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What really matters to FDA and why? A comprehensive review & analysis of FDA enforcement action on automated system validation

GxP regulations and associated guidance provide a framework for regulatory agencies to define quality and safety standards, compliance requirements and enforcement methods to guide the life science industry in general. However, the actual enforcement of specific regulation for a targeted GxP operation is often at regulatory agencies discretion. What will FDA really enforce with their limited resource and where they focus on? Facing the challenges from competing areas of regulatory requirements, business owners and regulatory professionals often struggle on how to identify the priorities and develop strategies that will make best use of limited resource to achieve business objective and meet compliance requirements at the same time.

This presentation presents research and review findings and trending analysis from the common FDA enforcement actions such as 483 observations, warning letters and consent decrees published in the last 10 years in the areas of 21 CFR Part 11 and computer system validation. The research revealed the multi-facet enforcement strategies based on product safety, consumer protection, liability and verifiability. For example, in the last 10 years, the FDA warning letters issued for 21 CFR Part 11 violations are overwhelmingly focused on medical devices products because the validation of embedded computer system of a medical device is integral part of FDA market approval. The agency is responsible to guard the safety of the marketed product, protecting the consumer by ensuring the claim are supported by scientific data and liable to verify the accuracy of research and manufacturing data of the product before market approval. However, the general uses of computer system to automate business process for efficiency improvement are less of enforcement attention even though they are equally covered by 21 CFR Part 11.

These findings can help audience to understand FDA enforcement priorities and develop their regulatory compliance strategy accordingly.

Biography

James Huang is a results-oriented, highly motivated, innovative strong leader with more than 19 years of proven performance history and leadership in pharmaceutical/biotech/medical device industries. Success has been acknowledged throughout the excellent services to major pharmaceutical companies such as Forest Lab, Pfizer, Deloitte Consulting, Almac Clinical Technologies, Eli Lilly, Johnson & Johnson, Abbott Lab, Novartis, Purdue Pharma, Dupont Pharm, MDS Pharma Services, etc. He is the sought after speaker for various industry conferences. In the last 10 years, he has delivered more than 15 presentations and speaker in the major industry conference such as DIA, PDA, ISPE on the topics of regulatory compliance, quality system and risk management.

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