KFDA-SUPAC
Recent Trend of Pharmaceutical Regulations

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Recently, the circumstance surrounding pharmaceutical products has greatly changed due to the international globalization : ICH regulatory harmonization, and the innovation of pharmaceutical sciences, advanced technologies and different medical system. Such changes have significantly affected our regulations that resulted in a recent great revision of our pharmaceutical regulations. Many generics have been used and there are so many generic drugs in our country. Since 2001 the generic drugs must be proved therapeutical equivalence by bioequivalence studies for the generic substitution. And it is important to preserve the quality of postapproval drugs.

The major change in our regulation is to be proved when there are making postapproval changes. The postapproval changes are including variations in the components and composition of formulation, the site of manufacturing, batch size, manufacturing process. The regulations defined levels of changes and dissolution and bioequivalence data should be submitted to the KFDA for each level of changes.

After new drug is approved by various preclinical and clinical studies, commercial product such as lot A is produced which is usually larger in the production scale compared with the clinical lot. Sometimes, the manufacturing method for the commercial products is changed and commercial lot B is produced. In this process, all of products should be the same in drug quality even if scale-up for oral drugs. The reason for the different dissolution may be ascribed to the failures in scale-up or poor data are available on the scale-up and manufacturing control. The identification of critical manufacturing variables and their control are very important for the quality assurance of drug products.

For these concerns KFDA and pharmaceutical industries have made much efforts during past 4 years. Manufacturing process changes should be conducted based upon not only by the product specifications, but also by the pharmaceutical and process developments data. All quality attributes potentially impacted by the changes should be evaluated. In vitro or in vivo equivalence tests for manufacturing changes should be carried out according to the procedures described in our guidelines.

FDA have already some guidelines for scale up and postapproval changes, SUPAC-IR and SUPAC-MR, and there is the draft guideline for manufacturing change of IR product in Japan.

In this time I would like to introduce "what are or will be changed in our regulation for the postapproval changes" and "what is the difference between our regulation and that of other countries".