



ALTA SCIENCES

SHAPING THE FUTURE OF MEDICINE: PHARMACEUTICAL FORMULATION DEVELOPMENT

Pharmaceutical [formulation development](#) is an integral part of preclinical safety testing. It ensures accurate dosing, stability, and safety of drug products, providing essential data for regulatory submissions and guiding the progression of a drug through the various stages of development.

THE ART OF FORMULATION—FROM CONCEPT TO CLINIC

Learn more about
formulation for preclinical
testing in this issue of
The Altascientist.



1

Chemical Characterization and Safety Assessment

Our scientists conduct thorough chemical characterization of the active pharmaceutical ingredient (API) and safety assessment of the drug substance, including its toxicity profile, as crucial first steps in the formulation development process.

2

Dose Selection and ADME Properties

We determine dose selection based on pharmacokinetics (PK) and pharmacodynamics (PD), as well as consideration of the API's solubility, stability, and bioavailability, and use it to guide the appropriate route of administration based on drug absorption, distribution, metabolism, and excretion (ADME).

3

Regulatory Compliance and Validation

Our manufacturing experts ensure the suitability of the chosen animal model and formulation for preclinical testing by complying with regulatory requirements and guidelines (e.g., GLP and ICH) and conducting validation studies.

4

Refinement and Advancement

We then optimize the formulation based on preclinical findings and prepare for clinical trials and regulatory approval.

TAILORED MANUFACTURING SOLUTIONS FOR PRECLINICAL AND CLINICAL SUCCESS

We design and optimize pharmaceutical formulations to maximize therapeutic benefits and ensure safety for clinical trials. With decades of experience and cutting-edge technology, we handle even the most complex APIs, including DEA-controlled substances and [highly potent compounds](#) in our state-of-the-art GMP manufacturing suites. Our integrated approach, combining formulation development with preclinical research, streamlines the drug development process and paves the way for successful clinical trials and regulatory approval.

Integrated Services

Having our own preclinical research team that works hand-in-hand with our formulation scientists offers numerous advantages, including streamlined development, optimized formulation, early risk identification, enhanced product quality, and cost efficiency.

Proactive Risk Assessment

We carefully craft every formulation, as it can facilitate preclinical studies and help predict the drug's behavior in humans. This contributes to the translational success of the drug candidate from the preclinical to the clinical phase.

Speed to Market

Our integrated teams move in unison to accelerate your drug development timeline, minimize risks, and ensure the manufacture of high-quality pharmaceutical products for patients worldwide.



How can we help?

[SPEAK WITH AN EXPERT](#)



altasciences.com | contact@altasciences.com

