A PROVEN APPROACH TO INCREASING COMPLIANCE WHILE INCREASING EFFICIENCY: A WIN-WIN FOR EVERYONE

Michael Bogan
ISPE Product Show
Track 1 Session 5
September 26, 2018

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

> **Agenda:**

- Introduction
- Problems we Face Today
- Develop a Plan
- Outline Benefits
- Simplify the Complex
- Process Overview
- Case Study

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Introduction

1st a bit about you so we can see who **we have** in the room with us (quick show of hands):

- How many Managers?
- How many Directors?
- How many Sr. Directors and above?
- How many are intimately involved in CQV activities in their organization?
- Any QA folks in the Room?
- How about Engineering?

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Introduction

Does anyone work in a functional group where your procedures and policies DO NOT impact the other organization?

Why did some of you choose or accept the assignment in your particular discipline and why this industry?

- Are you driven to succeed simply to provide for your family?
- Was it your vision to overcome challenges and obtain recognition?

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Introduction

2nd a bit about myself so you can see who **you have** in the room:

- Almost 30 years in the industry - focused in CQV
- Background in Manufacturing, Process Development and Tech Transfer
- Responsibilities for CQV activities included a 240,000 ft^2 manufacturing plant, one 368,000 ft^2 manufacturing plant, a 56,000 ft^2 central utilities building, 59,000 ft^2 cell culture facility and countless program level/life cycle projects…

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Problems We Face Today

Assigned high level objectives with an already **overwhelming workload** combined with the requirements of meeting compliance expectations creates anxiety and stress.

- Work comes from quality systems like Change Control, CAPA's, Validation Maintenance, Capital Work, Non-Capital Work, Mitigation Work, Deviations etc.
- What are the Ramifications?
  - What does Failure looks like?
  - What does Success look like?

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Problems We Face Today

We've all been in similar situations today at one time or another and it seems that there are limited choices to pick from when tasked to develop a lean, efficient and compliant CQV program:

- You may already know and understand your current situation and just looking to improve a few things or you may need to better understand what may be needed
- In either case you need a plan with a solid strategy
  - Remember what success feels like so lets start mapping out the plan

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Develop a Plan with Solid Strategy

- Align with Quality standards/corporate standards
- Align with the facility, utilities and process equipment engineering design
- Structure around specifications and data sheets
- Align with the automation aspects that are used to run processes and systems based (e.g. Delta V)
- Procedural and form based eliminating typical protocols which enables more efficient, compliant and consistent execution
- Provide an example of documents and cost reduction when compared to traditional strategies

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Outline Benefits to be Achieved

- Addresses compliance, scope, schedule and costs concerns
- Facilitates harmonization, regardless of manufacturer, and supports multiple sites
- Streamlines the overall work load and reduces the total number of documents
- Enables total leveraging capabilities from FAT to SAT to qualification for both mechanical and automated aspects

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Outline Benefits to be Achieved

- Remove documentation interdependencies and project delays
- Pre-approved acceptance criteria at system classification level, removing redundancy
- Deliver a higher level of requirement traceability
- Streamline change control and re-validation

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex

This C&Q Life Cycle approach is simplified and supports leveraging strategies for non-critical and critical aspects by eliminating traditional leveraging challenges:

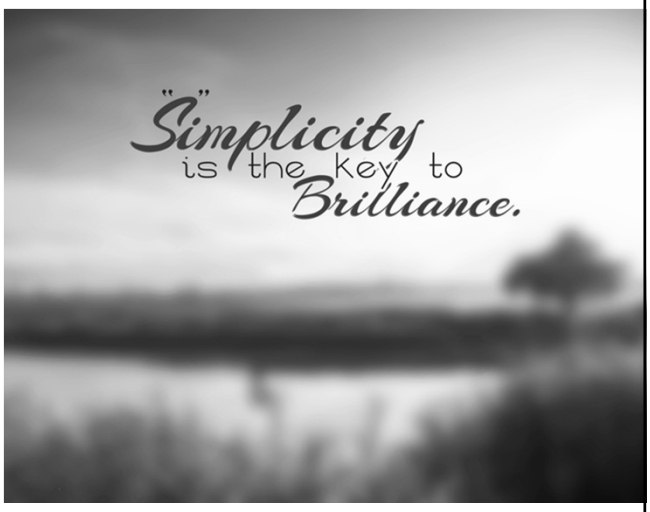
- Multiple protocols per system for commissioning and qualification
- Time consuming impact assessments by system listing all components
- Multiple acceptance criteria repeated across multiple protocols

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex

- Multiple deviations for same issues addressed in multiple protocols
- Inconsistent acceptance criteria verified across similar systems
- Inconsistent format and content across similar systems
- Burden of drafting and approving numerous protocols
- Although qualification scope is well defined, commissioning scope is not



