

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.

Using an Electronic System to Record Reagent Tracking and Solution Preparation

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INTRODUCTION

Chemical Inventory Management System (CIMS)¹ is a custom-developed application by Alturas 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 offthe-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.

TIMELINE OF CIMS DEVELOPMENT (2008-PRESENT)



¹ Chemical Inventory Management System (CIMS) underwent an update in September 2020. The application is now called Holmes.



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

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

CIMS - Browsing, Status Updating and	Tracking	
CIMS Items Browsing, Updating and Tra	acking	
Logged on user: utest2 Computer: I Supplier/Manufacturer Lot Number	ABAC Received Prepared Dels # Dels Expres Strenge Condition Strenge 22.2349:0208 Eff Another V In Strenge	
, ,	Solvert Name Jackson Dauchte Caudhe	
	Ascelude Asababie Units Croup Barcode VewyTdf polizizio4493/cK V Greep Rame	
Concentration Units 0.9958675 ug/ml	Print Croup Bicroshe Print Label Detailed Report Aust Trail DCT	
ne - Supplier - Lot N Fisher 01	amber - Punty - Current Punty - Amount - Units - Balance Used - Pipels N/A N/A 0.15 mi 0.3 N/A N/A 0.3 mi 0.4	
er • Amount • Units • 0.10 ml		
		CHILD
Child Items Balance Used • Pipeth 00 00 00 00 00 00 00 00 00 00 00 00 00	Barcolo Bern Name Lot Number - Amount - Units - 175210500M - 19 - 19 - 19 - 19 - 19 - 19 - 19 - 1	
04 Track Selected		
Child Items	Barcode - Item Name - Lot Namber - Amount - Units -	CHILD
04 01 Track Selected	122104601WS Text Standard 1 Solution 0.25 ml	

CONCLUSIONS

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





Alturas Analytics is a GLP compliant bioanalytical CRO specializing in MS/MS solutions supporting early discovery through late phase clinical trials.

In addition to providing PK support services to pharmaceutical companies worldwide, Alturas maintains an intensive research effort of applying new technologies leading to scientific advancement.

The "Alturas Way": Focused on MS/MS Bioanalysis and Pharmacokinetic Services

When choosing a bioanalytical services provider, you must consider the choices in the context of a rapidly changing and complex industry. Alturas Analytics is recognized as a pioneer and technology leader of MS/MS bioanalysis with a reputation built on performance history, personalized service and creative solutions to some of industry's greatest challenges.

"As a privately owned company, we focus on fostering lasting relationships with our sponsors while having the flexibility to accommodate unique needs as they arise."

- Robin Woods, President

Founded in 2000, Alturas remains privately owned, and operates with a commitment focused on the needs of our Sponsors. Frequent status updates and immediate access to technical experts who understand the urgency of each project are standards built into our routine workflow. Results are delivered on time with scientific integrity that exceeds industry standards.

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- » Antibody Drug Conjugates (ADC) and Other Conjugates
- » Quantitative Biomarker Analysis
- » Plasma Protein Binding Determinations
- » Microsample Analysis Techniques
- » SEND Compliant Datasets
- » Pharmacokinetic and Toxicokinetic Analysis
- » Rush/Next Business Day Data Delivery

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 - Immunocapture
 - PicoFuze™
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- » Compliant with FDA and ICH GLPs and Guidances
- » Onsite QA and IT Departments
- » Watson LIMS[™] Data Management and Security System
- » 21 CFR Part 11 Compliant
- » Validated Analyst® Software
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- » Holmes Electronic Lab Notebook
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- » Sciex Triple Quadrupole LC-MS/MS 6500+/6500/5500/4000 Systems
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- » Waters AQUITY UPLC[®] M-Class Systems
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