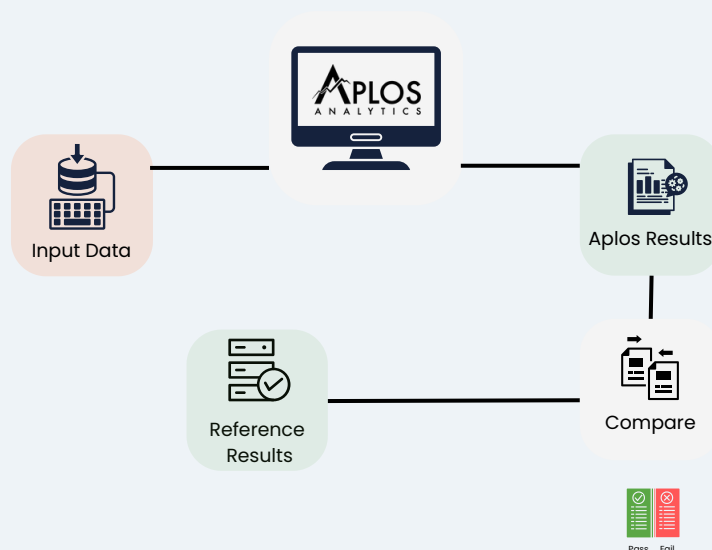


Regulatory Compliance & Validation

Aplos NCA is a powerful pharmacokinetic (PK) analysis software that can be used for non-GLP, GLP, and GCP analyses. Aplos NCA complies with regulatory requirements and ensures the integrity of PK Analysis for regulatory submission.

Aplos NCA includes a validation test module for all users at no additional cost:

- ✓ Validation test cases for 6 different analysis scenarios
- ✓ Expected results for each validation test case
- ✓ Automated validation test module
- ✓ Validation results report with full audit trail
- ✓ Unlimited validation tests during subscription period



Regulatory Compliance

PK parameters calculated by Aplos NCA are accepted by all global regulatory agencies including US FDA, PMDA, MHRA, and more. Aplos NCA is compliant with the following electronic records requirements (US 21 CFR Part 11) including:



Secure authentication



Comprehensive electronic audit trail



Version control for all files



Electronic records can be exported in human- and machine-readable formats.