A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex

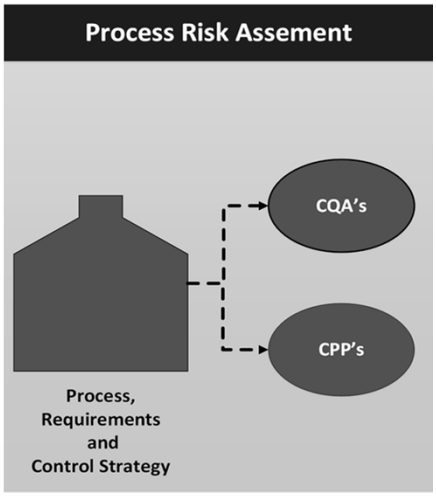
- Risk Assessments
  - Based on process criticality (CQA's/CPP's) which feeds into systems and component risk assessments
  - Each system & component to identify criticality based on product attributes
  - Performed for automation by equipment/unit, unit operation and phase level operation
  - Procedures and verification forms will control how items are verified
  - Test scripts will control testing to test automation aspects (high alarms etc.)

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Risk Assessment

- Process
  - Emphasizes product / process understanding, process control, based on sound science and quality risk management
  - ICH-Q8: Pharmaceutical Development
  - Critical Process Parameters (CPP)
  - Critical Quality Attributes (CQA)
  - ICH-Q9: Quality Risk Management - Failure Mode, Effects, and Criticality Analysis (FMECA)
  - Assessments are approved by Quality Unit

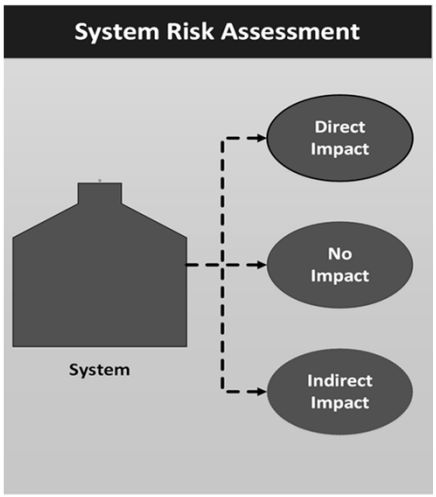


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Risk Assessment

- System
  - Each system is assessed to determine criticality
  - Multiple systems may be included on a single risk assessment
  - Assessments are approved by Quality Unit

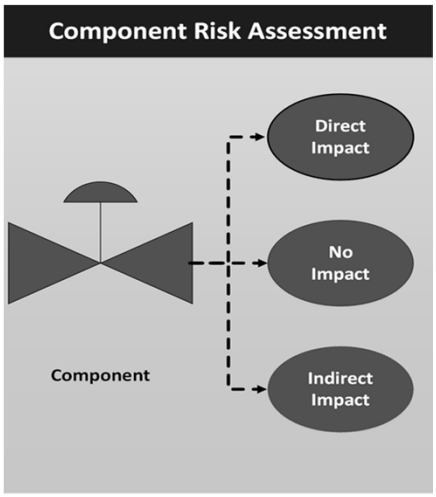


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Risk Assessment

- Component
  - Unit Class Level
  - Each component is assessed to determine criticality
  - Assessments are approved by the Quality Unit

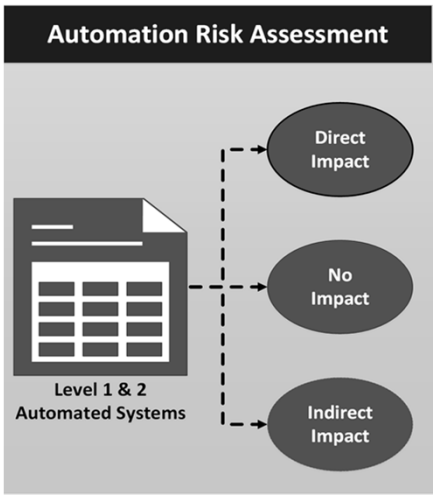


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Risk Assessment

- Automation
  - Level 1 and 2 automated systems are assessed to determine criticality
    - Level 1 includes PLC control system, operation and monitoring HMIs in local and global networks (Ethernet)
    - Level 2 includes advanced product control, quality assessment, and production optimization (Delta V)
  - Associated unit operations / procedures and phases, alarms and interlocks are assessed to determine criticality

