

Executive Summary

The history of Lean manufacturing is briefly discussed, tracing back to the implementation of the Toyota Way in the 1930's to the unique solutions to manufacturing challenges in post-World War 2 Japan. The growth of Lean ideas is traced until the term "Lean" was finally coined by John Krafcik in 1988. Major adoption of Lean was seen by western companies in the 80's & 90's. Today, the main topic of research in the field are methods for Lean implementation.

The history of the pharmaceutical industry was revisited, and manufacturing advances were studied. The pharmaceutical supply chain management and influence of JIT was analyzed. The pharmaceutical manufacturing industry is high-mix, low to medium volume operations and Lean methods such as KANBAN, POLCA, CONWIP are applied to manufacture drugs per patient demand. The current industry is susceptible to disruptions caused by events such as the COVID-19 pandemic that caused surge in demand while shortage of supplies. The result was a strain on drug production and failure of Lean methods to cope. Six sigma methodologies are used to improve quality of manufacturing processes by reducing variability and defects. Another lean based method of 5S is used to optimize layout of manufacturing plants and promote efficiency of KANBAN on the production floor.

Current methods of demand forecasting in pharmaceutical manufacturing are discussed, highlighting how due to the high profit margins in patented drugs, it is the generic drug manufacturers that are forced to bring value through an optimized supply chain. Secondly, current demand forecasting methods are a mix of excel based and qualitative methods with an average accuracy of 40%. There is a clear gap and need for the application of AI based forecasting technology to increase the accuracy of forecasts.

An updated framework was developed using best practices to improve the current Lean manufacturing methods in order to alleviate deficiencies of JIT based methods. The framework utilizes updated ERP systems and integrating AI to improve demand forecasting for better preparedness of raw material availability in uncertain circumstances. Furthermore, six sigma principles can be applied to the scheduling and planning process to reduce variability and improve KANBAN and POLCA implementation to continuously improve cycle times, product throughput, and inventory management.