

FDA Compliance: Electronic Submission and Validation

Paper FC01: XML Data Mapping under SAS 9 - From the Perspective of Electronic Submissions
Tianshu Li, Merck & Co.

Paper FC02: Data Standards With and Without CDISC
Sy J. Truong, Meta-Xceed, Inc.

Paper FC03: Automation of Patient Narratives
David C. Izard, GlaxoSmithKline
Eric M. Simms, GlaxoSmithKline

Paper FC04: Submission of Analysis Datasets and Documentation: Scientific and Regulatory Perspectives
Dave Christiansen, Christiansen Consulting
Stephen E. Wilson, FDA

Paper FC05: Build Portable Structures and Programs for Electronic Regulatory Submissions
Wei Cheng, Isis Pharmaceuticals

Paper FC06: Using Cyclomatic Complexity to Assess Test Coverage for SAS Programs
Michael C. Harris, Amgen, Inc.

Paper FC07: A Useful Macro for Converting SAS Datasets into SAS Transport Files
Xingshu Zhu, Merck & Co.
Shuping Zhang, Merck & Co.

Paper FC08: An FDA-Requested XML Replacement for SAS Version 5 Transport Files in U.S. Regulatory Submissions
Michael C. Palmer, Zurich Biostatistics, Inc.

Paper FC10: eCTD - A New Standard for FDA Electronic Submission.
Shawn Wang, MedXview, Inc.

Paper FC11: Critical Success Factors in Pharmaceutical Innovation
Thomas H. Burger, Eli Lilly and Company
Michael S. Lajiness, Eli Lilly and Company