

OVERVIEW

MEC CASE STUDY: PROCESS VALIDATION DOCUMENTATION AND TRAINING

MEC helped a client address a critical process validation knowledge and skill gap. An internal audit had determined their Master Validation Plan and related process validation documentation for their primary product was inadequate.

The client requested MEC's support and the solution included developing new procedures, work instructions, and templates. The client also realized they needed more than "read and understand" training in order for the new process to be implemented effectively. A MEC Consultant partnered with the client to also develop and deliver seven new training modules related to Process Validation, Master Validation Planning, and Test Method Validation.

APPROACH

The Process Validation procedures, templates and training were developed in stages and were implemented over a 12 month period. The implementation aligned with the dates the process validation activities and deliverables were needed by the client. This provided "just in time" procedures and training as the team moved through the validation activities.

The updated procedures, new templates, and the custom training were all developed collaboratively with the client. This approach allowed for knowledge transfer from MEC and ensured development of a Process Validation Subject Matter Expert (SME) within the client's organization.

In addition to improving understanding of process validation requirements, the client also needed help developing core skills to perform process validation activities. Therefore, three levels of training were developed, to target specific audiences:

Awareness – for the broad cross-functional leaders and individual contributors impacted by the process.

Understanding – for the individual contributors to understand why the process is needed and what steps are required in context of related processes.

Application – for the individual contributors to get detailed hands-on practice executing specific process steps.

The procedures and templates were developed first, and the training modules were then developed and delivered in stages. The following modules were prioritized so the client could establish their Master Validation Plan and understand key activities covered in the plan, including Test Method Validation.

1. Process Validation Overview (Awareness)
2. Master Validation Plan Training (Understanding)
3. Master Validation Plan Workshop (Application)
4. Test Method Validation Training (Understanding)

The client team was then able to directly apply the learning and developed their specific Master Validation Plan. The following modules were then created and delivered in time for the execution of the activities:

5. Test Method Validation Workshop (Application)
6. Process Validation Training (IQ OQ PQ) (Understanding)
7. Process Validation Workshop (OQ PQ) Application

Training development efforts included not only the training materials but also data files for exercises, including Minitab data for analysis, and test method validation scenarios. The training was delivered in person and included hands-on exercises and discussions. Participant questions were addressed in real-time, tying the training to their specific activities for a more effective learning experience.

RESULTS

The client provided positive feedback on the success of the Process Validation improvements overall, and the training program specifically. The participants were actively engaged, asked insightful questions, and demonstrated their ability to apply the concepts to their specific scenarios.

The client was able to produce a new Master Validation Plan that not only met compliance requirements, but also served as a practical and valuable cross-reference tool. They also developed and executed multiple test method validations and successfully completed the required process validation activities.

CONCLUSION

The development and delivery of the procedures, templates and custom training curricula represented a journey of growth and development for MEC's client. The MEC approach to partner with the client and provide knowledge transfer along the way proved valuable. When MEC walks with a client, rather than just do things for them, it leaves the client better able to do things on their own in the future. In this case, the client is now able to maintain the process and conduct effective training on their own.

Real change happened with this client team. During year-long journey, the client developed the skills and confidence to build a robust Master Validation Plan and complete the required process validation activities. The client now has a solid foundation of understanding, and can consistently produce higher quality process validation results.