ ☐ GMP Guide for Active Pharmaceutical Ingredients (PE 007-1)

Prices	PIC/S Guide and Seminar/Expert Circles booklets are invoiced at	CHF 40.- per copy postage included
	PIC/S Recommendations and Explanatory Notes are invoiced at	CHF 25.- per copy postage included
	➔ Documents with this sign are available at http://www.picscheme.org	

These publications can be obtained from

Secretariat to the Pharmaceutical
Inspection Co-operation Scheme
c/o EFTA Secretariat
9-11, rue de Varembé
CH - 1211 GENEVA 20

Tel.: +41 22 / 332 26 18
Fax: +41 22 / 332 26 22
e-mail: pics@efta.int
website: <http://www.picscheme.org>

PIC/S Recommendations, Explanatory Notes and Standard Operating Procedures

NEW	→	➔	☐	Explanatory Note for Industry on the Preparation of a Site Master File (PE 008-1) <i>(Replacing PH 4/93)</i>		
				☐	Recommendation on a Quality System for Official Medicines Control Laboratories (PH 2/95)	
				➔	☐	Standard Operating Procedure – Editing of PIC/S Documents (PI 001-2)
				➔	☐	Recommendation on Quality System Requirements for Pharmaceutical Inspectorates (PI 002-1)
				➔	☐	Recommendation - Guidance on Parametric Release (PI 005-1)
				➔	☐	Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-sterile Process Validation, Cleaning Validation (PI 006-1) ¹
				➔	☐	Recommendation on the Validation of Aseptic Processes (PI 007-1) ²
				➔	☐	Aide-mémoire – Inspection of Utilities (PI 009-1)
				➔	☐	Standard Operating Procedure – Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects (PI 010-1)
				➔	☐	Recommendation on Sterility Testing (PI 012-1)
NEW	→	➔	☐	Standard Operating Procedure – PIC/S Inspection Report Format	(PI 013-1)	
				➔	☐	Recommendation - Isolators used for Aseptic Processing and Sterility Testing (PI 014-1)
				➔	☐	Explanatory Note for the National Inspectors of PIC Competent Authorities on the preparation of information requested under Article 2 of the Pharmaceutical Inspection Convention (PH 8/92)
				➔	☐	Explanatory Note for Industry on the Preparation of a Site Master File to be part of the Information Requested under Article 2 of the Pharmaceutical Inspection Convention (PH 4/93) ³

¹ Replacing PR 1/99-2

² Replacing PE 002-2

³ Replacing PH 6/91

LIST OF PIC/S SEMINARS AND EXPERT CIRCLES BOOKLETS

Booklets on Seminars and Expert Circles organised under the auspices of PIC/S

Seminars booklets

- Manufacture and quality control under contract (Berne, Switzerland, July 1974)
- The manufacturer's quality control department. Structural and functional aspects (Copenhagen, Denmark, June 1975)
- Stability of pharmaceutical products (Salzburg, Austria, June 1976)
- Modern methodology for the isolation, identification and quantification of drugs and related substances (Uppsala, Sweden, June 1977)
- Inspection in tablet manufacture (Copenhagen, Denmark, June 1980)
- Good manufacturing practice in the manufacture of active ingredients (Liestal/Basle, Switzerland, June 1980)
- Application of GMP rules in the control laboratory (Budapest, Hungary, June 1981)
- Safety aspects of the packaging of pharmaceutical products (Lisbon, Portugal, June 1983)
- Requirements of good manufacturing practice and quality control in the production of biological products (Frankfurt a/Main, Germany, May 1984)
- Premises for pharmaceutical manufacture (Oslo, Norway, June 1985)
- Plastics and their pharmaceutical applications (Sigtuna, Sweden, June 1986)
- The business of pharmaceutical inspection (Cambridge, United Kingdom, September 1987)
- Water for pharmaceutical purposes (Jongny, Switzerland, September 1988)
- Contamination risks in the manufacture of parenterals (Baden, Austria, September 1989)
- Blood and blood products (Hillerød, Denmark, September 1990)
- Audit - Pharmaceutical Inspection (Felsötárkány, Hungary, June 1991)
- New aspects of products derived from biotechnology (Montecatini, Italy, May 1992)
- The Role of Inspection and Testing in relation to the Marketing authorization (Louvain-la-Neuve, Belgium, September 1993)
- Qualification and validation in Pharmaceutical Manufacture (Dublin, Ireland, July 1994)
- Inspecting the Manufacture of Sterile Products - Current and Future Trends (Hveragerði, Iceland, June 1995)
- Inspection of computer systems (Sydney, Australia, September 1996)

NEW
CD-R



- Manufacture and inspection of Active Pharmaceutical Ingredients (Naantali, Finland, June 1997)
- Quality System for Pharmaceutical Inspectorates (Zeist, Netherlands, June 1998)
- Non-Technical Aspects of Inspection (Oxford, United Kingdom, September 1999)
- The Inspection of Products derived from Biotechnologies (Colmar, France, October 2000)
- Utilities used by the Manufacturer of Pharmaceuticals (Prague, Czech Republic, May 2001)
- The Interface between Good Clinical Practices and Good Manufacturing Practices (Montebello, Canada, October 2002)

Expert circles

- PIC/s Expert Circle on Medicinal Gases (Sigtuna, November 1997) (PH 1/98)
- PIC/s Expert Circle on Blood (Saariselkä (Finland) 30 August – 1 September 2000)
- PIC/s Expert Circle on Blood (Stockholm (Sweden) 25-27 June 2001)

Prices

PIC/S Guide and Seminar/Expert Circles booklets are invoiced at	CHF 40.- per copy postage included
The CD-R from the Seminar in Montebello, Canada, in October 2002 is invoiced at	CHF 30.- per copy postage included
PIC/S Recommendations and Explanatory Notes are invoiced at	CHF 25.- per copy postage included
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