

Compliance by Design* (CbD) and Compliance Master Plan (CMP)—An Organized Approach to Compliance

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While now celebrating QbD technical process advancements, the industry has simultaneously experienced several terrible and well publicized events. People have died from occurrences connected to pharmaceutical products. These events have not been caused by manufacturing process problems, but rather are associated with deficiencies in compliance. All these problems do not have the same root cause. Some were caused by deliberate criminal actions (e.g., heparin deliberate substitution by oversulfated chondroitin sulfate [China] and diethylene glycol deliberate substitution for...

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