

## **ERREGIERRE S.p.A.**

Erregierre is a privately owned Italian company founded in 1974. Today Erregierre is one of the leading companies manufacturing Active Ingredients for Pharmaceuticals use (API).

The Company invests in human and technological resources to improve its know-how and to provide its international customers all over the world (Europe, America, Far and Middle East).

Erregierre is regularly inspected by AIFA and U.S. FDA.

Erregierre fully agrees with the European Commission's concerns about the introduction into the market of APIs coming from extra-European countries, where the compliance to cGMPs quality standards is not verified by an European Regulatory Authority. The Company shares the concerns relevant to such potential risk for human health due to a declared, but not verified "on site" compliance to the requested quality standards ( i.e. ICH Q7a).

Therefore ERREGIERRE suggests and strongly recommends to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way ERREGIERRE asks to consider what it's requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30<sup>th</sup> 2006 by European Parliament, that is:

- a) Mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU;
- b) Traceability of APIs (i.e. the possibility to locate the source).