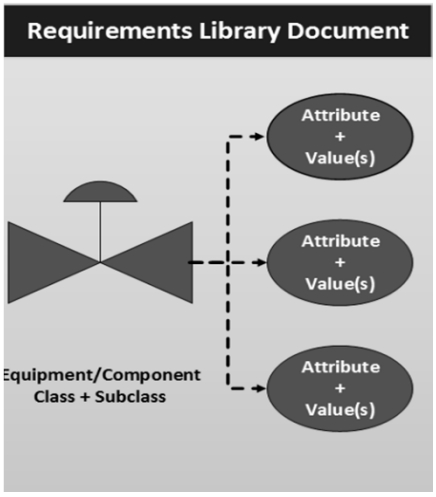


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Requirements Library

- Mechanical Strategy:
  - Component attribute and their values are pre-approved at the class level and do not contain tag numbers
- Automation Strategy:
  - FRS controls and values are pre-approved at unit operations, unit procedure and phase level
  - DDS Controls and values are pre-approved and tested at the CM and EM level

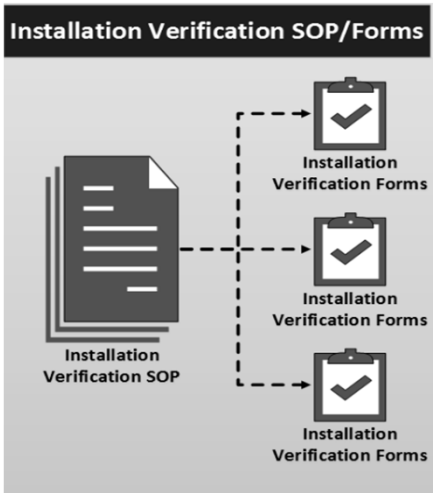


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Mechanical Strategy

- Mechanical aspects and components shall be verified using pre-approved forms by component or component class (e.g., diaphragm pump, temperature transmitter)
- Procedures for verification are contained within the associated SOP
- Acceptance criteria is contained within the Requirements Library Document

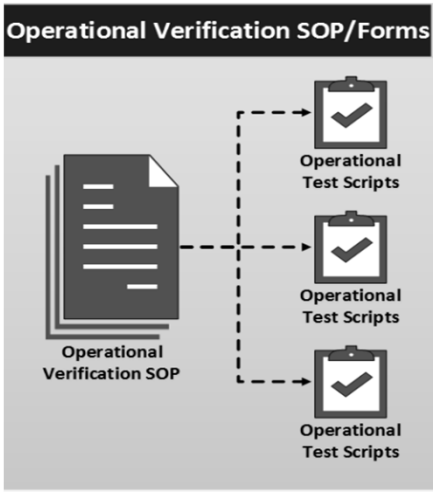


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Simplify the Complex – Automation Strategy

- Equipment module and control module testing will be leveraged into unit operations, unit procedure and phase level
- Automation verification shall be performed by pre-approved forms by unit operation class (e.g., alarms, interlocks, screen navigation)
- Uneventful testing will occur at the procedure and operation level
- Acceptance criteria is contained within the FRS / DDS

