Selfinspection and Auditing, Strasbourg, France
26th- 27th June, 2001

Tuesday 26th June, 2001:
Registration 9:00 h
Conference 10:00 – 17:00 h
Wednesday 27th June, 2001:
Conference 9:00 – 17:00 h

Venue

Hilton Strasbourg
Avenue Herrenschmidt
France, F - 67000 Strasbourg
Tel: +33-388371010, Fax: +33-388368327

Fee

Includes the congress documentation, lunch and refreshments on both days. Fee for attending the congress will be € 1140,– per delegate + VAT.

The registration fee is payable in advance after receipt of the invoice.

Special rates:

EARLY REGISTRATION: A 10% discount applies to registration received before March 16th 2001.
GROUP DISCOUNTS: Discounts for multiple registration are available on request.

Accommodation

PCS has reserved a limited number of rooms at the Hilton Strasbourg. Reservation should be made directly with the hotel. Be sure to mention the PCS congress to receive the specially negotiated rate.
The hotel is located within 20 minutes walking distance of Strasbourg Cathedral or 5-10 minutes by tram.

Cancellations

Should you be unable to attend the conference please inform us in writing nominating one of the following options:

1. Indicate the name of a substitute for the enrolled delegate (no time limit).
2. Receive a credit voucher for the full amount valid 1 year for any future PCS seminar or conference.
3. If you prefer a refund the following administration fees will apply:
   Cancellation before June 12th 2001: 10 %
   Cancellation before June 19th 2001: 50 %
   Refunding cannot be made for cancellations after June 19th 2001.

Conference Language

The official conference language will be English.

Registration Form*

Surname, First Name, Title

Department, Position

Company and Full Postal Address

Telephone Fax

e-mail address

Invoice recipient (if different from the above)

The course fee will be transferred within 14 days following receipt of the invoice

Date Signature

* Please fax or cut out and forward to

Pharmaceutical Consultancy Services

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D - 67433 Neustadt / Weinstr.
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or

Concordiaplein 2
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Telefon: +31 - 182 - 503280
Telefax: +31 - 182 - 502589
e-mail: info@pcs-nl.com

* or register by sending an e-mail to pcs@pcsdeutschland.de
* or use the registration form provided on our website at http://www.pcsdeutschland.de

Upcoming events and registration www.pcsdeutschland.de

Pharmaceutical Consultancy Services

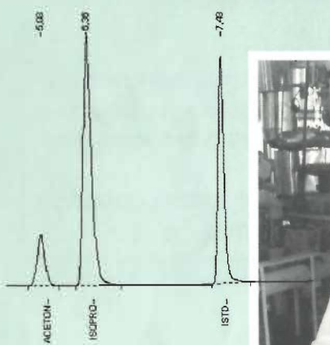
International Seminar on:

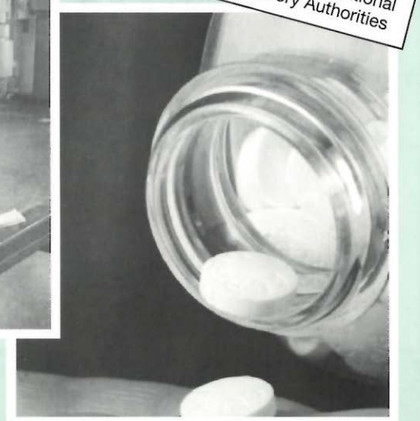
Self-Inspection and Auditing

- Principles and Practice -

Preparing, organising and performing professional GMP inspections

26th and 27th June, 2001
Strasbourg, France





Intensive Course Programme with International Acclaim

This seminar has already been attended by over 500 delegates representing major multinational organisations as well as Regulatory Authorities

PROGRAMME

- **Inspection types, methods and techniques**

  Comprehensive review of various inspection situations e.g. internal, external, suppliers etc. and the different inspectional approaches that can be applied, e.g. trace forward, trace back, complaints. Applying the „3 A principle" to inspections.

- **Planning, preparation and performance of inspections**

  Developing a systematic planning and preparation strategy for each inspectional situation. Consideration of the information necessary to plan a successful inspection. Critical success factors in the performance of inspections and audits, together with case studies, examples and practical tips.

- **Communication skills**

  Developing a good relationship using the EDICT model and building credibility. The use of power and influencing skills to direct the inspection. Maximising information flow through the application of good questionning skills. Learning to deal effectively with difficult behaviour.

- **Inspection checklists**

  The advantages and disadvantages of inspectional checklists. The *aide memoire* versus the detailed questionnaire. Criteria checklists, departmental checklists as inspectional tools. All delegates will be provided with an example of inspectional checklists.

- **Evaluation of inspection findings**

  The use of inspection findings (symptoms) to diagnose underlying quality deficiencies (diseases), classification and categorisation of inspection findings, to focus corrective action. Performing root cause analyses on inspection findings.

- **Inspection reports**

  Developing a consistent approach to inspection reports. Separating observations (facts) from opinions. How much detail should a typical inspection report contain? The use of draft reports to gain commitment.

- **GMP rating systems**

  Models for establishing a GMP rating system to quantify inspection findings will be presented.

- **QSIT**

  The QSIT approach. The recent FDA approach for inspections will be presented, and its application to GMP self-inspections considered. Inspection of quality systems versus compliance inspections.

SPECIAL TOPICS:

1. Inspecting a manufacturer of active pharmaceutical ingredients (APIs). Specific critical issues to be addressed in an API plant. Definition of a common GMP standard for evaluation of API manufacturers. Typical inspection findings.
2. Inspecting critical utilities: Planning and performance of effective inspections on critical utilities such as HVAC, water for injection, steam etc.
3. Good Development Practice: Performing inspections in development and research organisations, how much GMP is necessary during the various development phases. Simulation of a pre approval inspection (PAI) in a typical development situation.

PROGRAMME

- **Supplier audits**

  Special considerations when planning and performing audits on suppliers of active pharmaceutical ingredients (APIs). Practicalities of enforcing follow-up action or gaining commitment to change. The use of audits on suppliers to reduce testing of incoming raw materials.

- **Self-inspections from a regulatory perspective**

  How are self-inspection systems considered and evaluated by official inspectors.

- **Official regulatory inspections**

  Strategies and procedures within the Swiss inspectorate (RFS Nordwestschweiz) in Basel. How to ensure reproducible official inspections. The quality assurance system of RFS Basel. Experiences from an official inspector. Podium discussion: What can industry learn from the official system?

WORKSHOP

Delegates will be given the opportunity to analyse case studies from actual inspections, in order to diagnose quality system failures. In a role playing situation, delegates will be required to provide a "wrap-up session" for the inspections in question, and be expected to defend and justify their conclusions and recommendations.

Workshop issues:

- ➜ Raw materials
- ➜ Dispensing
- ➜ Facilities and clean rooms
- ➜ Hygiene concept
- ➜ Monitoring
- ➜ Equipment qualification
- ➜ Instrument calibration
- ➜ Change control
- ➜ Batch records
- ➜ Deviations
- ➜ Training
- ➜ Quality control
- ➜ SOP management
- ➜ Warehouse
- ➜ Water systems