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Sommario/riassunto

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