Risk-based Management of GMP Audits: An Approach for a Medium-sized Pharmaceutical Company

Viola Hieble-Gerhard
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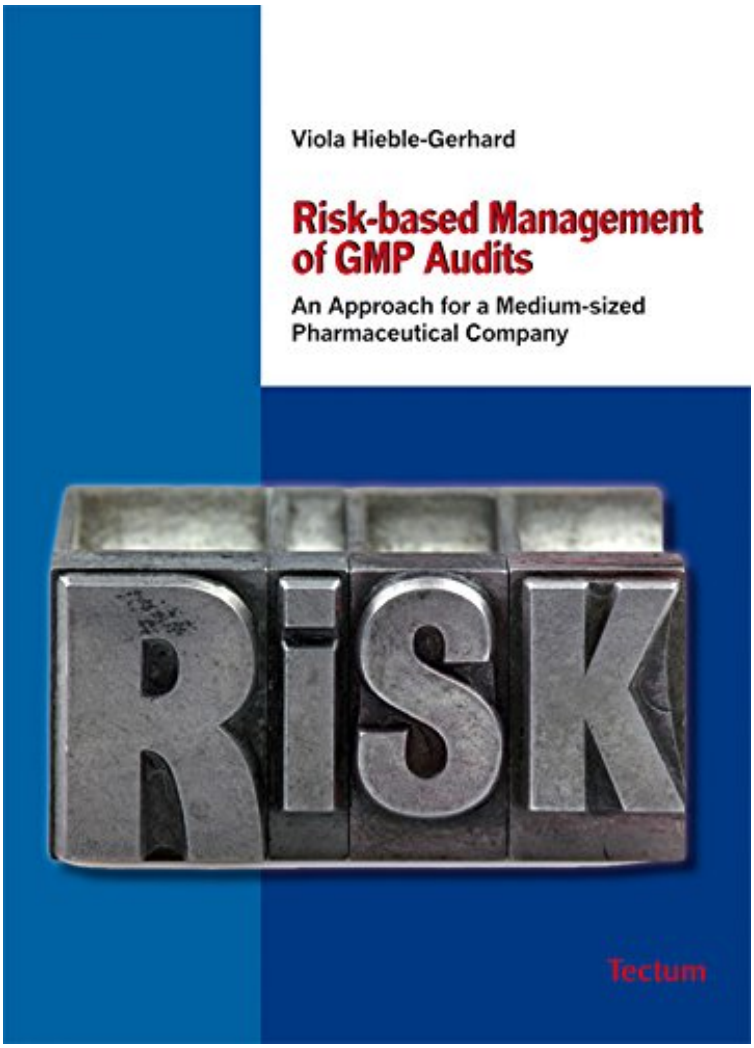

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Viola Hieble-Gerhard : Risk-based Management of GMP Audits: An Approach for a Medium-sized Pharmaceutical Company before purchasing it in order to gage whether or not it would be worth my time, and all praised Risk-based Management of GMP Audits: An Approach for a Medium-sized Pharmaceutical Company:

Within the European Union the manufacturing of medicinal products has undoubtedly reached a very high quality level. The principles of Good Manufacturing Practice (GMP) are required by law. A relevant part of the quality of finished products depends on the quality of the starting material, especially of the active pharmaceutical ingredients

(APIs). In the framework of globalisation and due to the ever-increasing cost pressure APIs are meanwhile sourced in a worldwide market, mainly in Asia. The risk of sourcing substandard, contaminated or adulterated products is an existent fact. Therefore, the quality management systems of the pharmaceutical manufacturers need to be adjusted to this challenge. Many initiatives have been started by authorities and the pharmaceutical industry during the last years in order to avoid the use of Counterfeit APIs or Rogue APIs and unclear supply chains. Indeed, full assessment of GMP compliance of API suppliers represents a cost-intensive and resource-requiring process. Setting reasonable priorities in the audit programme of a pharmaceutical company becomes possible through a risk-based management.