



Leading the Way: “Lean” Engineering to Validation Process - ICH Q9 and ASTM E2500 Implementation -

The ASTM E2500 consensus standard, incorporating ICH Q9 guidance, establishes a science- and risk-based approach to the specification, design and verification of pharmaceutical and biopharmaceutical manufacturing systems and equipment. The approach encompasses the project and system life cycle – from concept to retirement (cradle to grave) and provides manufacturing facilities that are *Fit for Use*. A key objective is to give industry the needed flexibility regarding how to implement the standard in a quality and value added manner. Although the process is generally the same for everyone, how organizations choose to implement the standard varies depending on business and quality drivers, corporate culture and established internal roles and responsibilities. Implementing and navigating the process can be complex from the perspectives of engineering, project management and people.

At IPS, our team of experts understands that implementing a new rationale and approach is an iterative process – setting goals and metrics and monitoring the program in a “continuous improvement” environment (plan, execute, feedback, adjust). We assist clients in the development and implementation of new approaches and practices that streamline engineering and qualification (verification) processes using the risk- and science-based approaches and tools found in ASTM E2500, ICH standards and the current ISPE C&Q guidelines and Good Practice Guides. We work with you to develop and execute a realistic plan that reflects your critical milestones, goals and objectives and outlines the activities required that will carry through to a successful completion. It is our experience that implementing the “lean” approach - for the right reasons - results in improved project cycle times (better on-line time performance) and a simplified and defensible compliance profile.

Our approach and our subject knowledge expertise in design and engineering, construction management, commissioning and qualification (verification) has been the cornerstone of our success. For over twenty years, IPS has delivered *Fit for Use*, fully functional, compliant facilities that have met the high level of quality, functionality, and Regulatory expectations our clients require.

We can help you “lean out” your engineering to validation process by providing tools that use an integrated risk-based approach to design and verification (Commissioning & Qualification):

- Streamline Costs, Optimize Value
- Focus on Product Quality and Patient Safety
- Categorize Risks, Value Map the Process
- Meet Business and Compliance Drivers
- Lean Quality Systems Implementation: Change Control, Calibrations, Investigations, Deviations, etc.
- Improve facility on-line time
- Better manage project information
- Provide for Appropriate Engineering Verification
- Balance Cost, Efficiency, Quality and Safety

Key IPS Value Add

- For a recent client, we developed new processes to speed the turnover of capital projects and enhance life cycle maintenance and management.
- Our implementation efforts significantly reduced redundant qualification testing and validation deviations.
- We defined documentation management and control strategies to streamline and direct compliance driven activities.



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