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**Pr case studies pdf creator** @ 2019 In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The underlying premise in ?? 210.1 and 212.2 is that CGMP sets forth minimum requirements to assure that drugs meet the standards of the FD&C Act regarding safety, identity, strength, quality, and purity.<sup>4</sup> Requirements with respect to data integrity in parts 211 and 212 include, among other things: