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CASE REPORT

Analysis of the Implementation of Total Productive Maintenance, Total Quality Management, and Just-In-Time in Pharmaceutical Manufacturing

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Abstract In the pharmaceutical industry, systems for improving operational effectiveness and efficiency are becoming more and more popular. In this paper, developments in the industry's improvements in operational effectiveness and efficiency have been analyzed. A holistic model is presented which builds the basis for the presented study results. The study includes data gathered from pharmaceutical production sites in surveys in 2004 and 2009. The analysis is divided according to the four sub-systems: Total Productive Maintenance, Total Quality Management, Just-in-Time, and the Management System. For each sub-system, key performance indicators and associated elements (practices and instruments) from 2004 to 2009 are investigated. The data indicates that the industry did make continuous steps towards "Excellence in Operations" between 2004 and 2009. Pharmaceutical companies took control over their former low asset utilization and managed to improve the efficiency of their quality systems; however, they are still far away from having any kind of "continuous flow", smooth production scheduling or make-to-order manufacturing. It can be said that most of the companies are still working on the effectiveness side rather than focusing on the efficiency side.

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Background

The pharmaceutical industry is facing severe quality problems. The Food and Drug Administration (FDA) is reporting an increase by 309% from 426 drug recalls in 2008 to 1,742 drug recalls in 2009 [1]. Some of the recalls may be triggered by an increase of FDA inspections of production facilities. But, the large majority of the issues leading to the recalls of drugs on the global market can be traced back to shortcomings in supply and manufacturing such as poor quality of raw materials, incorrect packaging, and contamination of products. The incident with heparin that resulted in 484 deaths in 2007 and 2008, was the outcome of deviations from "current good manufacturing practices" (cGMP) in the production and quality control of the drug's active pharmaceutical ingredient, manufactured by Chinese suppliers [2, 3]. Additionally, examples of issues with production sites of established pharmaceutical companies in the USA and Western Europe lead to the conclusion that poor quality is not only an issue for low-cost production countries. The cGMP and contamination issues with the Genzyme facility in Allston Landing, one of the largest cell-culture manufacturing plants in June 2009 resulted in an expenditure of $184.2 million for decontamination and fine and an estimated loss in revenue of $1 billion [4].

Due to the recent incidents, pharmaceutical companies either with in-house manufacturing or with external contract manufacturing are concerned with the capability