

GMP, GCP & QUALITY CONTROL

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PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

September 25-26, 2017 Chicago, USA

Data integrity requirements for GxPs

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This presentation will provide an overview of current regulatory requirements and guidance pertaining to data integrity. The presentation will review FDA, MHRA and other regulatory guidance related to data integrity. Approaches to performing data integrity assessments will be discussed and examples from audits and regulatory observations will be reviewed. Implementation of data integrity programs will also be reviewed. The following topics will be discussed at the conference: Review current regulatory data integrity requirements and guidance; approaches to conduct audits / assessments of data integrity programs; examples of data integrity observations and audit findings and; implementing data integrity programs.

Biography

Chris Wubbolt has provided quality assurance, compliance, and computer validation consulting services since 2001, specializing in establishing data integrity programs, performing data integrity audits, vendor audits, providing training, validation, and implementing six sigma based quality improvement processes. He has previously worked at Aventis Pasteur as Computer Validation Manager, working with GxP computerized systems. Prior to joining Aventis Pasteur, he worked at Johnson & Johnson's McNeil Consumer Products Company in the National Quality Assurance Group and at Lancaster Laboratories. He was a contributing member of the GAMP Laboratory Systems Special Interest Group, which published the guidance document on validation of laboratory systems, as well as a chapter chair for DIA "Peach" guidance on computerized systems used in clinical research. He is a Certified Six Sigma Black Belt, has a Master's degree in Quality Assurance and Regulatory Affairs and a BS in Physics and Computer Engineering. He was the previous President of both the New England Region Chapter Society of Quality Assurance (NERCSQA) and the Mid-Atlantic Region Society of Quality Assurance (MARSQA), and is currently the chairperson of the MARSQA computer validation committee.

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