



## THE EDQM/ EUROPEAN PHARMACOPOEIA SYMPOSIUM

2 September 2005

### PROGRAMME

Seoul, Korea

#### Friday 2 September 2005 (9:30 - 12:00)

##### **Opening remarks and general introduction**

9:30 - 9:40 By the Korean authorities and **Dr Agnès Artiges**, Director EDQM, Council of Europe

#### **SESSION 1: GENERAL INTRODUCTION TO THE EUROPEAN REGULATORY SYSTEM**

*Place and role of the European Directorate for the Quality of Medicines (EDQM) and 5<sup>th</sup> Edition European Pharmacopoeia within the European regulatory system*

*The 5th Edition of the European Pharmacopoeia: Implementation and the publication schedule  
The key steps in the elaboration of a monograph*

9:40 - 10:10 **Dr Agnès Artiges**, Director EDQM, Council of Europe

#### **SESSION 2: HOW TO FIND YOUR WAY THROUGH THE EUROPEAN PHARMACOPOEIA**

##### **- General organisation of the European Pharmacopoeia**

- *Introduction*
- *General notices*
- *General methods and reagents*
- *General monographs*
- *Specific monographs*

##### **- Role and status**

##### **- Specific monographs: Cases studies and links with the Certificate of suitability of monographs of the European Pharmacopoeia (CEP)**

*An example of an excipient: lactose*

- *How to deal with solubility, polymorphism, identification, ...*
- *Relation with TSE certification*
- *Functionality-related testing*

*An example of an active ingredient: famotidine*

- *How to read the monograph*
- *How to deal with organic impurities, organic solvents, catalysts,*
- *Assay*
- *Reference standards*

10:10 – 11:10 **Dr Claude Coune**, Head of Division II, EDQM, Council of Europe

11:10 – 11:20 Coffee Break

#### **SESSION 3: KOREAN AUTHORITIES – KFDA**

##### **- General introduction to the DMF system in Korea**

11:20 – 12:00 **Mr Joon Han Lee**, Deputy Director of Pharmaceutical Safety Division, KFDA

**Friday 2 September 2005 (13:30-16:30)**

**SESSION 4: THE EUROPEAN PHARMACOPOEIA  
CERTIFICATION PROCEDURE AND INSPECTIONS**

**- General considerations on the Certification procedure and inspections**

- *How to apply for a Certificate of suitability*
- *Comments on main deficiencies found in dossiers*
- *Revision and renewal*

**13:30 – 14:50 Ms Corinne Pouget**, Head of Certification Unit, EDQM, Council of Europe

**14:50 – 15:00** Coffee Break

**SESSION 5: KOREAN INDUSTRY EXPERIENCE**

**- Experiences and objectives for EU market**

**15:00 – 15:50 Mr J. K. Ko**, President, Hanmi Fine Chemicals Co.

**SESSION 6: PANEL DISCUSSION – Q&A**

**Discussion with the participation of the EDQM, KFDA and KPTA  
representatives**

**15:50 – 16:30** Discussion

**16:30** Final addresses and Closure of the meeting

**IMPORTANT: ADDITIONAL INFORMATION**

For more information on the EDQM and the European Pharmacopoeia, please visit our Exhibition Booth: **Number 1B16**

**ONE TO ONE CONSULTATIONS**

During the two days, it will also be possible to arrange a short one-to-one consultation with an EDQM staff member to discuss any issue or pose any questions. Topics covered will include: EU Regulations; European Pharmacopoeia & Monographs, revisions; Publications & Internet services; Certification procedure.

Times will be scheduled on 1<sup>st</sup> and 2<sup>nd</sup> September but places are **limited**. Please complete the booking form published on the EDQM website and return it to the EDQM to guarantee your appointment.

**FOR MORE INFORMATION PLEASE VISIT THE WEBSITE :** <http://www.pheur.org>