

# Unitides Laboratories

– A Specialty, Client-Centric Bioanalytical CRO

August 2023

[www.unitides.com](http://www.unitides.com)



# Unitides Laboratories Inc.

- A specialized CRO eager to tackle complex bioanalysis of small molecules, peptides, oligonucleotides, and biomarkers with top quality and efficiency
- Platform: Liquid Chromatography-Mass Spectrometry (LC-MS) and Liquid Chromatography-Fluorescence (LC-FL)
- Located in Madison, WI

***Unitides –  
A Unique and Specialty lab focusing on  
solving bioanalytical problems with  
quality and speed.***



# Dr. Fumin Li, Founder and Lab Director

- A well-known scientific expert and business leader
- Former Sr. Director of PPD, Bioa Operations Lead, Covance
- More than **16** years of experience in LC-MS-based bioanalysis
  - **40** peer-reviewed papers, **63** posters, and **4** book chapters
- Enabled > **100** validated bioanalytical methods and > **100** bioanalytical projects annually
- An Editorial Board member of journal *Bioanalysis* (Future Science)
- PhD, Iowa State University; Post-Doctoral Fellow, Pacific Northwest National Laboratory



# John Zulkoski, Operation Manager

- 25+ years of diverse experience in drug development and food safety at leading laboratories including Covance and Eurofins
- Oversees high-throughput sample analysis and manages advanced instrumentation fleets
- Incorporates innovative technologies and chromatographic techniques to enhance workflow and quality
- Executed successful global projects in GLP and GMP environments, supporting labs across multiple countries



# Vison, Mission and Strategy of Unitides

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## ■ Vision

- To become the Bioanalytical Center of Excellence for biotech and biopharma clients

## ■ Mission

- Excel in bioanalysis with experience, innovation, efficiency, and compliance

## ■ Strategy

- Deliver science-driven, on-time, cost-effective and fit-for-purpose bioanalytical solutions with client-centric services

# Laboratory Space and Instrument

- The new laboratory, ~6,000 ft<sup>2</sup>, is purpose-built to support regulated/GLP bioanalysis
  - State-of-the-art infrastructure to support regulated bioanalysis
  - Key SOPs are based on ICH M10 guidelines
  - Modular design allows for rapid expansion of instrument capacity
- Immediate instrument capacity
  - Two state-of-the-art Sciex API 6500+ coupled with Shimadzu UHPLC
  - LC-UV and LC/Fluorescence systems

# Services Offered

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- The lab is open for business in August 2023 and the services are offered in two stages:
  - We currently offer LC-MS/MS assay development for peptides, oligonucleotides, and small molecules, and sample analysis supporting drug discovery and exploratory endpoints in clinical studies (e.g., tissues, biomarkers, metabolites). We provide bioanalytical consulting services, from technical/regulatory input to project management.
  - Starting 2024, we will support regulated studies, i.e., clinical PK and GLP tox.

# Unitides Lab Current Offering: Example Projects

- Development and pre-validation/qualification of LC-MS/MS methods of
  - Peptides
  - Oligonucleotides (i.e., ASO and siRNA) in liquid matrices and tissues
  - Small molecules
  - Patient-centric sampling (e.g., Tasso<sup>®</sup> or Mitra<sup>®</sup>)
  - Biomarkers
- Discovery bioanalysis for peptides, oligonucleotides, and small molecules and biomarkers in support of in vivo studies
- Establish exploratory matrix stability and sample collection procedures
- Feasibility and troubleshooting of LC-MS/MS assays
- Bioanalytical consulting



## Why Choose Unitides?

- We provide client-centric services.
- We solve complex bioanalytical problems.
- We focus on quality and timely deliverables.
- We are cost-effective.



Main LC-MS Laboratory.  
Key infrastructures are in  
place for rapid expansion.



Extraction Lab with Class II, Type A2 Biosafety Cabinets, and freezers for short-term sample storage.



