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**NEWS RELEASE**

## **EFCG AND IPEC EUROPE JOIN FORCES TO CREATE A EUROPEAN PHARMACEUTICAL EXCIPIENTS CERTIFICATION PROJECT**

**Brussels, 30<sup>th</sup> September 2008.** In June, EFCG and IPEC Europe announced the signing of a Memorandum of Understanding that would lead to close collaboration of the two associations on the development of a certification programme for manufacturers and distributors of pharmaceutical excipients, covering both Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP).

The associations are now pleased to announce that they have formed a European Pharmaceutical Excipients Certification Project to develop advocacy and stakeholder management in Europe and to give advice to two European working teams.

A Certification Team will cover excipient classification (with global scope) and a European certification scheme. An Audit Team will tackle European auditor competency and an assessment body certification with the suggested involvement of European regulatory agencies. A European Stakeholder Workshop is being planned for early 2009 to review the progress of these two teams.

In parallel, IPEC Americas, IPEC Europe and PQG, are developing a certifiable, global standard, under the guidance of an IPEC/PQG steering committee.

This excipient certification programme is being developed in conjunction with other trade associations worldwide who have a similar interest in pharmaceutical excipients. This should result in a truly international certification programme.

Recently, several incidents concerning both pharmaceutical excipients and active pharmaceutical ingredients have highlighted the serious risk to patients that arises when the quality of pharmaceutical raw materials has been compromised. In the absence of any regulations that require GMP and GDP for excipients, there is a critical need for the excipient industry to demonstrate a commitment to the delivery of high quality products throughout manufacture and distribution.

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### **Note for Editors**

**EFCG** - The European Fine Chemicals Group - a sector group of CEFIC, the European Chemicals Industry Council - was formed in 2004 to be the forum, the focus and the voice for European Fine Chemical Manufacturers. The issues affecting its members' competitiveness drive EFCG. One such issue is the need for certifiable, enforceable, adequate and appropriate quality standards for pharmaceutical excipients destined for use in European medicines.

For further information of excipients, contact: Dr Tim Boelke, BASF, [tim.boelke@basf.com](mailto:tim.boelke@basf.com). For further information on EFCG, visit <http://efcg.cefic.org>.

### **IPEC EUROPE**

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed in 1991 by manufacturers and end-users of pharmaceutical excipients. It is an association comprising three regional pharmaceutical excipient industry associations covering the United States, Europe and Japan (which are known respectively as IPEC-Americas, IPEC Europe and JPEC). IPEC's objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of good manufacturing practice for excipients.

For further information of excipients, contact: Dr Iain Moore, Croda Europe Ltd, [iain.moore@croda.com](mailto:iain.moore@croda.com). For further information on IPEC Europe, visit [www.ipec.org](http://www.ipec.org).