Veloxity Labs

Accelerating Drug Development

Along the Entire Lifecycle

Andy Vick, PhD
Senior Vice President
BlueWater Biosciences, Inc.

Isa Kupke, PhD
Scientist II
Veloxity Labs

INTRODUCTION

In today's therapeutic development landscape, the pressure is constant: shorten timelines, reduce costs, meet regulatory expectations—without compromising scientific rigor. LC–MS/MS plays a pivotal role here, but only when it's applied strategically and early, and when methods are aligned to the next phase from day one.

Veloxity Labs was built to bridge gaps, eliminate rework and keep programs moving. Whether you're in early discovery or preparing for clinical validation, our approach ensures your bioanalytical strategy anticipates what's next—so you move forward faster and with fewer surprises.

FROM THE SPONSOR'S CHAIR

> "The single biggest accelerator I've seen for early programs is applying LC–MS methods for characterization and quantitation of biologics (particularly peptides and proteins)— instead of waiting weeks or months for custom reagents for ligand assay development, you get quick, fit-for-purpose data for lead optimization and candidate selection."
>
> — Andy Vick, PhD

BREAKDOWNS THAT COST TIME AND MONEY

Every delay compounds risk—missed milestones, budget overruns, erosion of investor confidence—and slower patient access to potential life-changing therapies.

And, because the IND is the FDA's permission to begin human studies, any delay at this stage has serious consequences. The IND review can already be lengthy; when compounded by bioanalytical slowdowns, progression into Phase 1–3 can be significantly delayed.

FROM THE SPONSOR'S CHAIR

> "Even in lead optimization, a $1M/month burn rate for biotech start-ups isn't unusual. A one-week delay could translate into ~$250K of potential impact—before you factor in missed milestones. And the real cost of delay is not a financial one but a potential direct hit to human health: **every day late is a day a patient waits**."
>
> — Andy Vick, PhD

Common failure points:

Delayed timelines — Slow CRO turnaround stalls PK/TK readouts, pushes critical milestones and slips Phase 1 first-patient-in.

Siloed phase transitions — Handing off between vendors or siloed teams forces method redevelopment and requalification, adding cost and weeks.

Noncompliant data (GLP/GCP, ICH M10) — Gaps in validation (selectivity, stability, matrix effects) or documentation trigger QA re-review and regulatory questions.

VELOXITY'S ADVANTAGE: INTEGRATED, PHASE-ALIGNED LC–MS/MS SUPPORT

We design methods with the next phase in mind, minimizing rework.

Early Discovery & Non-GLP

- Rapid method development (including LC–MS for biologics/peptides characterization & quantitation to accelerate selection).
- Fit-for-purpose bioanalysis for PK/TK decision-making.

Preclinical & GLP Studies

- ICH M10 and GLP/GCP-aligned method validation.
- Fit-for-purpose bioanalysis for PK/TK decision-making.

Clinical Development

- Bioanalysis of patient-centric samples from Tasso, Mitra® and DBS to reduce patient/site burden.
- Integrated biomarker analysis for efficacy & safety monitoring.
- TAT discipline and documentation that protect LPLV/DBL.

Post-Market / Lifecycle Management

- Bioanalytical support for new indications and combo therapies.
- Stability studies and bridging to extend product value.

FROM THE SPONSOR'S CHAIR

"In an ideal situation, vendors should always be one step ahead of your next bioanalytical need. If they're quoting your non-clinical work, they should already be lining up line-of-site activities to support your clinical method development and validation."

— Andy Vick, PhD

Veloxity Labs

PHASE-READINESS CHECKLIST

Specs locked
Matrix, range, volume, selectivity needs

Validation plan mapped
to ICH M10 (including stability, matrix effects)

Seamless bioanalysis to PK handoff
Templates pre-agreed

Sampling strategy finalized
Microsampling? Small volumes?

Documentation ready
for GLP/GCP review (SOPs, audit trail)

Contingency for interference/ low-signal cases
Alternative transitions, clean-up options

EMERGING MULTIPLIER: AI-ASSISTED REPORTING

PK reports at many CROs can take weeks. AI-assisted pipelines (e.g., automated PK table generation and drafting) are compressing that cycle to days or hours. At Veloxity, we focus on infrastructure and processes designed to deliver, including integrated bioanalysis and PK/TK analysis with automated non-compartmental analysis (NCA). You get streamlined reporting and high-quality results faster and more accurately.

