[S9-2] [11/29/2005(Tues) 09:30-10:00/ Guhmoongo Hall B]

Analytical Chemometrics for Process Analytical Technology

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Process Analytical Technologies(PATs) can be understood as integrated systems designed for continuous analysis and control of pharmaceutical manufacturing processes based on real-time or rapid measurements of quality and performance attributes of raw and in-process materials and processes to assure acceptable end product quality at the completion of the process. PATs are related with the concept that the quality of drug products should be built in the design of end products. In other words, quality control tests to end products cannot assure the quality of drug products. The meaning of "analytical" is a broad concept of integration of chemical, physical, microbiological and risk analytical methods.

One of the essential tools of PAT is a discipline of multivariate data acquisition and analysis, which is analytical chemometrics. The results from chemometric analysis are used for end point and instrument control in relation with monitor devices and finally enable continuous renovation and knowledge management.

The presentation will deal with basic concepts of analytical chemometrics for process analysis and control, which includes methods of multivariate statistics, pattern recognition, principal components analysis, multivariate regression analysis and so on. These algorithms will be discussed as chemometric and statistical tools needed for the use of PATs in pharmaceutical manufacturing, validation of chemometric based process analytical technologies and maintenance such as re-calibration, cause analysis of OOS findings, etc of chemometric based processes.

The discussion will be extended to some of the regulatory hurdles that may be encountered while changing from conventional methods for process monitoring and control to new PATs.