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3 Keys to Incorporating Lean Techniques into a C&Q Program

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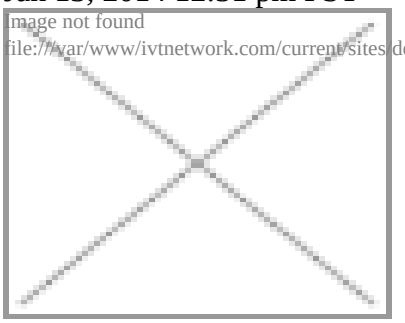

Every business seeks reduced project timelines, reduced project costs, and improved production. This is the essence of lean manufacturing, and it is the subject of Sujeev Ruban's presentation at IVT's **Validation Week** Canada. Adapted from the presentation, "Incorporate Lean Techniques into Your C&Q Program," the following are the three keys concepts that need to be implemented to have a successfully lean commissioning and qualification program.

Are there any other techniques to lower costs and improve production that you utilize in your facility? Let us know in the comment section below!

1. Measure

Simply measuring macro-level metrics associated with a commissioning and qualification (C&Q) program is vital to reducing cost. The second step in the all-to-familiar DMAIC cycle, proper measurement of the C&Q program can reduce variation associated with the process. Some examples of macro-level metrics associated with a C&Q program are schedule metrics (i.e., number of days for commissioning, IQ, OQ) and cost metrics (i.e., C&Q costs compared to the total cost of installation). While sifting through the data, it is important to determine the cause behind each measure and consider ways to streamline the process. For example, why are the costs so high? Why does C&Q take so long? How can I reduce C&Q efforts during the design and execution stage?

While measuring the key metrics of the C&Q process, in-depth analysis of deviations, including the identification of root cause and associated project stage, needs to occur. Identification of C&Q costs based on detailed work break down structure and facility and equipment performance post-turnover should also be initiated.

Primarily, measurement of key metrics requires taking the time to understand the state of your C&Q program. Proper measurement of key metrics will grant the opportunity for sustained change and will help identify new continuous improvement opportunities.

2. Standardize

Standardizing inputs of a C&Q program will focus effort and resources to where it matters without re-inventing the wheel for each project. Some areas of potential standardization follow.

Team Members

Opportunities to align priorities and availability of team members while maximizing continuity should be investigated. For example, there could be a dedicated team for each production area to support area specific projects, equipment, and technologies.

Furthermore, training, mentorship, and employee skill development should be implemented to reduce variability.

Pre-Approved Protocols

Developing pre-approved IQ/OQ protocols is a standardization that can reduce the cycle time, reduce variability in the process, and improve execution. Protocol development is a long process, any pre-approval can eliminate hours from the initial C&Q program. However, it should be noted that proper protocol standardization will require a concerted effort by team members to create a robust protocol and active management support to invest time and effort into pre-approved protocols.

Potential areas that pre-approved protocol can be utilized include biosafety cabinets, walk-in refrigerators/freezers/incubators, environmental monitoring, and air velocity.

Methods

Members of a team may not be familiar with the level of verification to be performed at each stage of the C&Q project. Additional data can be communicated in the validation master plan or site validation standard operating procedures to clarify without being overly prescriptive. Development of a verification matrix allows for the right balance of describing the anticipated verifications while allowing for standardization of verification methods.

Note, however, that standardization should come with clear processes to allow for continuous improvement.

3. Increased Usage of Vendor Expertise and Verifications

Throughout each project stage of commissioning and qualification, a vendor expertise and verifications can be utilized to increase efficiency and reduce efforts. A detailed example of suggested vendor participation in each stage can be seen in the below table.

Project Stage	Notes	Current Vendor Participation	Suggestions	Proposed Vendor Participation
Design	Vendor responsibility with customer review and approval	100%		100%
Risk & Criticality Assessments	Customer responsibility Vendor may or may not be involved in preparation of assessments	50%	Increased vendor participation in assessments Utilize vendor technical know-how to ensure assessments are well formulated	100%

Vendor Factory Verifications	Vendor responsibility Particular attention paid to modular and component level verifications (software, electrical, etc)	100%	Utilization of vendor factory verifications in lieu of subsequent re-verification	100%
Factory Acceptance Testing	Vendor generated and co-executed with customer	100%	Utilization of vendor factory verifications in lieu of subsequent reverification Incorporation of adequate customer oversight and change management processes	100%
Installation	Vendor responsibility	100%	Subsequent verifications based on understanding of equipment and impacted functions	100%
Vendor On-Site Commissioning	Vendor responsibility (typical intent to verify proper reassembly and function)	100%	Reduce duplication between vendor and customer on-site verifications through objective alignment	100%
Verifications Customer On-Site Commissioning Verifications	Customer responsibility (typical intent to verify outstanding FAT verifications and ensure successful IQ/OQ)	80%		
Vendor IQ/OQ	Vendor generated protocol, co-execution	80%	Reduce duplication between vendor IQ/OQ and customer IQ/OQ	100%
Customer IQ/OQ	Customer generated, customer executed	30%	Vendor involvement with protocol review Vendor support during entire IQ/OQ execution	
Customer PQ	Customer generated, customer executed Little vendor involvement unless there are unforeseen issues	20%	Vendor involvement for protocol review Contract incentives for successful PQ and final payment	50%

Tags:
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