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Using Electronic Lab Notebook Functionality for Validating Electronic Lab Notebook Workflows

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Purpose

The use of electronic laboratory notebooks (ELNs) for regulated bioanalysis requires validation of numerous ELN workflows (templates). Presented here is a strategy for using common ELN functionality to validate workflows such that reviews are more efficient and comprehensive than for traditional software validation. The resulting electronic records of the complete workflow validation process are readily accessible for future reference.

Segregation of Templates During Development and Validation

Templates are built, then validated, and then are made available for use in three separate, segregated parts of the hierarchy, each having different security permissions.

Template Building Folder
• Near universal access and permissions for all users
• For designing, building, and informally testing template prototypes
• Templates in this folder are prevented from being used elsewhere

Template Validation Folder
• Only ELN Administrator may move templates into or out of this folder
• Access and permissions very limited
• QA and Mgmt. review template validation results prior to Mgmt. approval

Approved Template Folder
• Upon approval, ELN Administrator moves locked template to this folder
• Logic embedded into each template ensures that only approved templates may be executed to support bioanalytical studies

Supporting Test Records

Approved Template Validation Records Folder (Archives)
• Numerous experiments and templates executed in support of template validation are moved by ELN Administrator to corresponding archive folder

Execution of Scripts as in Traditional Software Validation… with an Electronic Twist

Template Candidate: Workflow being validated
Validation Plan Experiment: Includes instructional scripts to be executed with a specific Template Candidate

The "Validation Plan" and "Template Candidate" are executed simultaneously in separate ELN experiments. Each time the Tester performs a script designated in the Validation Plan experiment, he or she version-saves the Template Candidate experiment in which it was executed, rendering the results forever retrievable. For each individual script in the Validation Plan Experiment, the Tester records the saved version of the corresponding Template Candidate experiment, along with any comments and unexpected observations.

> Unlike traditional software validation, where successful script execution is affirmed by a generic statement that "expected results were observed", the strategy described here yields electronic confirmation of observed results, as the result of each script execution is saved in a unique, retrievable version of the executed template candidate experiment.

Fig. 1 Portion of a Validation Plan Experiment Table

Fig. 2 Portion of Another Validation Plan Experiment Table

Fig. 3 Table From Template Candidate Experiment

❖ **Fig. 1** lists scripts such as **A** from Validation Plan Experiment

❖ **Fig. 2** is from the same Validation Plan Experiment, and lists specific input such as **B** required by Tester

❖ **C** describes expected results of script **A**

❖ **Fig. 3** is a specific table from the Template Candidate Experiment

❖ **D** is the actual result in the Template Candidate Experiment which **C** describes in the Validation Plan Experiment

❖ **E** is where the Tester documents the saved version of the Template Candidate Experiment containing the result of executing script **A**

Results and Conclusion

Strategic use of common ELN functionality can provide a straight-forward and comprehensive way to execute, review, and even reconstruct ELN workflow validations. Templates being built and validated are securely segregated from those approved for use. A complete electronic validation "package" corresponding to a specific ELN workflow, including supporting experiments and templates, is reviewed by Quality Assurance and approved by Management. This review process is efficient, yet thorough, as a view of every executed script result is a click away, and yields exactly what the tester observed during validation.