



# Internships at Pyxant Labs Inc.

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Pyxant Labs Inc. is a bioanalytical laboratory offering two distinct laboratory services: its GLP Contract Research Organization (CRO) unit supports drug development for pharmaceutical and biotech companies, while its CLIA Clinical Laboratory Services (CLS) division assays patient specimens, including urine and oral fluids, for prescribing physicians, clinics, and hospitals, for medication management and clinical diagnostics.

Founded in 2000, Pyxant Labs uses state of the art mass spectrometry to assay high value samples for regulated industries. Pyxant Labs practices within areas that draw upon the Company's key strengths: industry-leading scientific expertise, stringent technical-regulatory compliance, fast turnaround, and exceptional customer service. Pyxant Lab's greater mission is to improve patient outcomes by offering the most reliable laboratory results, fast.

## Internships for Undergraduate Students at Pyxant Labs Inc.

The 8-week internship for undergraduate students is designed to provide the candidates an opportunity to work in a laboratory supporting sample assays for biological specimens from pre-clinical and clinical studies and from medical practices. Our work is essential to pharmacokinetic and pharmacodynamic assessments during the drug development process as well as for assessing FDA-approved prescription drugs to aid care delivery in physicians' offices.

We indoctrinate every new employee through our "Pyxant Labs University" training program. The teaching curriculum includes:

- General safety in the laboratory, including biohazard and overall "laboratory hygiene"
- General laboratory operations for customized Laboratory Designed Tests on LC-MS/MS platforms
- Development of new bioanalytical methods
- The new drug development process, from discovery of new compounds to clinical trials: "the life of a sample" from technical, scientific, and development phases and regulatory requirements
- Training on CLIA, GLPs, GDPs and HIPAA
- Blood, urine, oral fluid, and tissue sample preparation strategies, reasoning, and techniques
- Basics of Ultra-Performance Liquid Chromatography in tandem with Triple Quadrupole Mass Spectrometer, the most accepted technology in the industry
- Hands-on work in the laboratory
- Basic understanding of study designs in preclinical studies and clinical trials
- Processing clinical diagnostics samples under CLIA as well as the process for reporting their results

A comprehensive training file required by the regulatory agencies will be assembled during the internship. GLP and CLIA completion certificates will be issued upon passing the exams.

### Who qualifies

College or undergraduate students pursuing a life science degree such as Medicine, Biochemistry, Chemistry, Biology, Veterinary Medicine, etc., with a GPA of 3.5 or better.

### Compensation

\$15/hour as actual laboratory work will be performed.



# 8 Weeks Internship Syllabus

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## Supervisor:

Shane Karnik, Laboratory Director

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## Week 1

Pyxant Labs Inc. Overview and Health and Safety

- Contract Research Organization (CRO) and Clinical Laboratory Services (CLS) – what we do as a company
  - Blood borne pathogen training
  - Hazard communication
  - Chemical hygiene
  - Standard Operating Procedures in a GLP laboratory: review all, learn associate Chemists SOPs
  - Glassware washing
  - Non-regulated lab support
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## Week 2

GLP and Regulatory Training

- 21 CFR part 58
  - 21 CFR 11
  - GLP/GDP slide show and test
  - HIPA Privacy Rule: slides show and test
  - Cybersecurity
  - Quality systems
  - Regulations: from FDA, EMA, OECD and CLIA
  - Sample receipt
  - Certificates of analysis
  - Non-regulated lab support
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## Week 3

Lab Skills

- Pipette training (types and application)
  - Analytical balances
  - UHP water systems
  - pH meters
  - Lab support
    - Reagent preparation
    - Sample and chemical receiving
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## Week 4

Bioanalytical (Slide Show/Lecture)

- Types of studies (toxicology, Phase 1 through Phase 3)
  - Types of extractions (PPT, SPE, LLE)
  - Lab support
    - QC and calibrator preparation
    - PSAE extractions
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## Week 5

- Daily: observe mass spectrometry expert troubleshoot overnight issues
  - Chromatography
  - Reverse phase vs. normal phase
  - Mobile phase additives (LC-MS/MS vs. LC/UV)
  - Instrument set up
  - Gradient vs. isocratic
  - Non-traditional chromatography (anion exchange, size exclusion)
  - Lab support
    - Instrument setup
    - Analytical run building
    - QC and calibrator preparation
    - PSAE extractions
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## Week 6

- Daily: observe mass spectrometry expert troubleshoot overnight issues
  - Mass Spectrometry
  - Types of mass spectrometry (HRAM, triple quad, SIM, MRM)
  - Monoisotopic mass vs. average mass
  - Tuning (precursor and product ion)
  - Lab support
    - Tuning compounds
    - QC and calibrator preparation
    - PSAE extractions
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## Week 7

- Daily: observe mass spectrometry expert troubleshoot overnight issues
  - Laboratory Life
  - Lab support: work with bioanalytical chemist and support as needed
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## Week 8

- Daily: observe mass spectrometry expert troubleshoot overnight issues
  - Putting It All Together (from Powder to Paper to Patient)
  - Archiving for GLP studies
  - What goes into a regulatory report?
  - How does a drug get approved?
  - Lab support: work with bioanalytical chemist and support as needed
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