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

Remote internal quality audits - effective and efficient

Garikapati Pavan Kumar

Wipro Technologies, India

Abstract

Every year about 20% of the FDA citations contain observations related to Internal Quality Audits. Most of these observations are related to audit procedures. Internal quality audit teams are always under the budget and time constraints to complete the audit cycles in the targeted period. Remote audits with a proper mix of onsite presence are becoming indispensable in changing global scenario to boost audit efficiency.

In all regulated companies, internal quality audit is mandatory to comply with regulations and ensure the continuous improvement of the quality system. It is important to ensure audit's frequency, and proper audit coverage for closing the non-conformities/observations in timely manner.

The cost pressures coupled with technology advancements are pushing many companies to internalize remote audit programs. Use of web based internal quality audit tools, online meetings and desktop sharing tools should allow the auditors to see information and collect objective evidence remotely and dispense the need of auditor and auditee to co-locate. These technologies are fundamentally changing the audit process and dramatically improving the audit efficiencies.

This presentation elucidates the remote internal quality audit process and its benefits to the companies. Many regulated companies also using these techniques not only in internal quality audits but also in vendor assessment. Entire interaction, communication, objective evidence, collection processes are changing very fast with technology advancements. These processes will be discussed using industry case studies.

Biography

Pavan Kumar Garikapati is a Regulatory, Quality and IT Compliance professional with 18+ years of experience. Pavan currently heads Regulatory domain practice, Medical Devices at Wipro technologies. Pavan is a certified Six Sigma Black Belt and certified lead auditor for Quality Management Systems. He has given consultancy to more than 50 companies in the field of Quality and Regulatory. Pavan has done his masters in manufacturing engineering and also in industrial engineering. Pavan has a bachelor degree in mechanical engineering and presented/published papers in the field in national/international forums.