Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)

CHAPTER 2

GOOD CLINICAL PRACTICE FOR THE DESIGN, CONDUCT, RECORDING AND REPORTING OF CLINICAL TRIALS

SECTION 1

GOOD CLINICAL PRACTICE

Article 2

1 The rights, safety and well being of the trial subjects shall prevail over the interests of science and society.

2 Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks.

3 Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4 The necessary procedures to secure the quality of every aspect of the trials shall be complied with.

Article 3

The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

Clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996).

Article 4

The protocol referred to in point (h) of Article 2 of Directive 2001/20/EC shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

Article 5

All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.