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Current trends in computerized system validation – challenges and solutions

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Abstract

Life Sciences companies are regulated and mandated to carryout Computerized System Validation (CSV) of the GxP Systems. They spend a lot of effort and money on validating computer systems. Plethora of regulations world over, changing technology landscape – Cloud, Virtualization, and upcoming SDLC models like Agile are vastly throwing challenges to industry and at the same time providing an opportunity for innovating new procedures, methodologies and approaches. Apart from these macro challenges industry is also plagued with lack of internal procedural harmonization, varied expert interpretations and lack of availability of trained resources.

Companies, while catching up with regulations, are also employing smarter ways of validation practices to effectively and efficiently validate computer systems.

An analysis of FDA 483 and Warning letters issued by US FDA summarizes the following points:

- About 4% of FDA 483's refer the CSV related observations and 8% of warning letters contains CSV related violations.
- Deficiencies are categorized in 3 broad areas - Software validation for automated processes, Documentation of software validation and Validation of changes to automated process software

This presentation discusses the macro and micro challenges the industry is facing in terms of CSV and elucidates practical solutions and trends emerging to mitigate risks and facing the challenges successfully.

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.