READ MORE → A Side-by-Side Look at Traditional vs. Integrated PK/TK and Bioanalytical Workflows

TRAPS & TIPS

TRAP: Assuming discovery formats will translate to GLP without re-engineering

TRAP: Waiting on commercial reagents for ligand assays

TRAP: Accepting vague promises of “fast”

TIP: Start with ICH M10 from day one (specificity, matrix effects, stability, carryover) to prevent rework

TIP: For peptides and other biologics, consider LC–MS characterization and quantitation to get decision-quality data

TIP: Ask your vendor for metrics and examples: quote turnaround, project start, QC’d data from sample receipt, on-time delivery %

Veloxity Labs

REAL-WORLD SNAPSHOTS: ELIMINATING REWORK AND GAINING MONTHS

Snapshot A — LC–MS vs ligand path

- A sponsor pivoted from a traditional ligand assay plan to LC–MS for peptide/biologic characterization and quantitation. Result: months saved in early decision-making; fit-for-purpose data supported confident down-selection without waiting on reagent campaigns.

Snapshot B — From stalled to solved

- A program spent ~three months with a large provider, struggling to progress. After transfer, Veloxity delivered core results in less than two weeks, enabled by people, processes and platform alignment (including automation, LC–MS method expertise and focused communication.)

FROM THE SPONSOR'S CHAIR

"INDs stall when QA re-review and slow data handoffs stack up. Tight quality discipline (starting at the bench), proactive communications and data packages aligned to ICH M10 keep submissions on track."

— Andy Vick, PhD

THREE PROCESS CHANGES THAT CAN ROUTINELY SAVE YOU WEEKS IN YOUR DEVELOPMENT TIMELINE

1. **Integrated handoff: Bioanalysis → Pharmacokinetics**
   Treat bioanalysis and PK as one critical, integrated path with a named owner on each side. Pre-agree on deliverables and format so PK analysis can start same-day.

2. **Accountability to timelines**
   If you promise a date, hit it—or escalate early with options. Put on-time metrics on the wall.

3. **Proactive culture**
   Don't just meet the spec: anticipate the next inflection point (assay transfer, GLP validation, clinical sampling) and prepare for it.

FROM THE SPONSOR'S CHAIR

> What does "speed with purpose" mean to me? It's speed—without sacrificing quality and value. It means high-class communication, defect-free outputs and honoring commitments. Do what you say you will do, when you say you will do it. It sounds trivial, but it's actually quite rare.
>
> — Andy Vick, PhD

