OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Pharmaceutical Regulatory Affairs

October 21-23, 2013 DoubleTree by Hilton Hotel San Francisco Airport, USA

Changing landscape of healthcare, regulations and role of RA

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Abstract

We are at the cross-roads of many big changes to healthcare laws, Regulations that impact the Life Sciences (Pharma, Bio and Medical Devices) Industry. This is the result of the accumulation of many changes over the past few years that are all coming together at the same time which will change the face of Healthcare. Facilitating these changes are also from the technological leaps in the Information Technology space.

Universal Device Identifier is one such big change that will change the face of the Medical Device Industry as well as Healthcare industry including pricing driven by outcomes. Sentinel for Medical for Devices to ensure Safety (of Medical Devices), is another. ICD 9 -10 is another. Medical Devices Tax, Tax for not having Health Insurance – to name few.

All of these changing laws and Regulations surrounding them will have a heavy impact on the Life Science Industry and Regulatory Affairs. Central to all this is the Role of a Regulatory Affairs Professional whose role is to understand and properly interpret the changes for correct interpretation of the and proper implementation for compliance, which is a huge Business Advantage. Add to this the changing Business Environment, Mergers, Acquisitions and Divestitures, expansions in Emerging Markets and other Geographies, this space (Regulatory Affairs) becomes even more critical and companies need to invest heavily to reap benefits since they (companies) need to evolve and devolve a Regulatory Strategy as a Business Strategy to cope with all these changes and still be successful as a business.

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.