

Istanbul, Turkey,

27-28 October 2005

at the Hilton Istanbul Hotel

Certification of Suitability of Monographs of the European Pharmacopoeia

*Implementation of the 5th Edition
New procedures for revision
and renewal of certificates*

Programme

Working language: English

International Conference

**Organised by the European Directorate
for the Quality of Medicines (EDQM)
of the Council of Europe**

Thursday, 27 October 2005, 9:00 - 12:00

Opening Session

- Welcoming addresses

9:00 Official representative of the Turkish authorities and **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

Plenary Session

Moderator: Dr M. Morris, Chair of the European Pharmacopoeia Commission

- Opening Remarks and Introduction: The Evolution of the 5th Edition of the European Pharmacopoeia and its impact on the Certification procedure. Control of Impurities: What has changed and general requirements

9:30 **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

- Overview of the Certification procedure, its objectives and its place within the European regulatory framework, and an update on the EU Review

9:50 **Dr J. L. Robert**, Chair QWP (EMA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of Europe)

10:10 Discussion

10:20 Coffee Break

- New developments in Certification: Implementation of the 5th Edition of the European Pharmacopoeia. Revision of the Notes for Guidance on TSE products. The new procedures for revision and renewal of certificates. Technical Advice: How to obtain advice and the benefits of exchanging information. Programme of Inspections: Why it was established, who is involved, and how it works

10:50 **Ms C. Pouget**, Head of the Certification Unit (EDQM, Council of Europe)

11:20 Discussion

- How to use Certificates of Suitability in MA Applications - Suggestions & perspectives: Viewpoint of a regulator

11:30 **Mrs E. De Rooij Lamme**, RIVM (NL), Chemical Assessor for the Certification Procedure

11:50 Discussion

12:00 Lunch break

Workshops and One-to-One Sessions

In the afternoon, there will be a series of parallel workshops (13:30-15:00 and 15:30-17:00) covering topics such as:

- **Workshop 1:** New procedures for the revision and renewal of certificates

With the participation of: *Dr P. Platzer*, Bundesministerium für Arzneimittel (A); *Dr C. Nopitsch Mai*, BfArM (D); *Mrs H. Bruguera*, Certification Unit, EDQM, Council of Europe and *Mrs C. Hurlé*, Certification Unit, EDQM, Council of Europe

- **Workshop 2:** An outline of the main deficiencies in dossiers and how to avoid them

With the participation of: *Dr S. Jones*, Medicines and Healthcare products Regulatory Agency (UK) and a second Chemical Assessor for the Certification Procedure ; *Dr P. Poukens Renwart*, Certification Unit, EDQM, Council of Europe and *Mr D. Byrne*, Certification Unit, EDQM, Council of Europe

- **Workshop 3:** Focus on sterile products: How to prepare a dossier and prepare for inspections

With the participation of: *Dr M. Dash*, Medicines and Healthcare products Regulatory Agency (UK) and a second Chemical Assessor for the Certification Procedure ; *Dr A. McMath*, Certification Unit, EDQM, Council of Europe and *Ms F. McLeod*, Certification Unit, EDQM, Council of Europe

- **Workshop 4:** Inspection of manufacturing sites: Chemical products

With the participation of: *Dr O. Gross*, WHO (CH) and a second Chemical Assessor for the Certification Procedure ; *Ms C. Pouget*, EDQM, Council of Europe and *Ms A. Gazal*, Certification Unit, EDQM, Council of Europe

Thursday 27 October 2005 afternoon (13:30 - 17:00)				
	Workshop 1 Revision & renewals procedures	Workshop2 Deficiencies in dossier	Workshop 3 Sterile products	Workshop 4 Inspections
13:30	Session 1	Session 1	Session 1	Session 1
15:00	75 participants	50 participants	25 participants	50 participants
15:00 - 15:30	Coffee break			
15:30	Session 2	Session 2	Session 2	Session 2
17:00	75 participants	50 participants	25 participants	50 participants
Friday 28 October 2005 morning (9:00 - 12:30)				
9:00	Session 3	Session 3	Session 3	Session 3
10:30	50 participants	75 participants	25 participants	50 participants
10:30 - 11:00	Coffee break			
11:00	6 One-to-One Sessions			
12:30	9 participants/session			

More information concerning the speakers and consultants in the workshops and one-to-one sessions is available on our website <http://www.pheur.org>.

Friday, 28 October 2005 9:00 - 16:00

Workshops and One-to-One Sessions

- Final session of each of the workshops

9:00

10:30 Coffee Break

- One-to-One personal appointments

11:00

Members of the EDQM scientific team and assessors will be available to discuss specific issues and to provide advice. The One-to-One sessions will be for 15 minutes per person and will be organised under several topics (such as renewals, variations, etc.). Prior appointment is necessary.

12:30 Lunch

Plenary session

- The Uses, Interests and Limits of Certificates: Viewpoints from the industry associations and regulatory authorities

14:00 Invited speakers: representatives from EFPIA, CEFIC-APIC, EGA and regulatory authorities

- Open Discussion & Debate: Views and questions from participants

15:00

- Final Conclusions. The benefits and cross-functional links between the Certification procedure, the European Pharmacopoeia, the EMEA, and National Authorities

15:30 **Dr J. L. Robert**, Chair QWP (EMEA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of Europe)

- Feedback from the workshops and the conference

15:45 **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

Close of meeting

16:00 Coffee break



Organisation

For more information, please contact the EDQM Public Relations Unit:

Mrs C. Larsen Le Tarnec, Mrs F. Baumgarthen • Tel.: +33 (0)3 88 41 30 30 • Fax: +33 (0)3 88 41 27 71

E-mail: publicrelations@pheur.org or visit the EDQM internet site: <http://www.pheur.org>

EDQM postal address: EDQM (European Pharmacopoeia) 226 avenue de Colmar, BP 907 •

F-67029 Strasbourg Cedex 1 • France