

THE INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL EUROPE
20TH ANNIVERSARY SEMINAR

26 JANUARY 2012

CATALONIA BERNA HOTEL, BARCELONA, SPAIN



**LOOKING
BACK,
MOVING
FORWARD**

25 January 2012 — The EXCiPACT Certification Scheme Launch

To all manufacturers, suppliers and users of pharmaceutical excipients,

SAVE THE DATE
25th January 2012
Catalonia Berna Hotel, Barcelona

The Launch of EXCiPACT™
the NEW international pharmaceutical excipients certifiable standard
for cGMP and cGDP Certification of excipient suppliers.

EXCiPACT
international excipients certification



EXCiPACT was initiated by a group of industry experts from the European Fine Chemical Group (EFCG), International Pharmaceutical Excipients Council (IPEC) Europe, IPEC Americas, European Association of Chemical Distributors (FECC), and the Pharmaceutical Quality Group (PQG) who have agreed to work together on the development of an international certification scheme for excipients suppliers.

The launch of the EXCiPACT Certification Scheme will take place on **25 January 2012** at 2 p.m. at the Catalonia Berna Hotel in Barcelona, Spain.

For further information please contact:

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IPEC Europe — 20th Anniversary Seminar — Looking back, Moving forward

SEMINAR PROGRAMME THURSDAY, 26 JANUARY 2012

08:15 REGISTRATION DESK

Session Chair: Dr. Patricia Rafidison

08:45 Opening Remarks — *Mrs. Beam Suffolk, IPEC Europe Chair*

09:00 IPEC Europe, 20 years: "The Good, The Bad and The Ugly" a retrospective — *Prof. Henk J. de Jong, Scientific Secretary FIP and Honorary member of IPEC Europe*

09:30 Harmonisation to become a reality — *Dr. Michael Wierer, Deputy Head, European Pharmacopoeia Department, EDQM*

10:00 Excipients global regulatory outlook: what is going on and what will change

- US regulatory outlook — *Mr. Dale Carter, IPEC Americas Chair*
- The current state of Japanese Pharmaceutical Excipients (JPE) and self-imposed standard GMP, GMP auditing board for pharmaceutical excipients in IPEC Japan — *Dr. Keiji Kijima, IPEC Japan Secretary General*
- Chinese regulatory outlook — *Mr. Martin Tao, Asia Pacific Regulatory Manager, FMC and IPEC China member*

10:45 COFFEE BREAK WITH POSTER EXHIBITION

11:15 Managing risk to fit excipient reality

- Supply chain security: European perspective
 - Regulator perspective — *Mr. Richard Andrews, Operations Manager MHRA*
 - Industry perspective — *Ms. Lynne Byers, VP, Quality Shared Services, GSK and Rx-360 Chair*
- Overview and Example of Quality Risk Assessments — *Mr. Steve Porter, Quality Assurance Director, Global External Sourcing, AstraZeneca and IPEC Europe Board member*

12:45 LUNCH

Session Chair: Ms. Kate Denton

14:00 Excipients: providing an innovative edge for drug developers

- Nanometric drug delivery systems: a story of amphiphilic excipients — *Prof. Patrick Saulnier, University of Pharmacy Angers (Fr)*
- Functional excipients for drug delivery and targeting — *Dr. Mark Perkins, Technical Product Specialist, Novozymes*
- Excipients: Challenges in paediatric formulation development — *Mr. Carl Mroz, Director Global Regulatory Affairs, Colorcon and IPEC Europe Quality & RA Committee Chair*

15:30 COFFEE BREAK WITH POSTER EXHIBITION

16:00 FDA's views on supply chain security — *Mr. Steve Wolfgang, PhD, Acting Associate Director, Risk Science, Intelligence and Prioritization CDER, FDA (by teleconference)*

16:30 Panel Session: *Facing up to the future*

17:00 CLOSING REMARKS — *Mrs. Beam Suffolk, IPEC Europe Chair*

18:45 Meet in the lobby

19:00 Departure from Catalonia Berna Hotel

19:15 Cocktail and IPEC Europe Award Ceremony

19:45 GALA DINNER





ABOUT IPEC EUROPE

IPEC Europe, the International Pharmaceutical Excipients Council Europe, is an association that serves the interests of producers, distributors and users of pharmaceutical excipients. Together with its sister associations, IPEC Americas, IPEC Japan and IPEC China, IPEC Europe is a member of IPEC Federation whose global membership extends to more than 200 companies.

IPEC Europe represents the views of its members to appropriate regulatory bodies (European Commission, EMA, European Pharmacopoeia) and is recognised by Government agencies around the world as the voice of European producers and users of pharmaceutical excipients. Combined advocacy is essential to ensure introduction to the market of safe new excipients which meet globally accepted standards.

In 2011 IPEC Europe counts 77 full members, plus 2 associated and 1 co-opted member. Activities are organised through Committees or Working Parties, the activities of which are communicated during the Annual General Meeting and in the IPEC Europe newsletter, which are regularly posted on the news section of IPEC Europe homepage.

REGISTRATION AND FURTHER INFORMATION

The Registration Fee is **200 Euro** for IPEC Europe member companies and **600 Euro** for non-IPEC Europe members. This fee includes the seminar material and covers the coffee breaks, lunch and networking dinner. The fee does not cover the accommodation.

To register or obtain further information please contact:

Event Solutions

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GENERAL INFORMATION

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