

Third Session, *session "A"*

Doing More Not Spending More

As a Global Compliance group we are stretching to deliver a robust QA program in an ever expanding regulatory environment. Our mission is to ensure comprehensive oversight of clinical research, wherever that research is taking place. We found ourselves covering more countries, more research activities and sometimes facing challenges of working with countries where there may be travel or cultural restrictions. One innovative idea we explored was the option of remote auditing. While it seemed a bit extreme, and possibly even scary at first mention, we were encouraged to think outside the box. Initial reaction within our group was mild skepticism. Is it possible to conduct an audit remotely? How do you trust the response? Our session will discuss our experience in the world of remote audits sharing our experience across three very different audit scenarios. This audit method will NOT work for every situation but it may be another tool to compliment onsite auditing. Using this method may allow you to strategize and prioritize your onsite activities by testing the control framework, using technology to deliver more without spending more.

Kerrick Wilson has worked in the pharmaceutical industry for 14 years and in Clinical Quality Assurance at GlaxoSmithKline for 8 years. His primary responsibility for GlaxoSmithKline CQA is to manage the external service provider assessments as well as provide consultation to the GSK clinical groups with regards to suppliers.

Patricia Owen is manager of Clinical Quality Assurance in Global Quality and Compliance at GlaxoSmithKline where she has been employed since 1997. She supports Biopharmaceuticals and Neurology global programs. Patti is a Certified Quality Auditor since December 1992.

session "B"

Data Analysis: A Baker's Dozen of Tools, Tips, and Tricks to Improve Data Display and Analysis When Using Microsoft Office Excel

This presentation will introduce over a dozen tools and methods to improve the analysis and presentation of your data. Examples to be presented include hidden capabilities within Microsoft Office Excel, screen changes to make data easier to view, locating and counting specific values in a spreadsheet, and becoming an expert with histograms. Laptops are recommended for a hands-on experience. Handouts with screen shots illustrating these methods will allow for immediate application to your project data.

Tedd Karr is an engineer, lecturer, consultant and Lean 6-Sigma practitioner with over 30 years of quality and process improvement experience. He is currently an Operations Data Analyst with a major Healthcare organization. Mr. Karr received a BSIE from NC State University and an MBA from East Carolina University and is an ASQ Certified Six Sigma Black Belt.

session "C"

Modular Test Automation

Many companies have recognized the value of test automation frameworks. Appropriate test automation frameworks maximize ROI on automation tools and minimize script maintenance. One of the most common frameworks is the modular test automation approach. This approach borrows its concept from software development: creating shared components within the automation suite. For test automation, the modular approach segments the application under test into functional areas that are mirrored when developing the automation modules. These modules are then linked together to form end-to-end automated test cases. While this approach encourages reusability and maintainability, there are many challenges that must be considered and addressed at the start of a project. This presentation will address these challenges.

David Dang serves as VP of Automation Solutions for Zenergy Technologies, a QA and testing solutions firm. David has over fifteen years in IT, with the last twelve focused on test automation and QA and test process improvement. He has extensive experience in designing, developing, and implementing advanced test automation frameworks that provide higher ROI by significantly reducing maintenance while increasing reusability. David has worked with over one hundred companies to assist and drive their test automation and QA projects. While he is an HP Certified Instructor (CI) for QuickTest Professional, WinRunner, and QualityCenter, David has expertise in a wide variety of automation tools including open source.