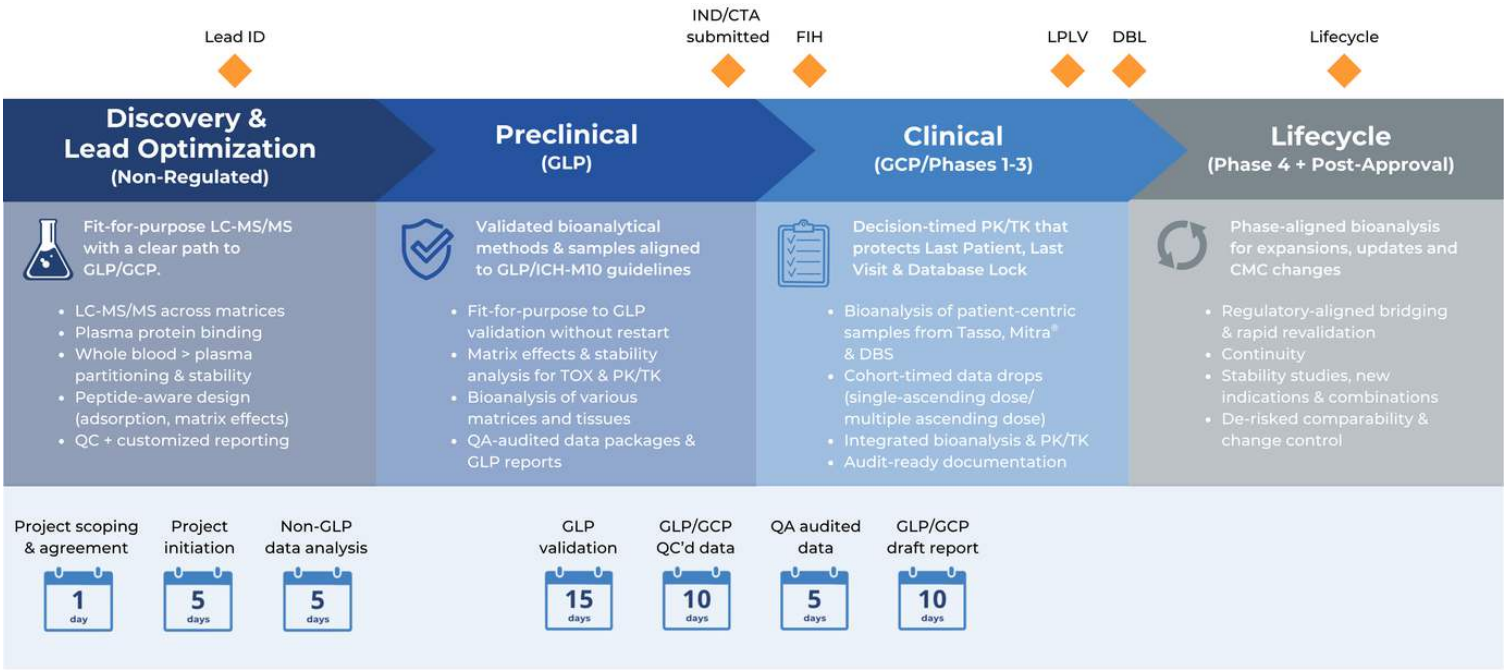
Veloxity Labs

IDENTIFY WHERE YOU ARE IN THE DEVELOPMENT PIPELINE —AND WHERE VELOXITY FITS

From first sample to submission, Veloxity aligns LC–MS/MS with your next milestone. We start with fit-for-purpose methods in discovery that carry forward to GLP, validate to ICH M10 and deliver decision-timed, seamless PK/TK in Phases 1–3. Microsampling and small-volume workflows reduce site/patient burden, while integrated bioanalysis and PK handoffs keep cohorts moving on schedule.

The result: inspection-ready packages that protect First-in-Human (FIH), Last Patient, Last Visit (LPLV) and Database Lock (DBL)—and smoother lifecycle updates afterward.

And, while exact timelines vary by scope, we always set expectations with our clients up front and publish actuals.



READ MORE

SPEED MEETS ACCURACY:
The Competitive Edge of Fast Turnaround Times and Precise Data in Bioanalysis

Veloxity Labs

REAL-WORLD USE CASE: ELIMINATING REWORK IN TRANSITION TO GLP

Sponsors often encounter unexpected hurdles when preparing IND applications — from QA data requiring re-review to gaps in communication. These issues can stall the submission process and create costly delays. Because the IND is the FDA's permission to begin human trials, even small setbacks at this stage can slow the entire development program.

Delays not only add significant direct and indirect costs but also undermine investor confidence, frustrate clinical teams and ultimately affect the patients who urgently need these treatments.

At Veloxity Labs, we help clients minimize these risks through rigorous QA, proactive communication and a data-centric mindset that keeps every detail aligned for success — ensuring IND submissions stay on track and programs advance at the speed of bioanalysis.

SCENARIO

A sponsor preparing their IND application discovers QA errors requiring data re-review. At the same time, communication gaps with their bioanalytical partner delay data delivery even further.

IMPACT

The submission stalls. Costs rise, investor confidence drops and teams are left waiting to start critical Phase I studies. Most importantly, patients who need these treatments are left waiting even longer.

SOLUTION

We minimize these risks with rigorous QA, proactive communication, and a data-centric mindset, ensuring IND submissions stay on track and programs move forward at the speed of bioanalysis.

Veloxity Labs

THE VELOXITY DIFFERENCE

We're more than a service provider—we're a strategic partner who keeps bioanalysis synchronized with development goals. Whether you're solving a current bottleneck or planning ahead to IND and clinical, we help you move with confidence—treating disease one sample at a time.

Speed with Substance
Operational discipline + communication + defect-free outputs; speed is in every step, not just at the end.

Regulatory Foresight
Methods and data ready for GLP/GCP and ICH M10 from the start.

Seamless Continuity
The same scientific partner across phases, with bioanalysis and PK/TK integration.

Built for Fast Starts
Capacity and automation to move when you are.

AUTHORS

Andy Vick, PhD
Senior Vice President
BlueWater Biosciences, Inc
LinkedIn

Isa Kupke, PhD
Scientist II
Veloxity Labs
LinkedIn

CONTACT US


info@veloxitylabs.com


www.veloxitylabs.com


801 W Main St.
Peoria, IL 61606

ABOUT VELOXITY LABS

Veloxity Labs is a bioanalytical CRO built for programs that need speed with substance. We deliver non-regulated, GLP and GCP-aligned LC–MS/MS bioanalysis across discovery, preclinical and clinical phases—producing high-quality data aligned to ICH M10.

Our scientists support a wide range of modalities—small molecules, peptides (including GLP-1 receptor agonists), proteins and ADCs—through phase-appropriate, fit-for-purpose methods built to streamline the path into GLP validation. We're also experts in microsampling and patient-centric sampling devices.

Veloxity supports programs across human and animal health—from emerging biotechs to global pharma — with rapid turnaround times and clear communication supported by robust QA and documentation.

We help teams accelerate the development of life-changing therapeutics—treating disease one sample at a time while moving at the speed of bioanalysis!

Learn more at veloxitylabs.com.

Veloxity Labs