ARTICLE

From complex peptides to novel drug delivery

Bioanalytical lessons for animal health drug development

INTRODUCTION

Innovation in drug development is often categorized in terms of human health or animal health. But advances in therapeutic modalities, drug delivery technologies and bioanalytical science increasingly create lessons and capabilities that can translate across both.

A recent collaboration between Toralgen and Veloxity Labs offers one example.

Toralgen is developing a proprietary nanoparticle platform designed to enable oral delivery of biologic medicines. In recent preclinical studies, the platform successfully delivered semaglutide, tirzepatide and retatrutide using a single nanoparticle formulation without peptide-specific optimization. Initial semaglutide studies achieved approximately 7% relative bioavailability, delivered 5–10X greater oral exposure than commercially available SNAC-based formulations and demonstrated minimal food effect.

Veloxity supported the program with bioanalytical method development, assay validation, advanced LC-MS/MS analysis and pharmacokinetic expertise needed to evaluate the platform's performance across multiple peptide therapeutics.

While the program is focused on human therapeutics, the work illustrates several considerations that are equally relevant as animal health drug development advances.

Innovation in one area of drug development can help inform what's possible in another.

NOVEL THERAPEUTICS REQUIRE EQUALLY SOPHISTICATED BIOANALYSIS

Complex peptides, proteins and other emerging biologics can present analytical challenges that differ significantly from traditional small molecules. As these modalities expand across animal health, developers need bioanalytical methods capable of generating reliable data across increasingly complex molecules, matrices and study designs.

The challenge can be particularly important in veterinary drug development, where sponsors may need to generate the greatest possible insight from a limited number of animals and samples. As fusion proteins, monoclonal antibodies, GLP-1–based therapies and other complex modalities are explored for veterinary applications, sensitive, fit-for-purpose bioanalytical methods can help maximize the pharmacokinetic information generated from each study.

This places added importance on tailoring methods to the needs of the individual program, including optimizing lower limits of quantitation (LLOQs) and calibration ranges to capture as much meaningful data as possible. Veloxity has experience working with animal health sponsors to optimize these parameters, respond to FDA Center for Veterinary Medicine (CVM) comments and provide the accurate analysis and documentation needed to support regulatory review.

In veterinary drug development, every sample matters. Sensitive, fit-for-purpose methods can help sponsors maximize the pharmacokinetic data generated from a limited number of animals and samples.

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DRUG DELIVERY CAN BE AS IMPORTANT AS THE THERAPEUTIC ITSELF

The Toralgen collaboration also illustrates the importance of evaluating not just a therapeutic molecule, but how that molecule is delivered. This has particular relevance to animal health, where route of administration, dosing frequency and ease of administration can affect treatment practicality, tolerability and adherence.

Bioanalysis helps determine how delivery choices affect drug exposure and which approach to advance.

Bioanalysis plays an important role in evaluating these choices. Across human and animal health programs, Veloxity has supported studies comparing multiple formulations of the same active ingredient, providing the rapid turnaround, accurate quantitation and robust methods needed to evaluate pharmacokinetic differences within a single study.

Alternative routes of administration can raise similar questions. Veloxity has supported bioanalysis for a therapeutic being evaluated for intranasal delivery to potentially reduce local tolerability issues, as well as animal health programs exploring oral versus topical administration to simplify dosing and potentially lower costs for owners.

Whether comparing formulations or routes of administration, fit-for-purpose bioanalysis provides the pharmacokinetic data needed to understand drug exposure and determine which approach warrants further development.

BIOANALYTICAL STRATEGIES MUST ACCOUNT FOR SPECIES AND MATRIX

Bioanalytical methods need to account for differences in biological matrices, pharmacokinetics and study design across species. An assay developed for one species or matrix cannot necessarily be transferred directly to another without first evaluating its performance in the new biological context.

That evaluation can reveal challenges that were not present in the original method. In one Veloxity program, for example, a method developed in rabbit plasma did not translate directly to human plasma. Testing in the new matrix revealed a reproducible interference that could affect accurate quantitation. The team adjusted the method to resolve the interference while keeping the development program on track.

The same principle is important in animal health, particularly for therapeutics intended for use across multiple species. Differences in endogenous components and pharmacokinetics can affect assay performance, making flexibility during method development and validation essential. Close communication between the bioanalytical laboratory and sponsor is also critical to ensure that adaptations address the scientific requirements of the specific species and matrix while producing accurate data and documentation that meet CVM expectations.

Bioanalytical methods are not necessarily one-size-fits-all across species. Differences in biological matrices and pharmacokinetics can require careful evaluation and method adaptation to ensure accurate quantitation.

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BRINGING BIOANALYSIS INTO THE CONVERSATION EARLIER

Perhaps the broader lesson is not about any single technology or therapeutic class. It is about when and how bioanalytical scientists become part of the development process.

For emerging programs, early collaboration can help developers understand what is measurable, identify potential analytical challenges and build methods around the data they will ultimately need to make development and regulatory decisions.

In one animal health program, Veloxity became involved during the non-regulated phase to develop a method capable of achieving a particularly demanding lower limit of quantitation (LLOQ). Working directly with the sponsor, the scientific team developed a robust method tailored to the program's needs. The resulting study data showed that expected plasma concentrations were well within the method's calibration range, providing greater confidence in the analytical approach before the program advances to regulated studies.

Rather than starting over when the program moves into regulated validation, the sponsor now has a method informed by real study data, potentially reducing the time and cost required for validation while maximizing the usable pharmacokinetic data generated from future studies.

As innovation continues across both human and animal health, the opportunity to apply scientific lessons across traditional industry boundaries will continue to grow. Advances in complex therapeutics and drug delivery will bring new analytical questions with them. Addressing those questions early can help animal health developers generate the evidence they need to evaluate promising technologies and move successful programs forward.

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ABOUT VELOXITY LABS

Veloxity Labs is a bioanalytical contract research organization (CRO) specializing in advanced LC-MS/MS and high-resolution mass spectrometry (HRMS) for small molecules, complex peptides, GLP-1 therapeutics, proteins and other emerging biologic modalities. The company partners with emerging biotechnology, pharmaceutical and animal health organizations to accelerate drug development through rapid study startup, expert method development and high-quality bioanalytical data.

Supporting discovery, preclinical and clinical programs, Veloxity delivers fit-for-purpose analytical strategies, pharmacokinetic expertise and regulatory-aligned bioanalysis that help clients make confident development, partnering and commercialization decisions. From novel drug delivery technologies and oral biologics to complex peptide therapeutics, Veloxity combines scientific rigor with responsive collaboration to help move innovative therapies forward.

Treating disease one sample at a time. Learn more at veloxitylabs.com.

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