

Systems Engineering: Lean Innovation

Situation

Emergence of ICH Q8/Q9/Q10 in combination with Quality by Design (QbD) and ASTM E2500 allowing for use of a risk-based approach with Good Engineering Practices (GEP).

Opportunity

Fully leverage the benefits during product commercialization and process management to do work once and ensure it's right while focusing verification and validation (V&V) efforts on aspects that impact patient promises and regulatory commitments.

Action

Guided development and revision of program management models with cross-functional governance to target the application of QbD in early developmental efforts, enhancement of GEP approach and assistance with redesign of V&V processes to fully leverage risk-based tools.

Result

- Improved understanding of relationship between Critical to Quality (patient promises/regulatory commitments) and key aspects of the process.
- Technical development approach to bridge between identification and validation.
- Ability to pull forward mid phase Technology Readiness Level (TRL) and Manufacturing Readiness Level (MRL) efforts under GEP.
- Significant shift from qualification to verification/commissioning based on a clear structure for risk-based decisions associated with Critical to Quality (CTQ) and supporting control strategy.

Services

- Commercialization support
- Process development and management
- Strategic planning
- Risk management
- Validation
- Life cycle planning
- Control of systems from concept through retirement