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4ᵗʰ International Summit on

GMP, GCP & Quality Control

October 26-28, 2015   Hyderabad, India

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Compliance and traceability (CAT) using regulatory intelligence (RI)

Given the increased scrutiny of the agencies and not forgetting the un-announced inspections in Europe, it is imperative to have a good handle on compliance as all compliance risks are business risks. Hence, Compliance and Traceability for the life sciences industry is the need of the hour, which will create a baseline for what are all the regulations and standards that a business needs to be complying to globally and also manage the new and changing regulations in an ongoing basis. To create the base line the source should be a dependable source of the global regulations and standards (called Regulatory Intelligence). Example of one RI source is Tarius (Denmark based), which will provide what regulations and standards to be complied to globally. Using this source, one can create a baseline and monitor for all the changing and new regulations (and standards). This will enable businesses to know and track what needs to be complied to and monitor it. This is known businesses can also do what is needed to comply and provide traceability to what is done to provide compliance evidence. This entire set up can significantly enhance compliance which will result in having a great control on price of non-compliance.

Biography

Rama K Pidaparti has over 25 years of industry experience. He has a MS in Computer Science and Healthcare and Life Sciences courses from Sloan School of Management. He has worked on regulatory compliance aspects from concept to post market, at multiple life sciences businesses such as GE Health care, Boston Scientific, Medtronic, Zimmer, Johnson and Johnson, Genzyme, Genentec, Millennium Pharmaceuticals. He is a seasoned Speaker on compliance related topics at life sciences events.

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Notes:

J Develop Drugs
ISSN: 2329-6631 JDD an open access journal

GMP Summit 2015
October 26-28, 2015

Volume 4, Issue 4

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