Using an Electronic System to Record Reagent Tracking and Solution Preparation

David Schumacher, Staci Loughney, and Rachel Walker, Alturas Analytics, Inc., 1324 Alturas Dr., Moscow, ID 83843, USA

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Alturas Analytics, Inc.
The LC-MS Experts

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INTRODUCTION

Chemical Inventory Management System (CIMS) is a custom-developed application initiated in 2008 that has evolved from a small database for tracking of a few basic reagents to a system that currently functions as an electronic laboratory notebook (ELN), illustrated in the timeline below. An off-the-shelf ELN can be cost-prohibitive and difficult to implement; the incremental process has resulted in numerous benefits.

Traceability is critical to QA auditors when reviewing laboratory activities that involve the preparation of reagents and sample processing. Through the use of the CIMS database, QA can audit all materials used in each batch of samples. CIMS can also monitor pipette verification through an add-on module.

SYSTEM ARCHITECTURE

CIMS is a client-server database application. The backend data storage requirement is Microsoft SQL Server. The user interface frontend is Microsoft Access or Microsoft Access Runtime. Programming languages are Microsoft VBA, Microsoft Jet SQL and Microsoft T-SQL.

Figure 1: CIMS Menu and Features

The main menu allows the user to navigate within the application. CIMS is a 21 CFR Part 11 compliant environment, including the features below. Additional features are described in Figures 2-4.

Item creation: All reference standards and reagents are assigned a unique CIMS barcode upon receipt, allowing review and tracking of original component items.

Mix creation: Calibration standards, QCs and other solutions used in the analysis of bioanalytical samples are assigned unique barcodes when created. CIMS interfaces directly with balances to capture weights, eliminating transcription errors. Concentrations are automatically calculated and expiration dates are assigned based on validated stability.

Reporting: Reports by client and study generate summary tables listing matrices and standard solutions included in batch records.

REVIEW BATCH RECORDS

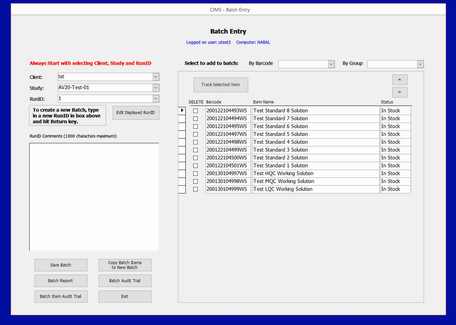


Figure 2: Batch Entry Menu

The Batch Entry menu allows scientists to add items used in each batch to a unique batch record traceable by client, study number and batch number. Batch records include solutions and materials used on each day of analysis. Auditors use this menu to confirm that all items used during the extraction and analysis of a batch were recorded and match the test method. The Batch Audit Trail records the date and time a batch record was created, and the Batch Item Audit Trail lists item addition and removal events.

TRACK TO SOURCE RECORDS

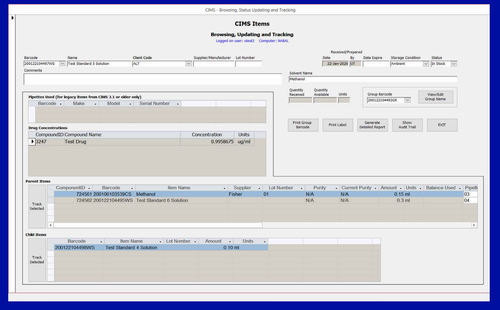
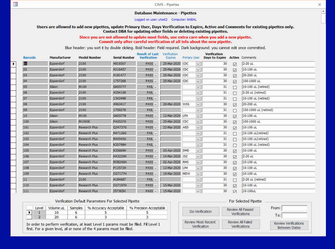


Figure 4: Item Browsing and Tracking

Items can be tracked to parent and child items to ensure that each item was prepared per the test method, used within its expiration date, and stored correctly. Solutions can be traced to stock solutions, ensuring the correct purity, lot number, and expiry were used. An audit trail can be accessed for each component, ensuring that any updates made to purity or expiration are attributable and traceable.

VERIFY PIPETTES



CHECK STATUS

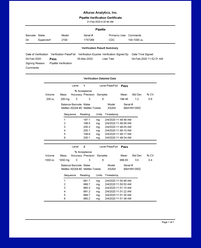


Figure 3: Pipette Tracking and Verification

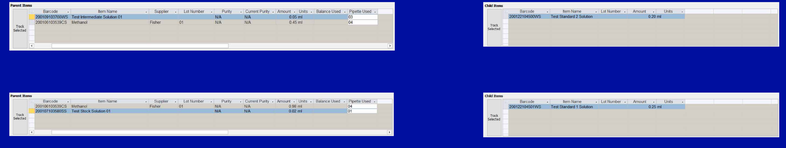
All pipettes are tracked and gravimetrically verified on a monthly schedule. An analytical balance captures consecutive weighings and transmits the data to CIMS, where it is evaluated against the acceptance criteria designated by SOP.

PARENT

PARENT

CHILD

CHILD



CONCLUSION

As a result of developing CIMS over several years, the following key benefits have been recognized by Alturas Analytics:

- Cost savings over off-the-shelf, full ELN systems
- Barcoding providing instant traceability
- Minimized storage space (no paper records)
- Customization meeting evolving needs
- Electronic pipette verification
- 21 CFR Part 11 compliance
- Electronic access to all batch and study records
- Ensured legibility of records
- Elimination of transcription and manual calculation errors
- Direct electronic connection to balances

Timeline of CIMS Development (2008-Present)

V1.0 (2008)
Initial product. Records and tracks chemical stocks, reagents, mixes and mobile phases only.

V2.0 (2009)
Version not released; more functionalities requested to evolve into a 21 CFR Part 11 compliant electronic notebook; became v3.0.

V3.0 (2009)
Keeps records for standards; records preparation of standard solutions. Mix preparation genealogy is recorded and traceable. E-signature and audit trail for all data creation/modification to meet 21 CFR Part 11 standards.

V3.1 (2011)
"Client" entity is introduced and standards are assigned client ownership.

V3.2 (2012)
Weights are read directly from balances through communication ports.

V3.3 (2013)
Creation of serial dilution of working solutions (Cascade Dilution). Added second person e-signature as witness for stock solution preparation.

V4.0 (2017)
"Study" and "Batch" entities are introduced to form a complete hierarchy of Client > Study > Batch > Batch Item. Archiving feature is introduced.

V4.1 (2017)
Reporting feature added to facilitate report writing/review. Added study-wide search and report feature for neat drug items used in ancestry of items in batch runs in the study, grouped by manufacturer/supplier, lot number and purity. "Stability Profile" introduced.

V4.1.1 (2018)
Added study-wide search and reporting feature for standard stock and working solution items in ancestry of mix preparation for all items.

V4.2 (2018)
User authentication changed to Windows Active Directory-integrated. Added study-wide search and report for all matrix items used in ancestry of mix preparations. New type of neat drug items added.

V4.3 (2019)
Added in-application pipette verification; pipette verification status verified when selected for mix preparation.