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.

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

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

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

Strategic use of common ELN functionality can provide a straightforward 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.

Results and Conclusion
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