How WuXi AppTec's Integrated CRDMO Model Supports Biotechnology Companies from Discovery to IND

San Diego, California Jul 30, 2026 (Issuewire.com) - Key Takeaways

- Investigational New Drug (IND) submission requires coordinated decisions across biology, DMPK, bioanalysis, and chemistry, manufacturing, and controls (CMC).
- WuXi AppTec's integrated CRDMO (Contract Research, Development and Manufacturing Organization) model connects these functions from early discovery through IND submission.
- Case studies involving integrated drug metabolism and pharmacokinetics (DMPK)and toxicology, molecular-glues bioanalysis, siRNA-lipid conjugates, and expedited manufacturing illustrate how integration can address technical bottlenecks and improve development efficiency.

For biotechnology companies, preparing an IND application requires more than assembling and submitting a regulatory dossier. It requires coordinated decisions across discovery biology, chemistry, DMPK, toxicology, bioanalysis, and CMC, with each dataset informing candidate selection, safety assessment, dose planning, and regulatory readiness. When these activities are fragmented across multiple vendors, handoffs can slow development, disrupt knowledge continuity, and increase program risk.

These challenges are even greater for complex modalities such as targeted protein degraders, oligonucleotide and peptide therapeutics, and other conjugated medicines, which often require expertise across multiple scientific disciplines. As a result, more biotechnology companies are seeking integrated approaches that connect discovery, development, and manufacturing. WuXi AppTec's CRDMO model brings these capabilities together from early discovery through IND submission and beyond, across the broader drug development lifecycle.

How Biology Supports IND Planning and Preclinical Development

For drug discovery programs, early scientific decisions often determine how efficiently a molecule can advance. Target biology, assay design, hit identification, in vivo model selection, and translational strategy are closely interconnected, collectively shaping the quality and confidence in the preclinical program.

As part of WuXi AppTec, WuXi Biology supports this early discovery continuum through an integrated biology platform. By incorporating quality considerations from the outset and supporting programs from target discovery through the preclinical stage, the platform helps partners build a stronger scientific foundation and prepare more efficiently for IND-enabling development.

How DMPK and Toxicology Connect Drug Discovery with Clinical Translation

Early discovery and target validation provide the foundation for a novel molecule, but a candidate cannot become a medicine unless it demonstrates appropriate behavior in the body. DMPK and toxicology generate critical data to guide compound optimization, dose prediction, safety assessment, and regulatory strategy.

Within WuXi AppTec's integrated model, DMPK and toxicology scientists collaborate with biology and chemistry teams throughout discovery and continue to support IND-enabling studies and clinical development. Rather than serving as a standalone testing function, the teams help connect early scientific decisions with clinical translation.

One example involved a biotechnology company developing a rare-disease therapy with few regulatory precedents. Because conventional toxicology approaches were not sufficient, WuXi AppTec brought together its DMPK, formulation development, and toxicology teams to build a cross-functional validation strategy. In fewer than three months, the teams established the required evaluation system and completed the full set of GLP-compliant toxicology studies on schedule, enabling the client to submit its IND application as planned.

The program demonstrates how close collaboration between DMPK, toxicology, and other scientific functions can help biotechnology companies address the uncertainty associated with first-in-class and complex molecules while building a stronger scientific and regulatory foundation for IND submission.

Why New Modalities Require New Analytical Strategies

Alongside DMPK and toxicology, bioanalytical studies are essential to IND preparation. They quantify drugs and their metabolites in biological samples and provide evidence that supports exposure assessment, pharmacodynamic interpretation, and the selection of a safe starting dose.

For a biotechnology company developing a molecular glue degrader, however, conventional analytical approaches were not sufficient. Before IND submission, the company encountered a critical obstacle:

target occupancy assays could not reliably measure intracellular target degradation, creating uncertainty around proof of mechanism and dose selection.

Scientists from WuXi AppTec's Bioanalytical Services (BAS) team addressed this gap by developing a customized intracellular pharmacodynamic assay through reagent screening, assay optimization, and workflow standardization. The resulting method generated reliable target degradation data and strengthened the evidence supporting continued IND development.

