



**IMMUNOLOGIX**  
LABORATORIES

Designed by Scientists, Run by Scientists

CAPABILITIES ARTICLE

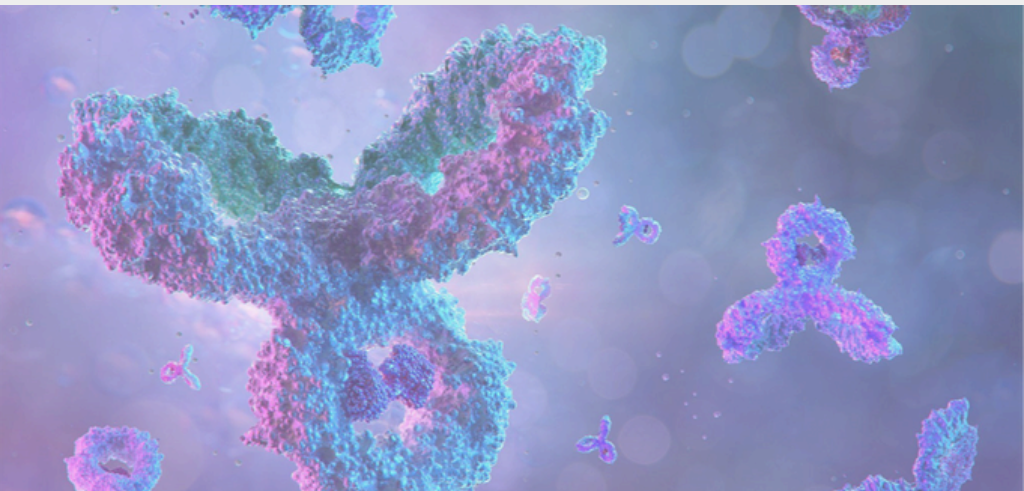
# THE IMMUNOLOGIX DIFFERENCE

INTEGRATED LABORATORY AND  
TRANSLATIONAL SCIENCES  
SERVICES

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BY KAYLA J. SPIVEY

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# INTRODUCTION

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## WHAT MAKES A LABORATORY SERVICES PARTNER TRULY DIFFERENT?

At Immunologix Laboratories, we've built our reputation on delivering exceptional laboratory and scientific services by bringing together two essential arms of scientific capability: state-of-the-art laboratory services paired with comprehensive consultative expertise through our Translational Sciences team. Since our founding in 2012 on the backbone of GXP Bioanalysis, we've built something unique in the industry – a true integration of sophisticated scientific expertise with cutting-edge laboratory capabilities that sets us apart from traditional service providers.

Our laboratory services form the foundation of everything we do, delivering high-quality bioanalytical, cell-based assay, and biomarker testing to support drug development programs. What sets us apart is how we've enhanced these core laboratory capabilities through seamless integration with strategic drug development expertise. Every project that enters our laboratory benefits from both world-class technical capabilities and robust drug development knowledge, creating a scientific ecosystem where the barriers between strategic thinking and technical execution have been eliminated.

Our growth trajectory reflects our commitment to expanding and enhancing our laboratory services while maintaining this core integrated approach. In 2017, we launched our biomarker sciences organization under the leadership of industry veteran John Allinson, bringing over 40 years of clinical biomarker experience to our team. Most recently, we've built laboratory capabilities in cell and gene therapies, maintaining our integrated approach as we support these emerging modalities.



# SECTION I

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## SCIENTIFIC LEADERSHIP IN LABORATORY SERVICES

Our approach to scientific leadership directly enhances the quality of our laboratory services. While our domain experts are globally recognized thought leaders who regularly speak at international conferences and author influential white papers, what truly sets us apart is our commitment to making this expertise accessible throughout our laboratory operations. We don't believe in siloing our scientific expertise in an ivory tower – instead, we ensure it directly benefits our laboratory work at the bench level every day.

This commitment comes to life through our daily scientific office hours, where our entire translational sciences team and senior scientific leaders come together to provide real-time support and guidance to our laboratory and support personnel. These sessions serve multiple purposes: troubleshooting complex analytical challenges, exploring new methodologies, and ensuring our laboratory work benefits from our collective expertise. Any of our laboratory personnel can access this resource on any given day, ensuring that each project benefits from over 100 years of combined translational experience.

Our commitment to scientific education and advancement is further demonstrated through our Rethinking Bioanalysis Scientific Discussion Forum series. In these forums, we invite the industry to join us to examine established laboratory practices in light of emerging data, challenging conventional wisdom when necessary. For example, recent discussions have explored evolving approaches to immunogenicity testing and innovative biomarker strategies, directly informing how we enhance and optimize our laboratory services.

## SECTION II

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# A FOUNDATION BUILT ON SCIENTIFIC INTEGRATION

At the heart of our organization lie four key capabilities, each representing a critical component of modern drug development support.

