

Alturas Advisor

FALL WINTER 2017-18

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MEET ALICE

(Alturas Lab Interface Communications Equipment) Information System

A connected workflow is required for a bioanalytical laboratory to operate with high productivity and efficiency. Communications, lab supplies, equipment lists, test methods, project management, and invoicing have traditionally been managed in separate locations with individualized design and use, creating an inefficient and unproductive system. Being a rapidly growing business, Alturas Analytics has grappled with decisions around the best business system to manage expanding operations.

Alturas Analytics has designed a fully integrated system to monitor laboratory operations from initial client contact to invoice creation to sample disposition that yields shorter times to data and final reports with a great degree of confidence.

Alturas would like to introduce the **Alturas Laboratory Interface Communications, Equipment** information system which is an interactive and real-time database that simplifies data management- also known as **ALICE**.

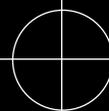
This sophisticated, customized software enhances productivity through streamlining processes and automating workflow with real-time visibility. **ALICE** facilitates the management of timelines for data delivery, interfaces with Watson LIMS, prompts personnel for the next step of data management (review, data delivery, report, invoice generation), and tracks the equipment for maintenance and calibration. The system also tracks assay data including number of samples/unit time and assay failure rate. Forecasting revenue and forecasting



project timelines for prudent resource management has enhanced operations substantially, and ultimately provides an exceptional client experience. This unique system has improved lab productivity. With the implementation of **ALICE**, Alturas Analytics is able to perform higher quality sample analysis in less time.

This custom built, integrated project management suite is transforming how the business is conducted, enabling Alturas to transcend any potential challenges that could cause bottlenecks and inefficiencies.

We expect this system to take our business to the next level of growth. Welcome to Alturas, ALICE.



SCIENTIST FOCUS

Sharon DeChenne

Sharon DeChenne is a Senior Scientist at Alturas Analytics. Her energy, attention to detail, and commitment to scientific excellence makes her a valuable part of Alturas' team of experts. Sharon's interest in expanding her knowledge of the industry and ability to expand her responsibilities within Alturas Analytics are important traits when one considers the company's record growth. Sharon is a warmly regarded and professionally respected member of the Alturas Team.

Sharon joined Alturas Analytics in 2012 while still a student of Chemical Engineering at WSU. Upon graduation with a Bachelor of Science degree in 2012, Sharon was hired



as Associate Scientist. Two short years later, she was promoted to Scientist. While a Scientist, she developed a training program for new scientist team members, which she implemented to great success. Many scientists at Alturas Analytics owe their success in part to Sharon's comprehensive and effective training program.

A promotion to Senior Scientist in early 2017 has Sharon partnering directly with clients, acting as Study Director and/or Principal Investigator for nonclinical and clinical studies, and ensuring projects are kept on track. Sharon continues to train and supervise personnel and enjoys the additional duties of her newest position.

When Sharon is not at work, she may be found with her husband and two little girls exploring parks and playgrounds around the area, and otherwise enjoying all manner of kid-friendly activities with family and friends.

ALTURAS PROFESSIONALS

Alturas Analytics' scientists, project management, and quality teams have proven their strength as managerial leaders, ensuring your study is managed and completed with scientific rigor and efficiency. Our teams provide the perfect blend of scientific expertise, guidance, and innovation needed to deliver successful project management services for your most challenging bioanalytical projects.

**|| Show us the
molecule and
we will develop
an assay for it.**

– SHANE NEEDHAM, PH.D.,
LABORATORY DIRECTOR AND CO-FOUNDER

COMPREHENSIVE, REGULATED DATA MANAGEMENT

Alturas Analytics upholds the most stringent data management and reporting procedures to guarantee reliable, reproducible, and compliant **SEND datasets**.

The Standard for Exchange of Nonclinical Data (SEND) specifies collection and presentation of nonclinical data in a consistent format, which allows data between organizations to be integrated and used more efficiently. This standardization model for the electronic representation of nonclinical individual data is intended to guide the organization, structure, and format of standard nonclinical tabulation datasets.

The submission of SEND datasets provides more efficient, higher quality regulatory reviews. Interchange between Sponsors, CRO's, and other entities is enhanced due to the standardization of structure and format, ensuring your project stays on track.

PROFICIENCY AND PRODUCTIVITY

Data integrity and timeliness are key deciding factors when choosing a bioanalytical CRO. Known as MS/MS experts, Alturas Analytics is continually building infrastructure through acquisition of capital equipment as well as software solutions that focus on proficiency and automation to provide the highest quality services that meet industry expectation. These investments increase capacity and productivity while decreasing overall timelines to the client.

Over the past year, Alturas invested in 3 additional LC-MS/MS systems, including a third **SCIEX Triple Quad LC-MS/MS 6500** to add to our suite of high performance instruments. The latest, most sensitive instrument from Sciex, a Triple Quad LC-MS/MS 6500+, is planned for installation before the end of 2017. The SCIEX 6500s introduce a series of advancements that increase ion production and transmission efficiency to the detector yielding greater sensitivity. This brings a high degree of redundancy and increased capacity for projects that require ultimate sensitivity such as highly potent drugs and topical formulations where concentrations in the peripheral circulation are typically in the low pg/mL range. With an increase in the development of highly specific and targeted drugs, Alturas is prepared to address the demand with the latest technology teamed with knowledge and experience.

