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A cost-effective and practical approach to risk-based computerized system validation (CSV) for pharmaceutical and medical devices regulated environments

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Medical devices and pharmaceutical organizations are responsible for ensuring that the risk management and validation activities are adequate for the computerized system in light of current business needs and regulatory requirements. By identifying the critical quality attributes of their business processes and applying adequate risk management techniques, regulated companies can ensure better compliance and improve business performance in a cost-effective manner. It is possible to decrease the effort and amount of work dedicated to computerized system validation at all risk levels, especially in low risk areas. In this way, the focus is on high risk areas where mitigations are implemented.

This presentation offers a practical set of tools to ensure a cost-effective approach to risk-based computerized system validation (CSV) while:

- Ensuring the system's quality, assessing the impact on product quality, patient safety, data integrity and support of business processes
- Ensuring compliance with EU/ FDA regulations
- Managing the risk associated with potential failures
- Adapting the rigor and intensity of the CSV activities to the risk level and type of system (COTS, configurable and custom)

Case studies are offered as examples to illustrate industry practice on how to perform adequate risk assessment and CSV, including the related documentation, while meeting the applicable regulations and standards (21CFR820 (QSR), 21CFR Part 11, ISO 13485, ISO 14971 and GAMP5).

This presentation can contribute to enabling companies to successfully implement a cost-effective CSV approach to implement reliable and suitable computerized systems in highly regulated organizations.

Biography

Ana Villar has 15+ years of experience in different quality and regulatory areas for the pharmaceutical and medical device industries. She holds an M.Sc. in Pharmacy and Pharmaceutical Technology. She has extensive knowledge and experience in Computer System Validation at several firms and as a consultant at large medical devices and pharmaceutical companies: Novartis, Lonza, Amgen, Merck, Grifols and Esteve. She has also conducted numerous drug, medical device and software audits for highly regulated industries.

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