Revised Provision for Specifications and Test Procedures of Drugs

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The Provision for Specifications and Test Procedures of Drugs was revised October 19, 2005. This Provision has been revised five times so far since the publication of the first provision on December 31, 1998 by the KFDA.

In accordance with speedy development of new drugs and improvement of science and technology, the need of revision of The Provision for Specifications and Test Procedures of Drugs through the ICH guidelines is getting higher.

As a consequence of that, the provision for Specifications and Test Procedures of Drugs has been updated.

The Major changes of the revision are as follows.

1. To make clear understanding of regulation, Glossary was newly added.

2. The Provision was categorized by Drug, Drug Substance, Herbal medicines, Biologics, Recombinant drug products, Cell therapy products, Gene Therapy, Quasi Drugs, In vitro diagnostic products to search easily.

3. The impurity regulation like degradation products and residual solvents was consolidated to harmonize with international regulations.

This presentation will focus on the outlines of the provision, principle of revision and the major changes of this revision. And I will show many examples.