International Conference organised by the
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

CERTIFICATION PROCEDURE
1992 - 2012: 20 Years of Experience
22-23 March, 2012

Duration: 2 days, Location: Palm Beach Hotel, Larnaca, Cyprus
Working language: English

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DRAFT PROGRAMME

Thursday, 22 March 2012

8:00-9:00 Registration

9:00-9:10 **Opening remarks**
Welcome Address

PLENARY SESSION

9:10-9:25 **The Evolution of 7th Edition of the European Pharmacopoeia and its impact on the Certification procedure**

9:25-9:45 **New developments in Certification and place of the procedure within the European regulatory framework**

9:45-10:15 **'Remember the Pioneers'**
Why did we invent the Certification Procedure? - Could not live without it!
Where do we stand after 20 years of running the certification procedure? A review

10:15-10:45 *Coffee break*

10:45 -11:05 **Use of CEPs outside Europe: Health Canada's experience**

11:05-11:25 **Use of CEPs outside Europe: Therapeutic Goods Administration's experience**

11:25-11:45 **Inspections of API manufacturers: What's new, new challenges to face, opportunities of international collaboration**

1145-12:05 **Inspections of API manufacturers: EDQM experience**

12:05-12:35 **Discussion**

12:35 -14:00 Lunch break

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WORKSHOP SESSIONS *(7 slides max. / presentation)*

There will be three parallel workshops (1st Session: 14:00-15:30 and 2nd Session: 16:00-17:30)
You are required to choose two workshops you wish to participate in when registering.

Time	Workshop 1	Workshop 2	Workshop 3
1st Session 14:00-15:30	**Process description and definition of starting materials**	**The EDQM inspection programme and international collaboration in the area of inspections of API manufacturers**	**Quality of antibiotics and fermentation products**
15:30-16:00	*Coffee Break*		
2nd Session 16:00-17:30 (Repeated)	**Process description and definition of starting materials**	**The EDQM inspection programme and international collaboration in the area of inspections of API manufacturers**	**Quality of antibiotics and fermentation products**

- **WORKSHOP 1**: **Process description and definition of starting materials**
  - National assessor taking part in Certification
  - Industry representative
  - National Inspector

- **WORKSHOP 2**: **The EDQM inspection programme and international collaboration in the area of inspections of API manufacturers**
  - U.S. Food and Drug Administration
  - Therapeutic Goods Administration – Australian Inspectorate
  - European Medicines Agency

- **WORKSHOP 3**: **Quality of antibiotics and fermentation products**
  - New EU Guideline on antibiotics
  - Quality of fermentation products
  - Ph. Eur. monographs for fermentation products

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Friday, 23 March 2012

PLENARY SESSION

9:00-10:00 **Feedback from the Workshops**

10:00-11:50 **The Interests, Use and Limits of Certificates: Viewpoints from the industry and regulatory authorities**

Industry Associations

10:00-10:10 European Federation of the Pharmaceutical Industries and Associations (EFPIA)

10:10-10:20 European Generic Medicines Association (EGA)

10:20-10:30 Association of the European Self-Medication Industry (AESGP)

10:30-10:40 European Chemical Industry Council (CEFIC) / Active Pharmaceutical Ingredients Committee (APIC)

10:40-10:50 China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

10:50-11:00 Indian Pharmaceutical Association (IPA)

11:00-11:30 *Coffee break*

11:30-11:50 *Regulatory authorities from Europe*

11:50-12:15 **Discussion**

12:15-12:45 **The benefits and cross-functional links between the Certification procedure, the European Pharmacopoeia, the EMA and National Authorities**

12:50 *Close of meeting*

13:00 *Lunch*