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Moving beyond part 11; Quality assurance considerations for translating cGMP compliance into electronic batch record initiatives

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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

Heather Schwalje is a Senior Consultant in the Emerson Life Sciences Industry Solutions Group. Over 16 years in the biopharmaceutical industry; her experience includes Quality oversight of large scale manufacturing facility / process design and start-up. In addition, she was responsible for compliance related activities in support of the highly automated manufacturing, laboratory and business systems. She has expertise in quality system design and implementation including support of consent decree compliance initiatives including participation in regulatory inspections from various agencies (FDA and EMEA). She consults with customers to help them define and justify projects, plan system and technology upgrades, and define front-end engineering and design specifications.