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Rama K Pidaparti

Wipro Technologies, USA

Medical devices - Regulatory intelligence - What is it?

It is fairly well known that the Medical Devices companies need to operate in a Compliant Regulatory framework. Not just FDA, EMA et al., but also FCC and many Standards (ISO and others). Scrutiny by Regulatory Agencies' is increasing and we see lot more Warning Letters too along with the increased scrutiny. Lot of fairly established (for a long time) Medical Devices Companies has well, to sort of decent ways to manage their Regulatory Compliance. But it appears that Warning Letters received by Medical Devices companies over the past few years put them on tight schedule to get compliant in areas they are not and then require them to overhaul their entire QMS.

Companies can definitely avoid getting into these situations. While the Mergers and Acquisitions can bring in disparate Quality Management Systems and lead to quality problems, often procrastination is leading to non-compliance, leading to warning letters. An effective way to manage Regulatory Compliance as well as being a better business is to have a good sustainable long-term M&A Strategy that is easy to execute for ensuring compliance. Problem could be that companies do not invest the time and money required to be compliant, while Warning Letters seem to ensure they do.

Biography

Rama Pidaparti is a Ph.D candidate from ASU and attended a Life Sciences and HealthCare courses from BEP Program at Sloan Business School, MIT. He has over 20 years of industry experience and is currently Principal Consultant, Medical Devices vertical, Wipro Technologies. He has worked at many large Global Medical Devices and Bio-Tech drug companies as a consultant, GEHC, J&J, Genzyme, Genentech, Zimmer, Medtronic, to name a few. 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.

ramakrishna.pidaparti@wipro.com