

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

Dear Inspectors and Guests,

I have pleasure to invite you to the 2003 PIC/S Annual Seminar on "The Inspection of Quality Control Laboratories", which will take place from 3 to 6 June 2003 at the Hotel Danube in Bratislava, Slovak Republic.

Bratislava ranks among the youngest capitals in Europe, but it is nevertheless a city with an eventful history of some two thousands years.

The city is situated on both banks of the river Danube at the foothill of the Small Carpathians in the centre of Europe. It borders with Austria and the Czech Republic in the West, Hungary in the South, Poland in the North and Ukraine in the East. Due to mild and warm climate, it ranks among the warmest spots in Slovakia with an average temperature of 9.9° C. With a population of 452,000 inhabitants, Bratislava is the most populous city in the Slovak Republic.

In the following pages you will find the Seminar programme and objectives, the Seminar registration form, the hotel reservation form and more details on how to participate at the PIC/S Annual Seminar in Bratislava.

I kindly remind you that as in the past, the Seminar will be preceded by a number of events, which are listed hereafter (see pre-Seminar programme).

The Organising Committee looks forward to seeing you in Bratislava

- Ludevit Martinec, Director of State Institute for Drug Control, Bratislava
Chairman of the Organising Committee
- Jana Jagelkova, Seminar Programme
- Stanislava Gajdosova, Practical Arrangements
- Jana Bauerova, Project Assistant



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

Pre-Seminar Programme

June 2, 2003

09:00 - 11:00 PIC/S Executive Bureau
11:00 - 12:00 Web Site Editorial Committee

12:00 - 13:30 *Lunch for Executive Bureau*

14:00 - 17:30 PIC/S Committee Meeting

19:00 - 22:00 *Dinner for PIC/S Committee Members*

June 3, 2003

09:00 - 17:00 PIC/S Committee Meeting

12:00 - 20:00 *Registration for the Seminar*

19:00 - 21:30 *Welcome Address & Reception in Palace of Primate*



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

I - SEMINAR OBJECTIVES AND PROGRAMME

The PIC/S Seminar is part of PIC/S continuous training programme in the field of Good Manufacturing Practice (GMP). It is open to inspectors from the PIC/S Participating Authorities, Observers and invited guests.

The objectives of the 2003 Seminar are:

- (i) to provide a forum for expert discussions on current regulatory issues related to GMP in pharmaceutical quality control laboratories;
- (ii) to harmonise inspection standards and practices; and
- (iii) to issue guidance documents in this field.

It is expected that both workshops and discussions between the GMP and GLP inspectors will result in an Aide Memoire on the inspection of pharmaceutical quality control laboratories.

Session I aims at presenting how PIC/S, the EU/EMEA, the OECD, FDA and WHO regulate quality control laboratories and Good Laboratory Practice (GLP).

Session II focuses on specific aspects in the pharmaceutical quality control laboratories such as use of the reference standards, validation, batch release, qualified person and microbial monitoring.

In Session III aspects related to the GMP inspection of the pharmaceutical quality control laboratories (such as sampling and testing of APIs, failure investigation, handling of results, investigation of equipment and documentation) will be discussed both in the plenary and in workshops. There will be four workshops on the preparation of the Aide Memoire, microbial monitoring, validation and documentation. The objectives of the workshops are as follows:

- To prepare a draft Aide Memoire on the inspection of pharmaceutical quality control laboratories;
- To identify critical failures usually found in laboratories;
- To exchange inspectors' experiences.

Session IV of the Seminar will report on the workshops and the elements of the draft Aide Memoire. Future trends and development in the field of pharmaceutical quality control laboratory practice will also be presented.



PIC/S 2003 Annual Seminar Programme

“The Inspection of Quality Control Laboratories”