Report Writing Manager

Meeting aggressive timelines is a collaboration of multiple functions that involve every facet of operation from first contact with the client, to generation of data through submission of the final report. It is a dynamic and complex process that poses potential for delays and a report deadline that typically remains unchanged. To streamline report writing and significantly reduce the amount of time for generation and review of the final delivery, Alturas has invested in an enhanced throughput software solution by **LABIntegrity: StudyDoc™ Report Writing Manager** an automated, adaptable program designed specifically for compliance. Data is date and time stamped and directly imported from the Thermo Scientific Watson™ database via locked field codes ensuring that table data cannot be modified which greatly reduces the review time. The program collates, organizes and generates reports using custom templates with the flexibility to edit text fields if needed while data tables remain locked. Manual processes are minimized freeing valuable Technical Writer, Principal Investigator and QA Auditor resources to expand in new directions that will enhance our current service offerings to the client.

Investing for the Future - Productivity and Increased Capacity

OUTREACH 2017-18

13th Annual Applied Pharmaceutical Analysis (APA) and Applied Pharmaceutical Software (APS)

Silver Sponsor

September 18-20, 2017

Omni Providence Hotel, Providence, RI

Presentations:

- *Microspray and Microflow Liquid Chromatography: The Perfect Fit for Modern LC-MS Bioanalysis*
- *Using Real-Time Watson LIMS Data Integration and Analytics to Monitor Data Quality and Productivity, an Application of the Business Integration Program in the Bioanalytical Lab*

Poster:

Quantitative HPLC-MS/MS Analysis of DM1 and DM1-MCC Extracted From Whole Blood Dried Onto a Mitra® Microsampling Device

21st North American Meeting of the International Society for the Study of Xenobiotics (ISSX)

Exhibiting – Booth 312

September 24-28, 2017

Rhode Island Convention Center, Providence, RI

Clinical & Pharmaceutical Solutions through Analysis (CPSA) USA

Enabling Personalized Medicine: Connecting People, Disciplines and Technology

October 23-26, 2017

Philadelphia, PA

American Association of Pharmaceutical Scientists (AAPS) Annual Meeting & Exposition

Exhibiting - Booth 1444

November 13-15, 2017

San Diego Convention Center, San Diego, CAD

57th Annual Meeting and ToxExpo - Society of Toxicology Attending

March 11-15, 2018

San Antonio, TX

12th Workshop on Recent Issues in Bioanalysis (WRIB) A Week of Bioanalysis, Biomarkers, and Immunogenecity Platinum Sponsor

April 9-13, 2018

Sheraton Philadelphia, Philadelphia, PA

66th ASMS Conference on Mass Spectrometry and Allied Topics

Poster

June 3-7, 2018

San Diego, CA

ANTIBODY DRUG CONJUGATES (ADCs)

EXPERIENCE

Ten years of assay development experience with Antibody Drug Conjugates (ADCs) has given Alturas Analytics the depth of knowledge to produce accurate and consistent measurements of ADCs in accordance with FDA guidelines. Our expert team possesses understanding of the critical factors inherent to ADC assay development that is applied to each unique project.

ABOUT ADCs: Potent and specific biopharmaceuticals that continue to show significant therapeutic promise, ADCs combine the specific targeting abilities of an antibody with a cytotoxin that attacks cancer cells that contain a unique marker. This significantly improves delivery of the toxin to the target tissue or tumor while minimizing exposure to healthy tissue. High specificity and therapeutic efficacy with potentially fewer side effects is a compelling combination representing significant opportunity for the pharmaceutical and biotechnology industries, and offers tremendous benefit to cancer patients.

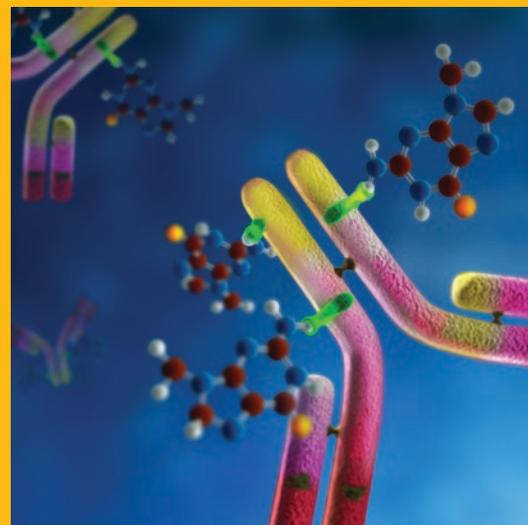
The complex nature of ADCs presents unique challenges in the bioanalytical laboratory that requires thorough understanding of the chemistries and the interactions between each component of the conjugate. Traditionally bioanalysis necessitates a combination of ligand binding and LC-MS/MS techniques to characterize the pharmacokinetics of the ADC. With advances in LC-MS/MS technology it is possible to perform each component on a single platform. LC-MS/MS of the toxin, linker, metabolites as well as signature peptides for quantitation of the antibody is becoming routine and accepted in our industry and provides a time advantage over traditional methods.

Alturas Analytics possesses the scientific expertise and a successful history of rapidly developing and validating complex methods that have supported thousands of regulated study samples. We are committed to drive technology that will provide data of the highest integrity in the shortest time possible.

THE ALTURAS DIFFERENCE

Our bioanalytical team has extensive experience developing and validating robust MS/MS methods across a wide variety of therapeutic agents and biomarkers in most every biological matrix. We support drug candidates from discovery through phase IV clinical trials and provide accurate and timely SEND compliant datasets to our clients. FDA compliant, state-of-the-art facilities with 24/7 monitoring and generator back-up, customized software that streamlines processes and automates work-flow with real-time visibility, and onsite QA and IT services ensure timely and accurate results.

We are the ideal choice for your bioanalytical needs.



The LC/MS Experts™

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