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Regulatory strategy should be business strategy

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Abstract

Regulatory Strategy should be Business Strategy since all Regulatory Risks are Business Risks but not all Business Risks are Regulatory Risks. Mergers and Acquisitions (M&A) (and Divestitures) are a major cause for disrupting Regulatory Compliance framework. Often they tend to disrupt standardization, if one exists. Other causes are diversified portfolios, in multiple geographies, M&A from different geographies. This problem gets more complicated for Medical Devices for different Classes of Devices.

The lack of standardization of QMS processes and other aspects lead to 483s and Warning Letters in some cases. While Cost of compliance is high and comes with the territory for Lice Sciences companies, price paid for non-compliance when found by an external agency is exorbitant and avoidable.

So to contain/minimize the price of non-compliance, it is important to put enough effort, time and money up front during the due diligence process of mergers and acquisitions. This due diligence should identify the differences in processes and systems used to implement them and how post-merger the compliance is achieved. While this is probably done, lot of warning letters today appears to be due to this inorganic growth in the Life Science Industry.

To ensure better compliance score, reduce the potential for 483s and Warning Letters from agency inspections, and improve business performance from both compliance and brand protection perspectives, it is very important to view “Regulatory Strategy a Business Strategy, that will strive towards standardization and harmonization of most of the processes and systems.

Biography

Rama Pidaparti is a Ph.D candidate from ASU and attended a Lifesciences and HealthCare courses from BEP Program at Sloan School of Management, MIT. Has over 20 years of industry experience and is currently Principal Consultant, Medical Devices vertical, Wipro Technologies. Has worked at many large Global Medical Devices and Bio-Tech drug companies as a consultant, GEHC, J&J, Genzyme, Genentec, Zimmer, to name a few. He has been helping the clients with Processes and Validated implementations of Computerized Systems for R&D, Quality and Regulatory areas. He is an invited speaker on Quality and Compliance topics at similar events in the past 10 years.