ABSTRACT

Title : A Study for Continuous Quality Improvement in Pharmaceutical Industry

A Case Study of a Human Medicinal Products Factory

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At present, the Pharmaceutical industries in Thailand need to have a higher production standard conforming to the PIC/S (Pharmaceutical Inspection Co-operation Scheme). It is, therefore, a must to implement the better quality management to assure the Pharmaceutical production system. The objective of this study is to determine the approaches to improve continuously the Pharmaceutical production quality.

In this study, the factors that affect the quality of the Pharmaceutical production shall be considered and implemented with the quality management system using quality tools such as 6 Sigma, Statistic Process Control, Cause and Effect Diagram and Risk Assessment.

From the study, it is revealed that the controllable factors are the physical and chemical properties of material, the production time, the production process, production environment and machine capability. The uncontrollable/unexpected factors are electrical breakdown, accidents, the absent and the operators' malfunction together with the uncertainty from the analysis. The improvement for the Pharmaceutical process in term of production efficiency can be increased by 18.85 % and in term of defects decrease by 4.25 %.