

For more information: Tony Scott info@efcg.cefic.org +441428653510

EU Health Inspectors and Qualified Persons gather in Barcelona for an unprecedented open discussion on compliance issues for active pharmaceutical ingredients

Brussels, 20 March 2006 – The European Fine Chemicals Group (EFCG), representing over 200 European producers of fine chemicals, are concerned that Member States have widely differing traditions and a diverse approach to meeting requirements in the fields of quality and safety standards of medicines. As a step to bring these traditions together, EFCG is organising its **1st Pharma Business Conference "The Sourcing of Compliant APIs" in Barcelona on 27-28 April 2006**, see <http://www.efcg-conference.org>.

With around 80% of the volume of active pharmaceutical ingredients (or APIs), used to make EU's medicines now being imported from India and China - from manufacturing plants unlikely ever to have been inspected by an EU official - the EU has finally implemented new laws making it mandatory for EU medicines to be made only with APIs that have been manufactured under GMP. However, as there is no systematic enforcement of this new legal requirement, the responsibility for compliance with the law to ensure the quality and safety standards of medicines, belongs to the Qualified Person (QP) in each pharmaceutical company.

The QP (also known as '*Director Técnico*', '*Pharmacien Responsable*', '*Sachkundige Person*'...) is, therefore, a critical element of the EU authorities architecture for the quality and safety of medicines' quality and is its sole goalkeeper. His or her signature vouches for the GMP compliance quality of the API used. The 1st EFCG Pharma Business Conference in Barcelona will answer the following questions:

- What is the QP's liability under the new regulations?
- How can the QP discharge the new responsibilities?
- What are Regulators expecting?
- How can API producers evidence compliance to their customers?
- Bad practices: what can go wrong? Dangerous precedents and API broker tricks
- How to establish a successful international GMP audit program?

The presence of senior staff from **EMA, EDQM, EU Commission, the German, French, Italian, Spanish and Swedish Medicines Agencies** indicates their concern and need to clarify the practical aspects of the requirements. In addition, industry representatives from Genzyme, Hovione, Medichem, and Merck Generics will discuss the new EU legislation from their standpoint.

Bringing together the key players responsible for the quality of APIs who determine the quality and safety of EU medicines – **QPs, QA people and Inspectors** – provides the opportunity for informal dialogue in parallel sessions (in Spanish, English, French, and German), between purchasers of APIs, producers of APIs and regulators to address the specificities of the situation in Member States. Copies of the conference proceedings will be made available, including transcripts of the Q&A sessions after approval of the health authorities. EFCG welcomes interested QPs, who may not be able to attend, to send their questions ahead to info@efcg.cefic.org

At the conference, EFCG will announce the findings of its Europe-wide benchmarking survey to establish the level of readiness of Health Authorities to ensure enforcement of the new compliance requirements. To date Denmark seems to have taken the lead in communicating its expectations - see a Q&A in their website <http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=8127#3>

EFCG is the Cefic sector group that represents the interests of the EU fine chemical producers and, through its members, it speaks for over 200 API producers. Working for a level playing field in Europe is the uphill battle EFCG continues to fight to defend the interests of European citizens, who may be exposed to non-compliant drugs, and the European fine chemicals industry, whose future competitiveness depends on effective enforcement of the new GMP compliance laws – see <http://efcg.cefic.org>

END