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Lean Manufacturing - A Continuous Improvement Plan

Indian Pharmaceutical market is approximately about US\$21.04 B, with a growth over 22% at 18.81% CAGR in last few years. India ranks 4th in terms of volume, in top 15 drug manufacturing worldwide. India has over 80 US FDA approved plants, 2nd highest in the world. Pharmaceutical industry is competitive in nature for manufacturing cost-effective generic drugs conforming to global standards and it is highly regulated & Knowledge intensive. Due to this very fact SMEs have a barrier to enter into the global market. To achieve and maintain a competitive position in today turbulent economy, pharmaceutical companies are pursuing a various improvement initiatives such as “Lean Manufacturing” for sustaining the business.

Understanding Lean

Every organization as a rule creates wastes. Lean Serves to *eliminate variability & waste* leading to Non Value Adds thus it optimize processes, eliminate defects and dramatically reduce Inventories and lead time. Lean, SixSigma, ToC, etc., are initiatives that were born from the pursuit of operational excellence within the manufacturing companies. While Lean Serves to eliminate waste leading to Muda, Muri and Mura.

Lean Transformation in Life Sciences Industries

While pursuing lean in pharmaceutical sector, it is very much essential to ensure that the GxP perspective is not impacted adversely as this sector is highly regulated and is governed by GxP(GMP,GDP,GAMP,GCP)., and Drug Master Filing is essential for business across regions. The impact in Pharmaceutical manufacturing activities is categorized as *direct and indirect impact /elements* from the GMP and regulatory perspective.

Direct Effect

Any activity or process, that get into the DMF principally includes site, material, test methods, production process, machine and process equipment which the manufacturer has to

comply while product distribution to customer. Any change in these components results in notification, updation and amendments to customers, as well as regulatory authorities like FDA. Therefore, while implementing lean the impact study is a must and must follow a consolidated plan and scheduling for all the direct components of DMF mentioned above. The project time for change implementation depends upon the following.

- a) Spread of your product registration (DMF)
- b) Customer base linked to DMF and life cycle of drug product dossier
- c) Cost benefit analysis of change

Depending upon the above situation timelines on change regularization can vary from 6 months to 36 months.

Indirect Effect

Involves removing waste from processes and system procedures like changeover time, WIP reduction, document flow, etc which can be made lean to improve efficiency.

Conclusion: Lean Implementation does Not Need to Be Complicated

Becoming lean is not a destination but a continuous process . There are no well-defined formulae, which can result in a lean organization. It has to be implemented respective to the intricacies and uniqueness of each organization. In drug manufacturing there are enough scope for going lean but with restrictions and limitations to realize the changes fast. Hence, patience and sustenance is the key to success. Lean requires the right systems to be in place and should be driven by the right kind of leadership. Above all, lean needs to be sustained over a period of time to bring about meaningful results.