

Alturas Advisor

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Expanding Bioanalytical & Biomarker Capabilities: Addition of TSQ Quantum XLS Ultra™ GC-MS/MS

Alturas Analytics, Inc. excels at addressing the bioanalytical industry's demands for sensitivity, selectivity, robustness and ease-of-use through our unmatched expertise and continued acquisition of top-shelf instrumentation. With our thoughts turned toward the future, we remain dedicated to the managed expansion of our throughput capacity and the variety of services offered in our laboratory.

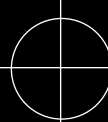
Over the past several years in particular, Alturas has introduced a variety of new services. Some examples are plasma protein binding, dose solution analysis and in order to address the growing need for sensitivity Alturas has introduced MicroFlow Liquid Chromatography (MFLC) and MFLC-tandem mass spectrometry (MFLC-MS/MS) services as well.

Additionally, Alturas Analytics now offers gas chromatography mass spectrometry (GC-MS) and gas chromatography-tandem mass spectrometry (GC-MS/MS) services for the analysis of molecules that are challenging for traditional liquid chromatography. Specifically Alturas has added one of Thermo Scientific's TSQ Quantum XLS Ultra™ GC-MS/MS systems to its current fleet of AB Sciex LC-MS/MS instruments. The TSQ Quantum XLS Ultra™ is engineered to meet the requirements of the most demanding of analyses across a wide variety of disciplines; including clinical and pharmaceutical research, biomarker quantitation, metabolomics, forensic toxicology, food safety, and environmental sciences ^[1].

GC-MS/MS analysis is picking up the pace to address the growing need for additional tools and techniques that can effectively quantify not only new drug candidates, but also play a significant role in the increasingly prevalent need to analyze and quantify biomarkers. Though LC-MS/MS has become the gold standard in the pharmaceutical industry, the paradigm is shifting back away from an "everything is possible" LC-MS/MS approach towards GC-MS and GC-MS/MS for proven, alternative solutions ^[2]. This swing from LC-MS/MS-centric analysis to inclusion of GC-MS/MS is not only due to issues of sensitivity, but also because of its provision of a practical approach for a general electron ionization (EI) technique that largely avoids the ion suppression effects frequently observed with electrospray LC-MS ion generation. GC-MS is a well-established technique utilized for the analysis of volatile species as well as semi-volatile molecules that



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are suitable for chemical derivatization to increase their volatility and thermal stability. Gas chromatography enjoys a number of advantages compared to LC techniques, including better chromatographic resolution and peak capacity, fewer solubility issues and better separation through manipulation of temperature gradients and stationary phases. The combination of gas chromatography with electron impact ionization MS (EI-MS) provides a very high degree of chromatographic resolution, analyte-specific detection, and quantitation of metabolites as well as the ability to identify unknown entities quickly. Indeed, the characteristic and constant fragmentation patterns for many compounds provided by electron ionization may be referenced for rapid structural identification, using resource libraries such as NIST, EPA and Wiley mass spectral databases [3].

Although there are many advantages possessed by GC-MS/MS compared to the LC variant, in many respects the same still holds true in reverse. In the hands of our highly experienced science team, the symbiotic qualities of GC-MS and LC-MS techniques provide the

ability to dependably quantify an extremely wide variety of analytes in a similarly large selection of matrices; spanning very large ranges for many properties such as thermal stability, solubility, relative volatility, molecular mass and more. This complimentary nature of both instrumental methods then has truly presented our expert leadership with the ability to analyze an even greater expanse of biomaterials than ever before in an increasingly effective and efficient manner.

Accordingly, at Alturas we benefit from an expansive array of bioanalytical applications; ranging from diagnostic and early medical intervention applications, to research on the pharmacokinetics and pharmacodynamics of drugs, metabolomics and metabolic profiling analysis, and increasingly applications in biomarker analysis. Our bioanalytical team is proud to deliver quality biomarker method development, validation and sample analysis services to global pharmaceutical and biotechnology organizations. With specialized expertise in method development, and “fit for purpose” validation for definitive quantitation

STAFF PROFILE:

Kerri Renner

Kerri Renner has been the Alturas Analytics, Inc. Administrator since the spring of 2009. Her enthusiasm, persistence and attention to detail contribute greatly to the smooth day-to-day operations of Alturas. In her role as Administrator Kerri oversees all areas of accounting; including accounts payable, receivable, and her most popular duty - payroll. She also assists with generating and maintaining important metrics that keep Alturas Analytics operating on-time and on-budget.

Working together with our marketing department and scientific operations, Kerri maintains a real-time projection of Alturas' upcoming volume of work. This allows for the efficient allocation of resources and ensures that we continue to meet sponsor timelines. It also helps maintain the sustainable, managed growth we strive for and to expand our line of services, all while maintaining the high quality science and customer service our sponsors have come to expect.



