Distinguished participants,

Warm welcomes to all of you, both to the European Union inspectors and to the inspectors coming from the developing countries. It is with great pleasure that I welcome you to this seventh GCP training course and to this wonderful city.

I would like to underline the relevance of this course as the annual main event in the inspectors' training. As everybody knows, the Directive 2005/28 requires that each Member State ensures to all GCP inspectors an appropriate training to maintain and improve their professional skills.

This training course represents not only a remarkable moment of your professional growth but it is also a chance - for every country - to raise awareness about the deep importance of common inspection procedures and methodology. This fundamental harmonization could be achieved only through training and exchange of experiences.
To this purpose, EMEA and FDA have jointly signed an agreement that facilitates the sharing of information, including reports about GCP inspections for specific products. This is another footstep toward the harmonization of the procedures and to reach a common approach.

-I have noticed that- some breakout sessions on different case studies have been included in this training course programme. This is very important to stimulate the discussion in order to achieve the same approach.

The Italian Medicine Agency has a specific interest in international initiatives in the field of regulatory activities and, in particular, AIFA has a programme dedicated to the promotion of GCP.

In 2008 and 2009 AIFA has implemented a specific project in collaboration with UNICRI, the United Nations Interregional Crime and Justice Research Institute, for the protection of human rights in the field of biomedical research and clinical trials, on the basis of the GCP principle *"the rights, safety and well being of the trial subjects are the most important considerations and should prevail over interests of science and society".*

The AIFA and UNICRI project has represented an effort to investigate the ethical and legal implications surrounding the conduct of clinical trials of drugs with human participants in developing countries and to support national sustainable capacity in health research.

The project has culminated in an international round table, held in Rome - at FAO headquarters - in December 2008 with the participation of European Union inspectors. The event has represented an opportunity for participants to exchange experiences and know-how, to promote the implementation of international instruments.

The programme of your training course foresees a specific session on "Inspections of clinical trials in third countries".
Because of the AIFA experience in this field, AIFA Inspectorate, engaged in these activities, will have the opportunity to present its experience.

I would like also to communicate to all the participants, EMEA, UE and extra UE Inspectorates that for the year 2010, AIFA is planning GCP training courses for inspectors of selected African countries, in collaboration with international Organizations, local Regulatory Authorities and available EU Inspectorates.
We believe that it is possible to achieve the international harmonization of inspection procedures and the respect of ethical principles of GCP at international level only by the integration of Member States projects with international projects and with the current EMEA initiatives, on the acceptance on clinical trials conducted in third countries.

In conclusion, I would like to wish to all of you that these three days of training would contribute to improve the acknowledge and the professional skills of each participant. This could represent one of the steps in reaching the harmonization I have just mentioned.

I hope that you enjoy all the cultural activities that our Agency has planned for this training course.

Finally, I would like to wish to you all the best, both during the time spent here in the meeting and in Rome!

Thank you