From the Viewpoint of Regulatory Authorities

Kazuhiko Mori (Pharmaceuticals and Medical Devices Organization)

The introduction of exploratory clinical pharmacokinetics studies (ex. micro dosing study) seems to improve efficiency and speed of new drug development significantly. However, many problems exist clearly, from the viewpoint of regulatory authorities when introducing it completely.

The biggest problem is how to consider a subject's risk and to cope with it. The first entry into human of the new drug candidate substance is not able to avoid the subject's exposure to the unknown risk to some extent. In that case, it is required to estimate known risk and reduce it and to detect the unknown risk which still remains especially at early stage of clinical development as well.

The pharmaceutical companies should notify a first time IND notification under the Pharmaceutical Affairs Law, and the regulation side is necessary to finish the investigation from a viewpoint of safety within 30 days. It is very important what kind of scientific data (non-clinical safety test results etc.) need to be prepared in advance. The fundamental points to consider are shown in ICH-M3 guideline.

If it considers that human micro dosing studies also receives this regulation, unless simple rationalization of the safety test data needed about each candidate substance will be carried out, it will become impossible to achieve the original mission of screening many candidate substances by humans quickly, under the present Japanese pharmaceutical regulatory system.

It is clear that positive approach is required also from a regulatory authorities side in how the new technique of realizing efficient new drug development is introduced, securing a subject's safety.