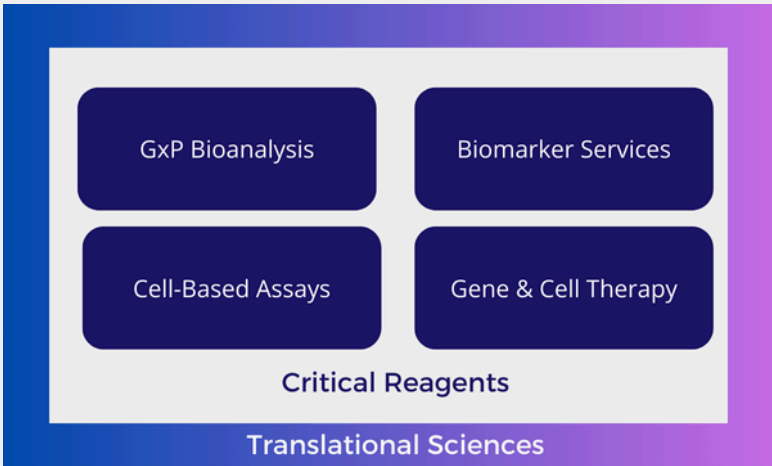
Our GXP Bioanalysis capability, which founded our organization, remains a cornerstone of our services. This isn't just about running assays – it's about bringing sophisticated scientific understanding to every analysis we perform. Our bioanalytical portfolio maintains a careful balance between PK and ADA work, including NAB studies, reflecting comprehensive high-quality, high-volume work across all of these domains.

We have taken bioanalysis a step further by expanding into specialized capabilities in cell-based assays, becoming the trusted laboratory partner even for organizations with sophisticated in-house resources. Our team's deep understanding of cellular mechanisms and assay optimization has made us the go-to partner for even the most challenging analyses.

Our biomarker sciences organization represents a service that brings together technical excellence with deep strategic understanding of how biomarkers can advance drug development programs. We've built a team that excels in both the technical and strategic aspects of biomarker development, from assay optimization through data interpretation. Our biomarker team works closely with sponsors to develop comprehensive strategies that align with program objectives while ensuring technical feasibility and regulatory compliance. This expertise has made us a trusted partner for programs ranging from early-stage biomarker discovery through post-market studies.

Surrounding all these laboratory capabilities is our Critical Reagents team, who are dedicated to ensuring the quality and reliability of the materials used in our assays. They handle everything from labeling for immunogenicity work to standard material characterization.

Our integrated Translational Sciences team is comprised of scientists who each have at least 15 years of direct drug development experience on the sponsor side. They understand the strategic, scientific, and technical landscape from late research all the way through post-market - including all the regulatory interactions along the way.



As you can see from the visual, Immunologix Laboratories brings together two essential arms of scientific capability - state-of-the-art laboratory services paired with comprehensive consultative expertise through our Translational Sciences team.

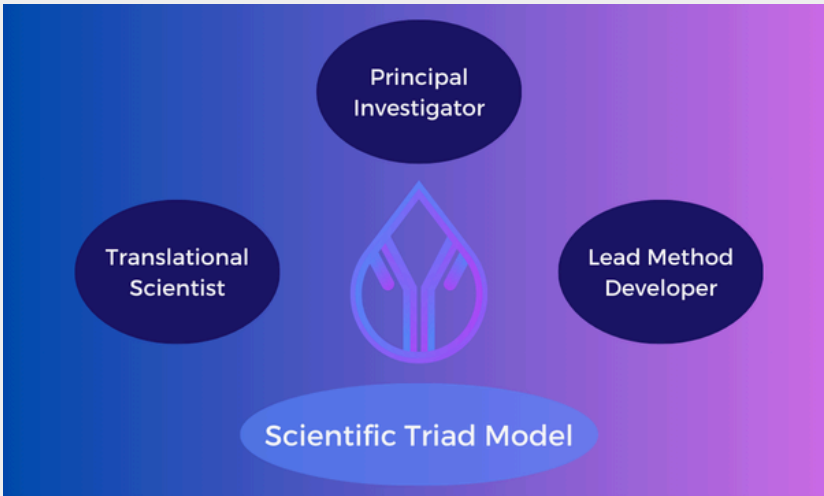
As we look to the future, our capabilities in cell and gene therapy represent our commitment to supporting emerging modalities. We've purpose-built these capabilities while maintaining the same rigorous standards that define all our work, spanning vector analysis, cellular kinetics, and advanced molecular techniques necessary for these innovative therapeutics.

# SECTION III

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## THE POWER OF THREE: OUR SCIENTIFIC TRIAD

At the center of our laboratory operations approach lies something unique in the industry: our scientific triad model. Every project that enters our laboratory is supported by three dedicated scientists working in seamless collaboration, bringing a minimum of 30 years of combined assay development expertise to bear on your project's success.



A Principal Investigator serves as the scientific point of contact, leading project communication and oversight through weekly or bi-weekly meetings. What may not be apparent in these interactions is the depth of scientific support working behind the scenes. The PI works in close coordination with two other key scientists to ensure comprehensive project support.

