

Brussels, 29<sup>th</sup> April, 2013

**Subject : Public consultation on the Draft Guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients of medicinal products for human use**

Dear Sir/Madam,

EFCG, the European Fine Chemicals Group, a sector group of CEFIC, the European Chemical Industries Council, is a non-profit association of European manufacturers of fine chemicals, including certain pharmaceutical excipients.

Since 2008, EFCG has developed a special relationship with IPEC Europe through common membership and close collaboration on projects involving pharmaceutical excipients. As such, we have been closely involved with their development of input to this consultation process.

We are, therefore, pleased to fully endorse the IPEC Europe document entitled *IPEC Europe Observations and Recommendations on "Guidelines On The Formalised Risk Assessment For Ascertaining The Appropriate Good Manufacturing Practice For Excipients Of Medicinal Products For Human Use"* to the public consultation process as submitted to DG Sanco on 26th April, 2013.

Yours sincerely,



**DR BRIAN M MURPHY**  
**PRESIDENT**