4 to 6 June 2003, Bratislava, Slovak Republic

JUNE 4, 2003

07:30 - 09:00 ***Registration for the Seminar*** *

SESSION I : INTERNATIONAL ASPECTS

- 09:00 - 09:25 Opening of the Seminar
L. Martinec, SIDC, Slovak Republic
L. Hamilton, PIC/S Chairperson, MPA, Sweden
- 09:25 - 09:30 Opening by Session Chairperson: *L. Hamilton, MPA Sweden*
- 09:30 - 10:00 PIC/S Approach to the Present and Future Practices of GMP Inspections in the Pharmaceutical Quality Control Laboratories
Speaker: H. Smallembroek, Health Care Inspectorate, The Netherlands
- 10:00 - 10:30 Why Good Pharmaceutical Control Laboratory Practice?
European Regulatory Perspective
Speaker: D. Cockburn, EMEA
- 10.30 - 11.00** ***Break***
- 11:05 - 11:35 GMP in the Pharmaceutical Laboratories for Quality Control Inspectors expectation. FDA view
Speaker : T. Arista, FDA, USA
- 11:35 - 12:05 WHO Role in the Regulation, Promotion and Enhancement of the Quality in the field of the Inspection of the Pharmaceutical Quality Control Laboratories
Speaker: A .van Zyl, WHO,
- 12:05 - 12:35 OECD GLP Guidelines and QC Laboratories
Speaker: R. Alexander, MCA, United Kingdom
- 12:35 - 14:00** ***Lunch***

* Participants can also register the day before between 12 am and 20 pm

SESSION II SPECIFIC ASPECTS

- 14:00 - 14:05 Opening by Session Chairperson: *F. Dansereau, HPFBI, Canada*
14:05 - 14:30 Reference Substances: definition and important relevant issues for their use
Speaker: J.M. Spieser, EDQM
- 14:30 - 15:00 Assessment of the QA System and GMP in Industrial Pharmaceutical Quality Control Laboratories. Current practices and experiences in the Pharmaceutical industry
Speaker: A. Šrank, Slovakofarma a.s., Slovak Republic
- 15:00 - 15:30 Good Microbiological Monitoring Practice
Speaker: C. Tompson, ISPE
- 15:30 - 16:00 Break**
- 16:00 - 16:20 Validation of the Analytical Methods - industry point view
Speaker: Z. Pavelek GM-project, Czech Republic
- 16:20 - 16:40 Validation of the Analytical Methods – inspectors point of view
Speaker: P. Sidhu, TGA, Australia
- 16:40 - 17:00 Batch Release and Qualified Person / Authorised Person
Speaker: J. Morénas, AFSSAPS, France
- 17:00 - 17:15 Closing remarks
- 17:45 -19:15 Sightseeing Tour of Bratislava**
- 20:00 - 22:00 Dinner in the Hotel Danube**

JUNE 5, 2003

SESSION III INSPECTION ASPECTS

- 09:00 - 09:05 Opening by Session Chairperson: *Ludevit Martinec, SIDC, Slovak Republic*
- 09:05 - 09:35 Sampling and Testing of APIs. Requirements and Inspectors View (observations on critical failure to comply to the current EC, WHO and PIC/S guidelines)
Speaker : A. Muir, TGA, Australia
- 09:35 - 10:05 GMP Aspects of Equipment and Instrumentation in Pharmaceutical Quality Control Laboratory (Inspectors view)
Speaker: V. Kment, SÚKL, Czech Republic
- 10:05 - 10:30 Documentation in Pharmaceutical Quality Control Laboratories (common systems, specifics on electronic documentation, LIMS)
Speaker: K. H. Menges, Regierungspräsidium Darmstadt, Germany

- 10:30 - 11:00** **Break**
- 11:00 - 11:30 Failure investigation, handling of deviations and out of specification results
Speaker: A.B. Hansen, Danish Medicines Agency, Denmark
- 11:30 - 12:00 Implementation and maintenance of QA system in OMCL network, development and application of the audit concept.
Speaker : J.M. Spieser, EDQM
- 12:00 - 12:30 Critical points during a GLP inspection
Speaker: H. Hartmann, Swissmedic, Switzerland
- 12:30 - 13:30** **Lunch**
- 13:30 - 13:45** **Instructions for workshops**
- 13:45 - 17:00 Parallel Workshops:
- A. Aide Memoire** for the Inspection of Pharmaceutical Quality Control Laboratories (discussion and drafting of Aide Memoire)
Leader: G. Werner, Paul-Ehrlich-Institut, Germany
Co-Leader: D. Krüger, Federal Ministry for Health, Germany
 - B. Inspection of the Activities of the Pharmaceutical Quality Control Laboratories related to **Microbial monitoring**** (comparison of inspection practices, discussion and drafting of chapter on microbial monitoring for Draft Aide Memoire on Inspection)
Leader : P. Hargreaves, MCA, United Kingdom
 - C. Validation** of laboratory equipment, instrumentation and methods (comparison of inspection practices, discussion and drafting of chapter on validation for Draft Aide Memoire on Inspection)
Leader: P.Sidhu, TGA, Australia
 - D. Electronic and paperwork documentation** in Pharmaceutical Quality Control Laboratory (comparison of inspection practices, discussion and drafting of chapter on documentation for Draft Aide Memoire on Inspection)
Leader: K.H. Menges, Regierungspräsidium Darmstadt, Germany
- Note:** **Coffee will be served on demand during workshops**
- 18:00 - 23:00** **Boat Trip & Dinner**

