Subject: Public Consultation on cGMP in Active Pharmaceutical Ingredients

Lodi (Italy) 6th of May 2008

Euticals Spa is a privately owned company manufacturing API and key Intermediates for the Pharmaceuticals Worldwide market.
The group is constituted of 4 sites located in Italy (Lombardia Region) .
The main focus is in Oncolitics,CNS,GI and Monobactams.
Main markets are US and Europe. We have also a significant presence in Eastern Europe, India, Japan, China and Korea. It is important also the involvement we have in the Custom Synthesis of New Chemical Entities with a potential Pharmacological Activity.
The total turnover is close to 50 mio of euros with 190 employees.
All plants operate under cGMP rules and apply the highest standards in order to deliver high quality products.

We are concerned about the possibility to introduce in the market the APIs non consistently produced according to cGMP. Based of our long experience in the industry we believe that a close monitoring of cGMP application must be in place. This can be assured only through an evaluation of the Quality Systems made by European Health Authorities.
Presently we do not feel that all products entering the European market are manufactured following the same level of standards (i.e. ICHQ7A). This definitely could harm the health of patients.

Therefore sharing the same European Community concerns, we propose to make a legislation which take care of the aforementioned issues.
In order to do that it may be useful that the new regulation consider what is reported in Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by the European Parliament that basically ask for manufacturing sites inspection made regularly by European Regulatoriy Agencies and a complete traceability on where that products have been manufactured.

We do hope that this sensitive topic will enter soon in the European Parliament agenda with a fast approval track.

Respectfully

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