



ARE YOU READY?

CONFIDENTIAL CLIENT, EUROPE

DE-RISKING AUTOMATIC VISUAL INSPECTION (AVI) THROUGH INTEGRATED VALIDATION

CASE STUDY: DRIVING
OPERATIONAL READINESS



De-risking Automatic Visual Inspection (AVI) Through Integrated Validation

PROJECT OVERVIEW

Our initial involvement was focused solely on qualification witnessing for a complex Automatic Visual Inspection (AVI) line, featuring intricate integrations across multiple vendors and a newly customized machine model. However, it quickly became evident that simply observing the qualification process would not suffice to ensure the project's success. Our role evolved to provide the necessary technical leadership to transform what was initially a fragmented approach into a cohesive, compliant validation strategy that would pave the way for production readiness.

THE CHALLENGE: ALIGNING STRATEGIC OBJECTIVES

The project began during a phase of organizational transition for the client, with the Validation Team and the newly established Vision System Team working in parallel. While the restructuring aimed to strengthen specialized expertise, this shift resulted in some initial challenges during the Site Acceptance Test (SAT). Specifically, the vision system testing was carried out using the client's previous approach, which integrated the test within the standardized SAT protocol for AVI machines.

During the SAT witnessing phase, it became clear that several tests required deeper integration and alignment. Recognizing this, we took a comprehensive approach, reviewing the client's internal Standard Operating Procedures (SOPs) and developing a customized integrated IOQ protocol to fill the gaps.



As we conducted the integrated IOQ tests, we identified a critical misalignment: the vendor's baseline recipe and the client's test were not fully aligned with the certified kit of PFS syringes defined by the client, failing to meet the inspection efficiency requirements of USP <790>. Furthermore, the client's testing approach was based on standard procedures and did not fully consider the specific characteristics and requirements of this new AVI equipment.

To address these challenges, we convened a collaborative retrospective meeting with all client departments and the two vendors. This meeting provided an opportunity to reassess the approach and identify areas for improvement. It became evident that the vision system phase had not received the dedicated oversight it required. In response, we worked with the client to pause the project temporarily, giving the client the time needed to refine the recipe and re-test the vision system.

OUR STEPPED APPROACH: PARTNERING FOR SUCCESS

Recognizing the risks and opportunities inherent in the situation, we expanded our scope from passive witnessing to active, strategic involvement:

- **Bespoke Protocol Engineering:** Through a thorough review of the client's SOPs, we customized an integrated IOQ protocol that addressed gaps in the existing vendor SAT protocol, ensuring that the machine met all regulatory requirements.
- **Critical Witnessing & Strategic Pause:** We recommended a temporary hold on the project to allow the vendor to optimize the recipe and the Vision System experts to develop a tailored test protocol. This strategic pause was pivotal in preventing what could have been a 100% failure during the PQ phase.
- **Project Steering & Mitigation:** Acting as a technical bridge, we facilitated alignment between the client and the vendors, ensuring all parties were moving forward on a data-driven, compliant path.
- **Expert Mentoring:** By empowering the client's internal experts, we helped them prioritize the vision system, preventing costly revalidation cycles and enabling more efficient long-term outcomes.

TEN ACTIONABLE TIPS FOR SMOOTH AVI SYSTEM VALIDATION

1. Engage experts early to identify design flaws in equipment, especially when collaborating with new vendors.
2. Manage organizational changes by ensuring specialized teams have clearly defined workflows before project initiation to avoid gaps.
3. Never assume vendor-standard tests (SAT) meet your site's specific SOPs.
4. Standardization can ensure consistency, but customized equipment needs site-specific adaptations.
5. A proactive validation approach driven by risk mitigation helps prevent systemic failures.
6. Maintain control over integration documentation in multi-vendor projects.
7. Clearly define the roles and responsibilities between the client and vendor before testing begins.
8. Transparency in addressing failures is more valuable than simply signing off on a flawed protocol.
9. The power of the pause: if a system isn't compliant, putting it on hold is a strategic decision, not a setback.
10. View validation as a guarantee of quality, not just a bureaucratic hurdle.

IMPACT & VALUE ADDED TO THE PROJECT

Our proactive intervention turned a challenging situation into a strategic success:

- **Cost Savings:** By halting the process during IOQ testing, we saved the client from the significant costs associated with failed production batches and unnecessary validation cycles.
- **Risk Mitigation:** Our involvement helped the client avoid potential regulatory non-compliance and the risk of inspection observations.
- **Enhanced Operational Awareness:** Through close collaboration, the client recognized the importance of integrating vision system and validation expertise from day one for specialized AVI lines. This realization ensured that the line was not only “tested” but truly production-ready.
- **From Risk to Readiness:** Through our strategic oversight, we converted a non-compliant process into a solid, production-ready asset, safeguarding the client’s long-term success.

CONCLUSIONS

The success of this intervention is a testament to both our commitment to technical integrity and the client’s proactive approach. By recognizing early the need for additional expertise and reaching out to us for support, the client demonstrated significant foresight in ensuring the long-term success of the project. Our role in providing an honest “Reality Check” and offering strategic guidance allowed us to identify and address potential risks before they became insurmountable issues.

True operational readiness goes beyond simply meeting regulatory requirements—it involves having the courage and insight to reassess and rebuild foundational elements when necessary. The client’s willingness to pause, reflect, and collaborate with us ensured the validation process was not only compliant but fully aligned with the unique demands of the new AVI equipment. Together, we transformed initial risks into a strategically sound, production-ready solution, safeguarding the client’s future success and ensuring a seamless path to operational excellence.





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