ALTASCIENCES

CASE STUDY

Rapid Formulation Pivot Preserves GLP Study Timeline

THE CHALLENGE

A sponsor initiated a GLP repeat-dose toxicology study in canines at **Altasciences' nonclinical research facility in Columbia, MO**, using oral gavage as the intended route of administration. During formulation development, the test article presented significant viscosity challenges, resulting in a formulation that was too thick to be reliably or safely administered via gavage.

This issue emerged late in the study startup phase, creating a high risk of delays, potential protocol amendments, and added costs, including possible schedule shifts and associated delay fees.

ALTASCIENCES' APPROACH

Recognizing the urgency, the Altasciences team rapidly mobilized a cross-functional solution by integrating expertise across our platform:

- The nonclinical team quickly assessed alternative dosing strategies to maintain study integrity and regulatory compliance.
- In parallel, we engaged the CDMO team at **our facility in Philadelphia, PA**, leveraging our formulation and manufacturing expertise to evaluate viable alternative delivery approaches.
- Within a compressed timeline, the formulation and manufacturing team developed a capsule-based dosing solution tailored to the physicochemical properties of the test material.
- The nonclinical and CDMO teams worked collaboratively to ensure seamless coordination of capsule production, quality considerations, and delivery to the Columbia nonclinical site without disrupting scheduled study activities.

THE SOLUTION

Altasciences proposed implementing a capsule dosing formulation as a practical and scientifically sound alternative to oral gavage that would:

- enable accurate and consistent dose delivery despite formulation limitations
- maintain compliance with GLP study requirements
- avoid the need for extensive reformulation efforts or study redesign

THE OUTCOME

- **No study delay:** The program remained on its original timeline with no need to reschedule in-life activities.
- **Cost avoidance:** The client avoided significant delay fees and additional formulation development costs.
- **Operational continuity:** Seamless coordination between our CDMO and nonclinical teams ensured uninterrupted study conduct.
- **Strengthened partnership:** Demonstrated Altasciences' ability to solve problems in real-time and deliver integrated solutions across services.

KEY TAKEAWAY

By leveraging internal collaboration between **Altasciences' nonclinical and CDMO teams**, we were able to rapidly pivot in response to an unexpected formulation challenge, preserving both the timeline and budget for the sponsor.

Accelerate Your Timeline. Avoid the Delay.

Save 8 Weeks by Working With One Integrated Vendor

8 WEEKS FASTER.
One Integrated Partner.
One Seamless Path.

By eliminating delays between vendors and keeping everything aligned, **you save 8 weeks and get to market faster**.

CONTACT US TO GET STARTED

ABOUT ALTASCIENCES

Altasciences is a drug development organization dedicated to safely accelerating early-phase development for biotech, biopharmaceutical, and pharmaceutical companies. By combining the scale and expertise of a leading CRO/CDMO with the flexibility and personalized approach of a mid-size partner, Altasciences delivers unified solutions across nonclinical, clinical, bioanalytical, formulation, and manufacturing services. Through intentional integration and true collaboration, the company removes barriers from lead candidate selection to clinical proof-of-concept—helping sponsors save time, reduce complexity, and make confident, data-driven decisions that enable earlier returns on investment. Guided by over 30 years of experience, Altasciences helps clients reach critical milestones faster.