



Applying Lean Six Sigma in the Pharmaceutical Industry

Bikash Chatterjee

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Bikash Chatterjee emphasizes the criticality of applying the principles of Lean and Six Sigma within the paradigm of the drug development process. His guide to operational excellence in the pharmaceutical and biotech industries is a focused summary of the application of Lean Six Sigma theory to the regulated life sciences. From molecule discovery to the application of PAT Applying Lean Six Sigma in the Pharmaceutical Industry will highlight the importance of framing these initiatives within the key deliverables of drug development manufacturing and quality. Challenging conventional wisdom the author offers a quality and efficiency perspective as a foundation for the principles of Quality by Design, PAT and the new philosophies underlying Process Validation. Each chapter includes discussion around the considerations for applying Lean manufacturing and Six Sigma principles and their tools, culminating in a case study to illustrate the application. The book is organized to reflect the major work centers involved in the drug development lifecycle. Each chapter is stand-alone but together they illustrate the necessary synergy between Lean, Six Sigma and compliance sensibilities required to be successful in the pharmaceutical industry. These design, manufacturing and management techniques are not without their challenges. Bikash Chatterjee's book offers the roadmap for an industry that is struggling to reinvent many of its development and business processes.

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