



ISPE Pacific Northwest Chapter

Presentation Title: Evolving C&Q Practices using QRM and Risk-based Approach - ISPE C&Q Baseline Guide 5 2nd Edition Highlights

Abstract

The ISPE Commissioning and Qualification guide was first issued in 2001 and reflective of that time. With emerging markets, changes in the regulatory landscape, advances in commissioning and qualification methodology, the commissioning and qualification CoP has rewritten the guide to align with present day requirements and best practices applicable to the current market. This guide considered applicable regulatory requirements as identified in ICH and ASTM E2500. The Guide provides a well-defined framework for a lifecycle QRM and risk-based approach to verification and documentation of fitness for use.

Areas of Focus:

Review of the new elements including an integrated approach for developing and executing a commissioning and qualification plan, risk assessments and verification. Description of the new and improved methodologies to test once through verification and use & acceptance reports. The expanded role of Engineering using GEPs and Quality's focus on that which is deemed critical.

In this presentation, participants will be able to gain an overview of the new C&Q guide, clearly understand of the updates within the revised Baseline Guide, understand the tools provided to projects to drive efficiency and to reduce duplication of C&Q efforts during execution.

Target Audience

Plant management, Production/Operations, Maintenance, Engineering, Automation, Validation, Quality

Speaker

Steven Wisniewski is Principal Consultant for CAI. Steve has more than 35 years' experience in the pharmaceutical, biotech, and device industries. Steve has served in manufacturing facility and corporate senior management roles at Sterling Drug and Bausch & Lomb. He has completed a wide variety of pharmaceutical manufacturing, filling and critical support operations to major R&D laboratories, facilities and upgrades. He holds a BSME from Rensselaer Polytechnic Institute and is an active Member of ISPE. He served on the ISPE board of directors and was chairman of the board in 1991. Wisniewski served four years as chairman of the ISPE Community of Practice for C&Q and was on the ISPE task team that developed the ASTM E2500 Verification Standard. In addition, he served as a leader of the Task Teams that produced the ISPE Guidance documents in support of QRM based C&Q in 2011, and is lead author on the Task Team for the recently issued he 2nd Edition Baseline Guide 5, C&Q addressing application of QRM to C&Q. He is an instructor for ISPE training courses on C&Q



and was on the Team that developed the PDA TR for Application of QRM to Facilities, Systems, and Equipment.