The Translational Scientist brings a crucial drug development perspective to your project. All our PIs work directly with a member of the Translational Sciences team, ensuring that every project benefits from both strategic and practical drug

development experience. This pairing comes automatically with each PI assignment, embedding strategic thinking into every project from day one.

The triad is completed by a Lead Method Developer, the scientist who will be at the bench executing these experiments. We also assign a backup method developer to support our lead, ensuring continuous project progression. These scientists work closely together daily, sharing insights and addressing challenges in real-time.

Beyond the core triad, every project benefits from additional layers of scientific support. Our project support team, comprised of senior-level laboratory supervisors, maintains boots on the ground every single day. These experienced scientists are physically present in the laboratory, available to help address any issues or questions that might arise in real-time.

Perhaps most unique is our scientific office hours program, which enables a forum for all our teams to discuss their projects every single day. When your triad team participates during office hours, they gain access to over 100 years of drug development experience in a single room. In 2024, we opened these sessions to our project sponsors, creating unprecedented access to our collective expertise.

### **Clients have leveraged these office hours in various ways:**

- **Discussing specific assay development challenges**
- **Seeking input on broader bioanalytical and biomarker strategies**
- **Reviewing regulatory questions and crafting responses**
- **Exploring drug development perspectives for program planning**
- **Addressing technical hurdles with creative solutions**

This comprehensive support structure ensures that your project benefits from both focused expertise and broad scientific insight. The triad model isn't just a management structure – it's a fundamental reimagining of how laboratory science should be conducted. By bringing together strategic insight, drug development

experience, and technical expertise in a coordinated team, we ensure that every project starts with the right foundation and maintains scientific excellence throughout its lifecycle.

Thanks to this level of scientific support, from technical to strategic to regulatory, we're proud to say that when clients choose to work with us, they choose to stay with us. Our sophisticated scientific model naturally attracts complex projects, including those requiring specialized expertise or enhanced oversight. We've built our organization around the belief that successful drug development requires seamless integration of strategic insight and technical expertise, and our triad model brings this philosophy to life in every project we undertake.

## SECTION IV

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# QUALITY SYSTEMS AND TECHNICAL EXCELLENCE

Our commitment to quality is embedded in every aspect of our operation. Our dedicated Quality Control team works closely with our data systems group to ensure accuracy of deliverables, while our independent Quality Assurance team maintains GLP and GCP compliance through regular inspections and comprehensive oversight. These efforts are supported by FDA 21 CFR Part 11 compliant systems, including Watson LIMS, and ZenQMS, all backed by robust data security measures.

Our current 33,000-square-foot facility is adjacent to Tampa International Airport and houses sophisticated instrumentation carefully selected to support the most demanding projects. From Molecular Devices systems for robust ELISA work to advanced Simple Plex™ Assays on the Ella™ Platform from ProteinSimple™, a Bio-Techne® brand for biomarker analysis, our technical capabilities are matched only by our expertise in applying them. Our location provides not just convenient access but ensures operational stability through timely sample shipment receipt, reliable power systems, and comprehensive backup capabilities.



## SECTION V

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### PROJECT EXCELLENCE THROUGH COMPREHENSIVE INTAKE

Our project intake process exemplifies our commitment to scientific excellence. When you partner with us, your project begins with the immediate assignment of your scientific triad team through our RAPTOR system. A comprehensive intake meeting follows, where we explore your program's background, therapeutic hypothesis, and technical requirements. We then develop a detailed project strategy, followed by careful method development planning that sets the stage for success.

This careful attention to project initiation is supported by ongoing access to our scientific office hours, regular project team meetings, and proactive risk management. Our support system ensures that your project benefits from our collective expertise throughout its lifecycle.

## SECTION VI

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### BUILT FOR PARTNERSHIP

Our balanced portfolio, serving both large biotech/pharma companies (55%) and small to medium-sized enterprises (45%), enables us to stay at the cutting edge while maintaining the infrastructure for programs of any scale. This diversity of experience allows us to maintain expertise across therapeutic areas while adapting to varying sponsor needs and resources.

Our sophisticated scientific model naturally attracts complex projects, including those requiring specialized expertise or enhanced scientific oversight. Many sponsors choose us specifically for challenging programs that have not found success elsewhere, knowing that our integrated approach and deep expertise can help overcome technical and strategic hurdles.

The Immunologix difference isn't just about what we do – it's about how we think. We believe that successful drug development requires seamless integration of strategic insight and technical expertise. This philosophy guides everything from our organizational structure to our daily operations. When clients choose Immunologix Laboratories, they're not just selecting a laboratory service provider – they're gaining a partner that understands how to bring together the best in scientific expertise, strategic thinking, and practical execution to advance their drug development programs.

## SECTION VII

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# READY TO EXPERIENCE THE IMMUNOLOGIX DIFFERENCE?

Our scientific team is eager to discuss how our integrated approach can support your drug development programs. Reach out and [connect with our experts](#) to start a conversation about your specific needs. Whether you're facing complex analytical challenges or seeking a long-term laboratory partner, we're here to help advance your programs with the highest levels of scientific rigor and strategic insight.