



Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics

Brian K. Nunnally, John S. McConnell

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The pharmaceutical industry is under increasing pressure to do *more* with *less*. Drug discovery, development, and clinical trial costs remain high and are subject to rampant inflation. Ever greater regulatory compliance forces manufacturing costs to rise despite social demands for more affordable health care. Traditional methodologies are failing and the industry needs to find new and innovative approaches for everything it does.

Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics is the first book to focus on the building blocks of understanding and reducing variation using the Six Sigma method as applied specifically to the pharmaceutical industry. It introduces the fundamentals of Six Sigma, examines control chart theory and practice, and explains the concept of variation management and reduction. Describing the approaches and techniques responsible for their own significant success, the authors provide more than just a set of tools, but the basis of a complete operating philosophy. Allowing other references to cover the structural elements of Six Sigma, this book focuses on core concepts and their implementation to improve the existing products and processes in the pharmaceutical industry. The first half of the book uses simple models and descriptions of practical experiments to lay out a conceptual framework for understanding variation, while the second half introduces control chart theory and practice. Using case studies and statistics, the book illustrates the concepts and explains their application to actual workplace improvements.

Designed primarily for the pharmaceutical industry, **Six Sigma in the Pharmaceutical Industry: Understanding, Reducing, and Controlling Variation in Pharmaceuticals and Biologics** provides the fundamentals of variation management and reduction in sufficient detail to assist in transforming established methodologies into new and efficient techniques.

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