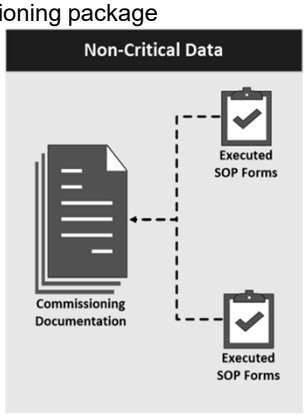


A Proven Approach to Increasing Compliance While Increasing Efficiency

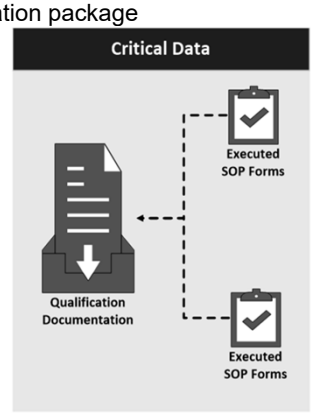
A Win-Win for Everyone

Simplify the Complex – Data Organization

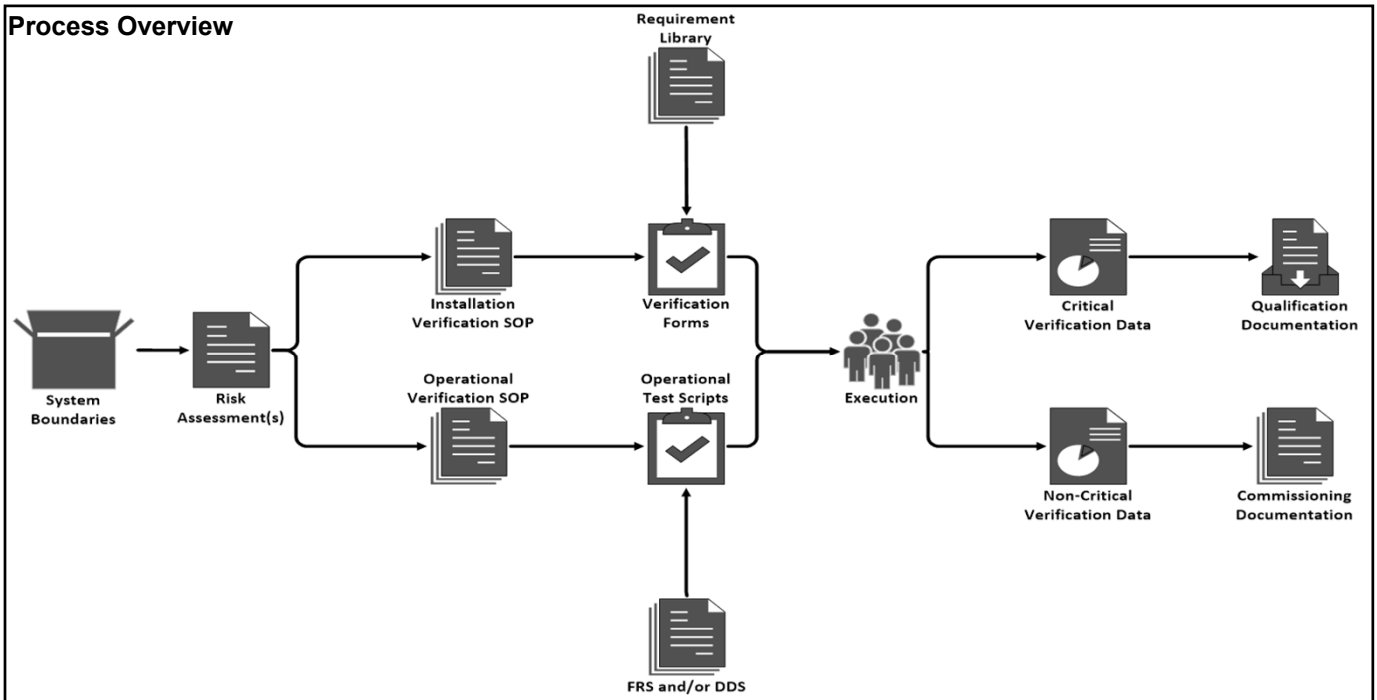
- Non-Critical execution documents feed into the commissioning package



- Critical execution documents feed into the qualification package



Process Overview

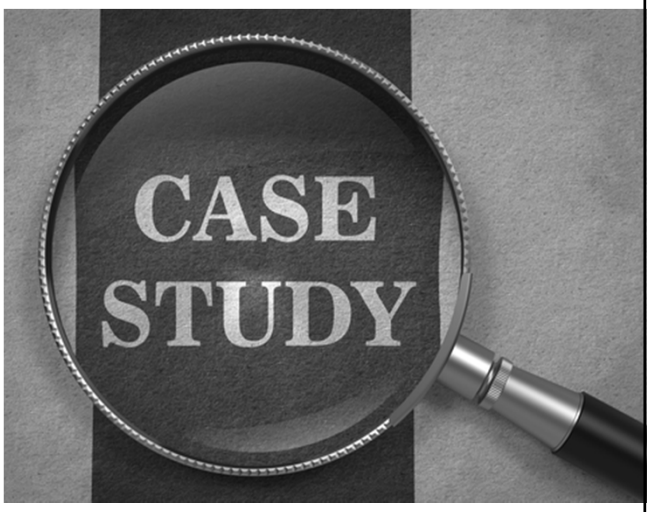


A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Case Study Project

- The example project presented on the next slide have the following parameters
  - 200 systems
  - 150 systems with functionality
  - 125 critical systems (requiring qualification)
  - 100 critical systems with functionality (requiring qualification)
  - 100 stick-built systems (no FAT required)
  - ~75 Component Classes



A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Document Reduction Compared to Traditional Approach

- Form-based
- Governed and Controlled by Approved SOPs from all functional areas
- SOPs & forms eliminate need for an IQ Protocol or OQ protocols
- Only initial project would require writing all of the Library documents, subsequent projects require appendices
- Aligns with business objectives, is executable and provides value by realizing benefits

Deliverable	Current Typical Practice	Proposed New Practice	Future Facility
Total:	1,100	306	226+
CIA	200	1(1)	0
FIA	150	1(1)	0
Trace Matrix	0	1	1
FAT	100	1(2)	0
SAT	200	0(2)	0
IQ Protocol	125	1(3)	0
IQ Report	125	125	125
OQ Protocol	100	~25	~25
OQ Report	100	100	100
Library	0	75(4)	0+

A Proven Approach to Increasing Compliance While Increasing Efficiency

A Win-Win for Everyone

Summary

- Remember the problems we all face in today's working world
- Develop a plan with solid strategy
- Outline the benefits to be achieved
- Simplify the complex
- Remember what success looks like