JUNE 6, 2003

SESSION IV THE FUTURE

08:30 - 08:35 Opening by Session Chairperson: *Hans Smullenbroek, IGZ, The Netherlands*

08:35 - 10:00 Reports on workshops

10:00 - 10:30 ***Break***

10:30 - 11:15 Quality Control Laboratory in the Manufacturing Area: The Future Trends
Speaker: S. Folestad, AstraZeneca R&D, Sweden

11:15 - 11:30 Evaluation

11:30 - 12:00 Invitation to the 2004 PIC/S Seminar in Spain

12:00 Closing

Lunch



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

II - SEMINAR REGISTRATION

1. REGISTRATION

Registration	Before March 14 th , 2003	Between March 14 th and April 30 th 2003
PIC/S Committee* and Seminar	695,- €	785,- €
Seminar Participant only	645,- €	720,- €
Accompanying person	410,- €	490,- €

* The PIC/S Committee meeting is open to PIC/S Members and Observers only.

IMPORTANT

- Each PIC/S Participating Agency can be represented at the Seminar by 3 participants. If you wish to send more than 3 participants, please contact the State Institute for Drug Control, Bratislava, tel/fax.: +421 2 55 56 41 27, e-mail: gajdosova@sukl.sk
- Non-PIC/S Members can be represented at the Seminar by 1 participant. If you wish to send more than 1 participant, please contact the State Institute for Drug Control, Bratislava, tel/fax.: +421 2 55 56 41 27, e-mail: gajdosova@sukl.sk
- The registration fee includes :
 - lunches and dinners as indicated in the programme, in particular:
 - Welcome address & reception at the Palace of Primate on Tuesday
 - Dinner in the Hotel Danube on Wednesday
 - Boat Trip & Dinner on Thursday
 - Sightseeing Tour of Bratislava on Wednesday
 - Coffee breaks
 - 10% PIC/S administrative tax

NB: Fees include all taxes and amenities;
Breakfasts are included in the room price.

2. PAYMENTS

Once the registration has been confirmed by the State Institute for Drug Control, participants must pay their registration fee within 30 days to :

*Pharmaceutical Inspection Convention
Account No. R 3260.86.99
Banque Cantonale de Geneve (BCGE)
Rue de la Corraterie 4
CH-1204 Geneva
Switzerland*

- In details of payment please write your SURNAME & initials
- The swift code for international payment is: BCGECHGG
- Payments should be made by bank transfer (charges to be born by payer)

3. CANCELLATION POLICY

- | | |
|---|---------------------------------|
| ▪ cancellation less than 21 days but more than 14 days before the start of the Seminar: | 25% of the fee will be retained |
| ▪ cancellation less than 14 days but more than 7 days: | 50% of the fee |
| ▪ cancellation less 7 days: | 75% of the fee |
| ▪ no show up: | 100% of the fee |



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PIC/S SEMINAR REGISTRATION FORM

Please return this form including parties 1-6 not later than: March 14th 2003 to:

**Mrs Stanislava Gajdosova
State Institute for Drug Control
Kvetná 11
825 08 Bratislava 26, Slovak Republic,
fax : +421 2 55 56 41 27,
e-mail: gajdosova@sukl.sk**

Title : _____

Mr Ms

Family name : _____ First name : _____

Position : _____

Organisation : _____

Address :

Postal Code: _____

Country : _____

Telephone : _____

Fax : _____

E-mail : _____

1. ATTENDANCE

- A. PIC/S Executive Bureau - Monday, June 2, 2003
- B. PIC/S Committee -Monday & Tuesday, June 2 & 3, 2003
- C. Welcome Address & Reception - Thursday, June 3, 2003
- D. Seminar - Wednesday to Friday, June 4-6, 2003

2. PARALLEL WORKSHOPS PARTICIPATION

A.	Aide Memoire for the Inspection of Pharmaceutical Quality Control Laboratories	<input type="checkbox"/>
B.	Inspection of the Activities of the Pharmaceutical Quality Control Laboratories related to Microbial monitoring	<input type="checkbox"/>
C.	Validation of Laboratory Equipment, Instrumentation & Methods	<input type="checkbox"/>
D.	Electronic and Paperwork Documentation	<input type="checkbox"/>

3. SOCIAL EVENTS

- Sightseeing Tour of Bratislava on Wednesday

4. DINNERS

At the Hotel Danube on Wednesday and Boat Trip & Dinner on Thursday

Please indicate your preference :

- Fish
- Meat
- Vegetarian

5. SHUTTLE SERVICE

The organiser will reserve shuttles for transfer between the Vienna International Airport (Swechat), the Bratislava Airport and Hotel Danube in Bratislava.

