[W-4] [10/22/2004(Fri) 11:50-12:30/Room 205]

Process Analytical Technology (PAT) for Pharmaceutical Industries

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Process Analytical Technology(PAT) means the integrated system 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. PAT is related with the concept that the quality of drug products should be built in the design of end products. In other words, quality control test 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.

The tools of PAT are: ① multivariate data acquition and analysis(Analytical Chemometrics), ② upfront process analyzers and process analytical instruments, ③ process monitors for end point and control instruments, ④ continuous renovation and knowledge management tools.

Application of PAT increases the efficiency while reducing the risk in the aspects of quality and official management. This aspect is achieved by: ① reduction of production cycle by on-line, in-line, at-line and non-invasive measurements and control, ② prevention of faults, scraps and reprocessing, ③ possibility of real-time release, ④ increased automation for safety of operators and reduction of human errors ⑤ use of continuous process to increase the efficiency and to control the variability.

The presentation will deal with the following subject to establish the basic concepts of PAT: ① examples of unit processes for the production of drug products which can be enhanced by PAT, ② analytical instruments for process analysis and comparison of on-line, in-line, at-line and non-invasive analyses, ③ analytical chemometrics for process analysis and control, which includes methods of multivariate statistics, pattern recognition, principal components analysis, multivariate regression analysis and so on. In addition to this, relationship of PAT with official managements by pharmacopoeia and/or official analytical methods will be discussed, and safe win-win approach to PAT for KFDA and pharmaceutical industries will be discussed with examples made by USP and American FDA.