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

**James Huang**

*Forest Laboratories Inc., USA*

## Abstract

With the progression of automated solutions being applied to commercial biopharmaceutical manufacturing, the translation of cGMP to batch recording is necessary for fully realizing the benefits of electronic systems. Most configurable off the shelf applications for process control and Manufacturing Execution Systems (MES) provide full compliance with Part 11, however depending on HOW those systems are configured, the compliance with cGMPs is variable and requires oversight in the development and deployment by Quality to ensure appropriate controls are in place. In order for this be successful, many components are required including the philosophical transition of the Quality Assurance unit and Quality processes as well as adoption of new skill sets of Quality Professionals. This presentation will discuss considerations for Electronic Batch Record definition, management, execution and reporting to achieve and improve compliance as well as lessons learned including operator / analyst training, human centered design optimization and the elusive search for the pristine batch.

## Biography

James 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 speakers in the major industry conference such as DIA, PDA, ISPE on the topics of regulatory compliance, quality system and risk management.

james.huang@frx.com