## Key Infrastructures Are in Place to Support Regulated Bioanalysis

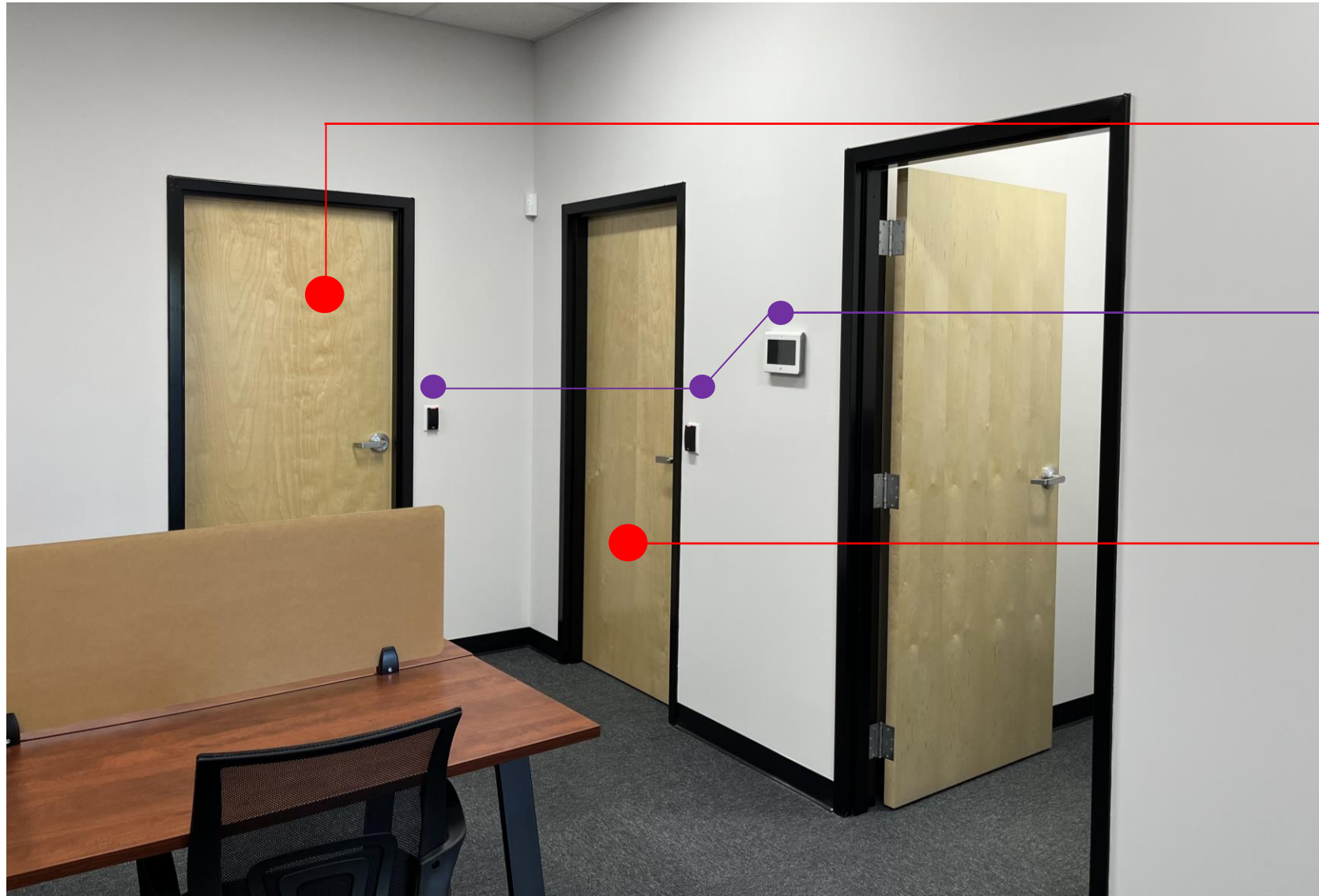
Freezers For Sample Storage



Dark Room



## Key Infrastructures Are in Place to Support Regulated Bioanalysis



- Archive Room
- FM200 Fire Suppressant

- Access Control System

- IT Room with Servers –  
Intranet for Sensitive Data
- FM200 Fire Suppressant

## Key Infrastructures Are in Place to Support Regulated Bioanalysis



Nitrogen Tower for Uninterrupted N<sub>2</sub> Supply to Mass Spectrometers



Backup Generator for Uninterrupted Power Supply to the Entire Lab



**We courteously invite you to visit Unitides or schedule a technical discussion!**

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# Thank You!

Let us partner with your R&D team, working on challenging and/or novel bioanalytical assays to provide solutions to your mission-critical projects.