If you request a shuttle service, please complete the following details:

Shuttle from the Vienna International Airport (Swechat) to Hotel Danube:

Arrival date:		Flight no:	
Expected time:			
Departure date:		Expected time:	

Shuttle from the Bratislava Airport to Hotel Danube

Arrival date:		Flight no:	
Expected time:			
Departure date:		Expected time:	

6. ARRIVAL BY CAR OR OTHER TRANSPORT

For participants arriving by car, a parking place in the Hotel Danube will be reserved. Please complete the following details:

Arrival date:		Number of days:	
Expected time:			
Departure date:		Expected time:	

Please specify if you arrive with another kind of transport (train, boat, hydrofoil) to Bratislava.



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

III - HOTEL REGISTRATION



HOTEL DANUBE

www.hoteldanube.com

LOCATION :

The hotel is conveniently located in the heart of business district and surrounded by the historical site of the Old Town.

ACCOMMODATION

The hotel features 278 guestrooms on 5 floors. All bedrooms are fully air-conditioned, with mini bar, IDD telephone, satellite television and movie channel.

RESTAURANT & BAR

Presbourg Restaurant, Le Café Viennois, Amadeus Bar

OTHER FACILITIES

Business centre, congress hall, conference rooms, fitness centre, swimming pool, sauna, jacuzzi, solarium, exercise room and aerobic room.

PAYMENT OF THE HOTEL DEPOSIT

Payments of one night deposit must be made in € by 15th April 2003:

a) by bank transfer (charges to be born by payer) to:

*Imperia Ltd.
Account no: 02-03470280/7500
Československá obchodní banka, a.s.
pobočka zahraničnej banky v SR
Nám SNP 29
815 63 Bratislava 1
Slovak Republic*

- In details of payment please indicate the reference "PT 270" and your SURNAME!
- The swift code for international payment is: CEKOSKBX
- Extras must be paid directly at the reception before departure.

b) by credit card:

Visa

American Express

MasterCard

Eurocard

Diners Club

Card No:

Holder:

Expiry Date:

Signature:

CANCELLATION POLICY

- | | |
|--|---|
| ▪ cancellation less than 30 days before arrival to the hotel | 50% of the hotel deposit will be retained |
| ▪ cancellation less than 21 days before arrival to the hotel | no refund |



PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

HOTEL RESERVATION FORM

Please return this form before 14th March 2003 directly to:
 Mrs Jana Bauerova, Imperia Ltd., Reservation Services
 Tomasikova 32, 821 01 Bratislava 2, Slovak Republic

fax.: +421 2 54 78 80 04, e-mail: bauer@nextra.sk,

tel.: +421 2 903 403 795

Family name: _____ First name: _____

Position: _____

Organisation: _____

Address: _____

Postal Code: _____ Country: _____

Telephone: _____ Fax: _____

E-mail: _____

I wish to make the following hotel reservation

HOTEL DANUBE BRATISLAVA	Single room <input type="checkbox"/>	Double room <input type="checkbox"/>
	140,- €	170,- €

Note: all rates in € include accommodation and hot breakfast.

Check-in date	Check-out date	Number of nights	Special request
			Smoking Non-smoking Other



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IV - USEFUL INFORMATION

SEMINAR SECRETARIAT :
PIC/S Annual Seminar 2003
State Institute for Drug Control
Kvetna 11
825 08 Bratislava 26
Slovak Republic

tel./fax: +421 2 55 56 41 27 or + 421 2 55 56 50 81

e-mail: gajdosova@sukl.sk or sekretariat@sukl.sk

mobile phone: +421 903 474 120

For having more information please visit following web sites:

www.slovakia.org

www.slovakia.org/tourism/visainfo.htm

www.bratislava.sk

www.sukl.sk

**HAVE A NICE AND PLEASANT
STAY IN SLOVAKIA**

