Applying GAMP5 to Life Science projects - and Adding Value

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Summary

For each topic, GAMP5 expectation, project implementation and value added are covered:
Input to the Validation Plan gave a better understanding of the system being supplied. This lead to effective planning.
Input to the Risk Assessment meant suitable actions were decided. This helped focus project resources.
Early completion of traceability matrix helped provide an accurate proposal. The URS/FS link gave an efficient DQ.
A configuration administrator meant the code on all systems was current.
Test documentation executed to customer standards meant the tests were leveraged, hence reducing test repetition on site.
Reporting gave proof that lifecycle activities had been performed well.
Input to SOPs meant that key computer system functions were correctly explained, enabling good use on site.

Problem

GAMP 5 is the Life Science Industry Guide for delivering and operating automated manufacturing systems in a manner that is compliant with regulations. The expectations of GAMP5 are above and beyond Emerson's normal engineering processes. We need to perform these extra activities in a way that adds value to the project for both our Customer and Emerson.

Solution

Ensure the extra activities are included as part of the FEED / proposal stage:

- Validation Planning

- Risk Assessment and Management
- Traceability
- Documented Configuration Management
- Test execution practices including review
- Validation Reporting
- SOPs (Site operating procedures)

Perform the agreed activities in a manner which adds value.

Results & Benefits

- Effective project execution
- Focus on areas of high risk to patient safety, product quality and data integrity
- All requirements met
- Improved DQ process
- Timely code transfer so build on good foundation
- Customer's on site tests reduced
- Proof that lifecycle activities are completed
- Key computer functions e.g. Backup/Restore, Security Mgt, System Admin, are performed well on site