A History of a cGMP Medical Event Investigation

Michael A. Brown

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Case study details the right way and the wrong way to successfully develop and market a new drug

Beginning with the untimely death of a young mother, *A History of a cGMP Medical Event Investigation* unfolds a fictitious case study that captures how unchecked human flaws during the development and launch of a new drug can lead to disastrous consequences. Moreover, it illustrates how and why Six Sigma principles and methods should be applied to fully comply with FDA regulations at every stage of drug development and commercialization.

From initial transgenic mouse studies to the FDA fatality investigation, this case study introduces all the key regulations and practices that govern the development, manufacture, and marketing of a new drug, including:

- FDA Investigational and New Drug Application Processes
- FDA Code of Federal Regulations' current Good Manufacturing Practice (cGMP)
- ISPE Good Automated Manufacturing Practice (GAMP)

Readers will also be introduced to a variety of managers and researchers whose personal agendas conflict with best practices and therefore compromise the safety and effectiveness of a new drug product. Throughout the case study, the author offers tested and proven practices and tips so that these human flaws are not translated into drug product flaws. These practices and tips are critical and typically can only be learned through years of experience working in competitive drug development environments.

A History of a cGMP Medical Event Investigation is ideal for students in biotechnology, pharmacology, engineering, and business management as well as professionals in biomedical and drug development. All readers will discover what can go wrong in developing and bringing a new drug to market. Most importantly, they will also learn how to apply Six Sigma principles and methods to ensure safe and effective product design, development, and manufacturing.

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