
Change Control and Risk Management Recap: Day 2

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Tuesday was an action packed day at Change Control and Risk Management. At any moment, attendees were able to choose from three different 90-minute presentations. Topics discussed includes risk management for CSV systems, gap analysis for change control systems, information security risk management, developing "lean" change control systems, and maintaing compliance during change control.

Editorial Advisory Board Member Neil Duser's presentation "Apply Risk Management for Computerized and Automated Systems" provided clarification for an area that often goes overlooked in pharmaceutical and medical device manufacturers. Automated and computer systems have become essential and commonplace. These systems are inherently high-risk. Duser discussed most at risk features of computer and software systems, as well as the most high-risk events that can jeopardize a computer system. These events can vary between characteristic (e.g., security, human factor, performance, logical, system specific), severity, priority, and likliehood. As technology continuously increases in scope, and the ability to keep information secure becomes more and more outdated, Duser's presentation provided insight in the steps pharmaceutical manufacuters need to take to remain compliant.

Change Control chairman Joe Zec gave us another winner with his day two presentation, "Implement Change Control Procedures During and After Validation." With a special focus on software validation, Zec introduced the attendees with the concept of "timing" change control. When change control is implemented too soon, it can needlessly slow the process a time when efficiency is required. It can also create unnecessary overhead, which never looks good for any department! However if change control is implemented too late, the baselines are too established. Zec explains that during the documentation development, change control should be implemented after the first review. Change control should also be implemented at lifecyle milestones. Zec also provided case studies to illustrate this point.

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