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A personal history of regulatory submissions technology

Regulatory submissions today fall under pretty strict standards: If it isn't an eCTD (electronic Common Technical Document) it's still likely to be based on the CTD, whether it's electronic or not. Harken back to the days when publishing involved custom software; where a submission could mean shipping 150 pounds of equipment, or transporting multiple laptops across international boundaries; where reviewer demands could involve a 6AM phone call and a 7AM plane ticket. But it wasn't all bad: the early days of electronic submissions resulted in an unprecedented level of interaction between reviewers and regulatory and led to our modern standards.

Biography

Joel Finkle is a Director of Regulatory Innovation and IDMP Strategy for ACUTA. In this role he brings new technologies and regulatory data standards to ACUTA's bio/pharmaceutical customers to ensure compliance and process improvements, as well as providing the focal point within the company for other industry standards and regulatory guidance. He came from a background in the Pharmaceutical industry and with software and consulting vendors, with over 30 years' experience in software development and support of electronic submissions, publishing, and document. He is currently a Member of the HL7 Regulatory/Clinical Information Management group, and the IRISS Forum.

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