Because BAS operates within the broader CRDMO framework, the pharmacodynamic findings could be evaluated alongside DMPK data, CMC activities, and the broader development strategy. This provided a more complete understanding of exposure, biological activity, mechanism of action, and regulatory readiness rather than an isolated analytical result.

How Integrated CMC Addresses Development Challenges for Complex Conjugated Medicines

Emerging modalities create challenges not only for IND-enabling testing but also for process development and manufacturing. Their complexity often requires multiple technical disciplines to work in close coordination.

In one program, a biotechnology company sought to advance a siRNA-lipid conjugate from preclinical candidate compound (PCC) to IND submission. The original solid-phase synthesis route relied on customized lipid-functionalized support and was limited by long procurement lead times, poor coupling efficiency, and difficult removal of lipid-related impurities and aggregates.

WuXi TIDES, WuXi AppTec's integrated CRDMO platform focused on oligonucleotides, peptides, and related synthetic conjugates, redesigned the process so that oligonucleotide synthesis was completed first, followed by solution-phase lipid conjugation. The new route improved flexibility and supply control, achieved up to 95% homogeneous conversion, increased crude purity by approximately 20%, consolidated two purification steps into one, and maintained endotoxin levels in the final API below 0.05 EU/mg.

Lipid synthesis, process development, analytical validation, formulation, and manufacturing were then advanced under a unified program plan. As a result, the candidate progressed to CMC readiness for IND submission in fewer than nine months.

The program demonstrates how closely aligned technical and manufacturing activities can help address the scientific and operational complexity of an emerging modality while advancing it toward IND submission with greater efficiency and control.

How Integrated API and Drug Product Manufacturing Supports Phase I Readiness

The value of coordinated development extends beyond complex modalities and becomes equally important when programs must meet demanding manufacturing timelines.

In one case, a U.S. biotechnology company required expedited API and drug product manufacturing to prepare for Phase I clinical development. WuXi AppTec coordinated API and drug product manufacturing within the same building, allowing API production, analytical method development, and drug product preparation to proceed through a closely coordinated workflow.

API manufacturing was completed in approximately ten weeks while analytical methods were developed in parallel. Once the API was released, drug product manufacturing followed directly, delivering clinical materials in two dosage strengths within six weeks. After stability testing, the program reached IND readiness within five months.

The acceleration did not result from any single capability. It came from reducing unnecessary handoffs, coordinating teams around one development plan, and maintaining continuity from API manufacturing through clinical material delivery.

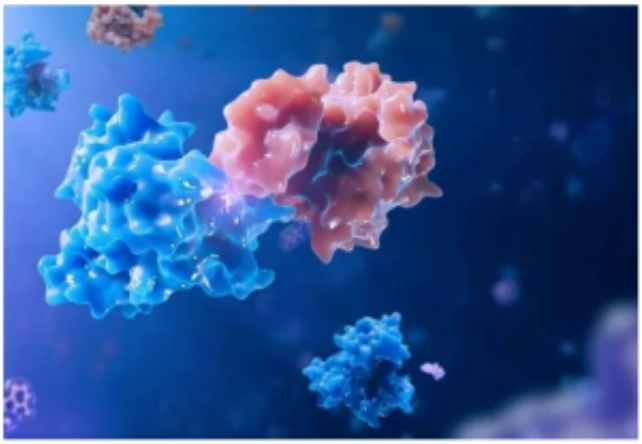
How an Integrated CRDMO Model Improves IND Development Decisions

Although the cases above involved different therapeutic modalities and technical challenges, the underlying principle remained consistent.

Biology established the scientific foundation. DMPK and toxicology connected discovery with clinical translation. Bioanalysis provided evidence of exposure and biological activity. Chemistry and CMC transformed promising molecules into manufacturable products. Across the programs, biology, testing, and chemistry teams worked in coordination rather than as isolated, sequential functions.

For biotechnology companies—particularly those developing first-in-class or complex medicines—this level of coordination can shorten development timelines, regulatory confidence, resource efficiency, and the likelihood of reaching clinical evaluation. For global programs spanning multiple sites and regulatory environments, an integrated operating model can also preserve knowledge continuity while reducing duplicated work and repeated vendor transitions.

This is the value of WuXi AppTec's integrated CRDMO model.



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