Strategy for Designing Electronic Lab Notebook Workflows Both Flexible Enough for R&D and Comprehensive Enough for Regulated Work

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Purpose
Electronic laboratory notebook (ELN) workflows are typically designed for either research or regulated use. Documentation requirements for regulated sample analysis are unnecessarily comprehensive and rigid for free-form research. Creating and validating separate templates targeted for different uses is inefficient. Presented here is a widely applicable, strategy for designing practical ELN workflows (templates), whereby the same template can be used across the full range of regulatory requirements, from non-regulated R&D to fully regulated sample analysis.

Results
Validated ELN workflows provide diverse utility throughout method development, method validation, and sample analysis. With the embedded logic strategy described above, any workflow functionality of interest during method development is available without requiring undue, or impractical, regulatory compliance. For example, numerous (even expired) reagents could be tested during method development to determine the resulting level of carryover, without halting the experiment if the reagents or results were unacceptable. However, these same workflows are also sufficiently flexible and comprehensive for use during method validation and sample analysis to confirm a litany of mandated acceptance criteria. Despite using the same validated workflows, however, data obtained during method development is segregated from use in support of regulated sample analysis.

Conclusion
This strategy allows research chemists to benefit from the same useful ELN workflow functionality required for regulated work without incurring unwarranted regulatory burden.

Simple Concept Yields Significant Flexibility
Logic embedded into each workflow is written to turn on and turn off specific functionality based upon the type of experiment selected. Four experiment types are provided as options in Bioanalytical methods within an ELN:

- **Method Development**: No mandatory user entries or error checking required, yet still provides useful ELN functionality as desired:
  - Accurate, reproducible calculations
  - Comprehensive record of equipment, supplies, and reagents used
  - Screen captures, notes, and data files easily retrievable and shared

- **Method Validation**: All mandatory user entries and error checking required, except QC need not be within stability (not yet established)
  - Fresh Calibrators are required
  - System Suitability is required

- **Long Term Stability**: All mandatory user entries and error checking required, except for ensuring long term QCs are within stability (not yet established)
  - Fresh Calibrators are required
  - System Suitability is required

- **Sample Analysis**: Both yield standard Experiment ID (circled in red)

Note the Experiment ID has a leading “MD” (method development) automatically applied for use in segregating this data from regulated use. Numerous other error checks are not applied.

Key Features of Strategy:
- Validating a single, multifunctional template is more efficient than validating multiple templates targeting different experiment types.
- Valuable ELN functionality is made available and practical for R&D experiments to whatever extent desired by the end user for any given experiment.
- Experiments performed during R&D, where 21CFR Part 11 compliant documentation and error checking are not required, are exempted from use in support of regulated sample analysis.

![Diagram of workflow types and their features](image-url)