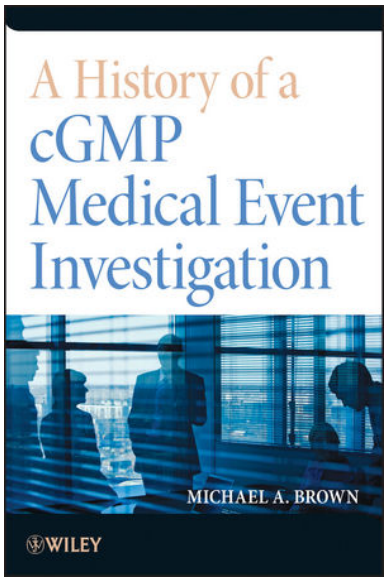

A History of a cGMP Medical Event Investigation

Michael A. Brown

E-Book	978-1-118-49488-2	November 2012	**$38.99**
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DESCRIPTION

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.

✍ ABOUT THE AUTHOR

MICHAEL A. BROWN, PhD, PE, is a Visiting Professor at the University of Illinois at Chicago. Dr. Brown has twenty-five years' experience in the biomedical industry in a product and process design capacity with responsibilities for worldwide engineering and management. He has served as a lead engineer on numerous products, process, and equipment projects including design, implementation, and qualifications. He is a registered Professional Engineer and a certified Six Sigma Black Belt with considerable experience in team leadership. The material presented in this case, including the FDA regulations and Six Sigma concepts, was tested in an engineering senior design course taught by Dr. Brown over a three-year period. Student feedback noted that the difficult design principles were explained in an easy-to-read story that introduced them to the Six Sigma methodologies in an engaging manner.
