[S4-1] [10/22/2004(Fri) 9:30-10:00/Room 204]

Guideline on Safety Pharmacology Studies

Young-Ok Kim

Drug Evaluation Department, KFDA

The "ICH Guideline on Safety Pharmacology Studies for Human Pharmaceuticals" was recommended at step 4 of ICH Process on November 2000 by the ICH (ICH S7A) and distributed to the world in 2001. The guideline is based upon the vest currently available science. The objectives of safety pharmacology studies are : 1) to identify undesirable pharmacodynamic properties of a substance that may have relevance to its human safety; 2) to evaluate adverse pharmacodynamic and/or pathophysiological effects of a substance observed in toxicology and/or clinical studies; 3) to investigate mechanism of the adverse pharmacodynamic effects observed and/or suspected. A new chemical entity should be assessed for side effects, initially in those physilological systems which are generally agreed to be the key systems that are essential for life, these core system include the central nervous system, cardiovascular system and respiratory system in safety pharmacology studies, and the studies should be conducted according to good laboratory practice(GLP) guideline. The pharmaceuticals to be tested are described in ICH S7A. principles and recommendations concerning study design, including concentration and dose ranges, described in ICH S7A also apply to the studies conducted in accordance with the present guidelines

However, the Korea Food and Drug Administration(KFDA) notified the guileline for general pharmacology in 1997, and the KFDA general pharmacology studies have been considered as an important standard in drug safety assessment and thes were orginally referred to those designed to examine effects other than the primary therapeutic effect of a drug candidate. The KFDA guideline on general pharmacology study and ICH guideline on safety pharmacology study is very similar, however there are some difference such as "core baterry", a point of time studing according to test items. And it is difficult fo us to review the data of safety pharmacology study submitted instead of the general pharmacology for drug approval.

Therefore, now the KFDA is preparing the "KFDA draft guideline on safety pharmacology studies for human pharmaceuticals", will be enacted after a while, and also the KFDA will enact the amendment of GLP guideline including the safety pharmacology study. I would like to talk about the KFDA draft guideline on safety pharmacology studies for human pharmaceuticals and draft amendment of GLP guideline.