As an Idaho native, Kerri grew up in both northern and southern Idaho. She graduated from Northwest Nazarene University in Nampa, Idaho with a bachelor's degree in Accounting and Business Administration. Kerri and her husband Dave have 3 children. Currently two of them are in college and one is serving in the U.S. Air Force. They all enjoy typical northwestern recreation such as camping, biking and boating. As an avid soccer fan; whenever Kerri isn't busy keeping the lights on at Alturas, she and her family enjoy travelling to Seattle to cheer on the Seattle Sounders.

of a large host of endogenous analytes; Alturas is one of the few bioanalytical laboratories successfully employing LC-MS/MS and GC-MS/MS technique for the quantitation of endogenous molecules and contract biomarker research or services.

Providing

- LC-MS and LC-MS/MS biomarker assays
- GC-MS and GC-MS/MS biomarker assays
- Biomarker method development
- Biomarker method validation - "fit-for-purpose" for definitive quantitation
- Biomarker sample analysis

Our team brings the experience and knowledge you need to address your most demanding bioanalytical challenges with the outstanding customer care and attention to detail that our clients have come to expect. Please visit us online at alturasanalytics.com or call 208-883-3400 for more information regarding our services, assays and research initiatives. Whatever your bioanalytical needs, we look forward to providing you with excellence.

1. www.thermoscientific.com/en/product/tsq-quantum-xls-ultra-gc-ms-ms.html
2. **Handbook of GC/MS: Fundamentals and Applications**, edited by Hans-Joachim Hübschmann, John Wiley & Sons, 2009
3. **Current medical research with the application of coupled techniques with mass spectrometry** Joanna Kaluźna-Czaplińska, Med Sci Monit. 2011; 17(5)

Outreach 2014-15

Chemical and Pharmaceutical Structure Analysis (CPSA) 17th Annual Symposium on Clinical & Pharmaceutical Solutions through Analysis

Short Course:

"Method Development for LC/MS: Traditional Approaches and Emerging Trends"

Oral Presentation and Exhibit

September 29 - October 2, 2014

Sheraton Bucks County Hotel

Langhorne, PA

19th North American Regional ISSX Meeting and 29th Annual JSSX Meeting

Exhibit (Booth #604)

October 19-23, 2014

Hilton San Francisco

San Francisco, CA

American Association of Pharmaceutical Scientists (AAPS) 2014 Annual Meeting and Exposition

Exhibit (Booth #2840)

November 2-6, 2014

San Diego Convention Center

San Diego, CA

Pittcon

Oral Presentation

March 8-12, 2015

Ernest N. Morial Convention Center

New Orleans, LA

Society of Toxicology 54th Annual Meeting and ToxExpo

Exhibit (Booth #1802)

March 22-26, 2015

San Diego Convention Center

San Diego, CA

9th Workshop on Recent Issues in Bioanalysis (WRIB)

Exhibit (Booth #TBA)

April 13-17, 2015

Hilton Miami Downtown, Miami, FL

2015 AAPS National Biotechnology Conference (NBC)

Exhibit (Booth #103)

June 8-10, 2015

San Francisco Marriott Marquis

San Francisco, CA

63rd ASMS Conference

Attending

May 31- June 4, 2015

America Center

St. Louis, MO

16th Annual Land O'Lakes Bioanalytical Conference

Attending

July 2015

Fluno Center

Madison, WI

DISCUSSION CORNER

Alturas Analytics, Inc. Supporting the Animal Health Industry

The market for veterinary pharmaceuticals and vaccines is currently estimated at \$22 billion per year, and is projected to grow by approximately 6% annually through 2016. As the burgeoning middle classes in developing markets such as China and Brazil continue to expand, demand for drugs and vaccines by both private and agricultural interests are expected to follow suit. This fact certainly isn't lost on the pharmaceutical industry. Over the past several years giants like Merck, Eli Lilly and Zoetis have been pursuing mergers, spinouts and acquisitions to secure a promising place in these growing nations.

Unlike traditional preclinical or clinical studies, the FDA's Center for Veterinary Medicines (CVM) requires the submission of significantly more information including all raw data generated, chromatograms from failed runs, SOPs and personnel records. In order to help streamline the submission process, Alturas Analytics has developed custom reporting templates that conform to the CVM standards. In order to provide a more seamless transition for your drug candidate, Alturas Analytics, Inc. has also formed several strategic alliances with in-life facilities - both domestically and abroad that have companion- and farm-animal handling capabilities. This allows Alturas to function as a "one-stop shop" while maintaining a single point of contact and continuing to focus on our bioanalytical strengths.

As the needs of the regulated pharmaceutical industries continue to evolve and expand, it's imperative that CROs be able to adapt their services and expertise in order to provide the latest in bioanalytical support. Alturas Analytics, Inc. has the instrumentation, capacity, and experience to provide excellent bioanalytical support for animal health medicines. With more than 25 years of combined experience in Animal Health and over 100 years of combined bioanalytical experience, our scientists have developed numerous proprietary and non-proprietary bioanalytical assays.

Whether your candidate is a new chemical entity, novel formulation, or bioequivalent drug we can help make your program a success.



The LC/MS Experts™

www.alturasanalytics.com

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