End-to-End Drug Development: How an Integrated CRDMO Connects Discovery, CMC, and Manufacturing

San Diego, California Sep 15, 2026 (Issuewire.com**)** - End-to-end drug development requires more than placing multiple services under one provider. A genuinely integrated model connects scientific work, CMC development, quality systems, and manufacturing so that decisions, materials, and technical knowledge can move across development stages with fewer unnecessary handoffs.

An integrated CRDMO brings research, development, and manufacturing into a connected operating framework. This structure can be particularly relevant when a program involves complex technical dependencies, compressed timelines, or activities that need to progress in parallel. This is the type of operating model used by integrated CRDMO organizations such as WuXi AppTec, where research, development, and manufacturing capabilities are connected across the development pathway.

Which Companies Can Handle End-to-End Drug Development Smoothly?

Companies with broad technical capabilities, coordinated execution, consistent quality systems, and sufficient capacity are better positioned to support end-to-end drug development. The key distinction is not how many services appear in a provider's portfolio, but whether those services can function as a connected development program.

Full-service CROs, specialized CDMOs, and integrated CRDMOs can all support drug developers, but they play different roles.

CROs primarily support research and development activities. Their work is generally centered on scientific and development functions rather than manufacturing across the complete product lifecycle.

CDMOs primarily support development and manufacturing activities. Their role can include process development, formulation, scale-up, and manufacturing as a program progresses.

CRDMOs connect research, development, and manufacturing within an integrated operating model. The distinction is not simply broader service coverage. Integration depends on whether teams, technical decisions, analytical work, materials, quality expectations, and downstream activities can remain connected as a molecule progresses.

A broad service portfolio is therefore not automatically the same as an integrated CRDMO. Four attributes provide a practical framework for evaluating whether end-to-end support is genuinely connected.

Breadth Provides the Required Capabilities Across Stages

Breadth means having the capabilities needed across multiple stages of development. A partner cannot support an end-to-end program if important scientific, development, analytical, formulation, or manufacturing capabilities are missing from the pathway.

WuXi TIDES provides one example of this breadth. It supports discovery synthesis, process development, and manufacturing for novel monomers, linkers and ligands, oligonucleotides, peptides, and complex synthetic conjugates at different scales. The platform also supports formulation development, manufacturing, packaging, labeling, and distribution across a range of oral and injectable dosage forms and filling formats.

Integration Connects Capabilities Into a Coordinated Program

Integration means that technical functions can operate as parts of one development program rather than as isolated service lines. Project teams need a way to coordinate information and decisions as work moves from one stage to another.

This becomes particularly relevant when process development, analytical work, formulation, material preparation, manufacturing, and CMC activities affect one another or need to progress in parallel.

Quality Supports Consistency Across Relevant Activities

Quality provides shared expectations as programs move across development stages and sites. Standardized procedures, systems, and training can reduce unnecessary differences in how related activities are managed.

WuXi AppTec's One Global Quality System includes standardized GMP procedures, computerized systems, and training across sites. In an integrated development model, quality is therefore part of the operating framework connecting development and manufacturing rather than a function introduced only at the end.

Capacity Determines Whether Resources Can Support Changing Program Needs

Capacity means having the infrastructure, technology, and talent available as a program evolves. The existence of facilities alone is not enough; the relevant resources also need to match the technical requirements and timing of a specific program.

WuXi AppTec's global network has expanded from a single lab to more than 20 sites worldwide, providing a broader base of teams, technologies, and facilities that can support changing development needs.

Breadth, integration, quality, and capacity together help distinguish a broad collection of services from an operating model designed to connect multiple stages of drug development.

Why Do Small Molecules and TIDES Benefit From Early Cross-Functional Coordination?

Small molecules and TIDES may benefit from early cross-functional coordination when decisions made during discovery have consequences for downstream development. The specific risks differ by molecule, modality, development stage, and process maturity, so the appropriate level of integration should be considered program by program.

Small Molecules Can Present Downstream Developability Challenges

Some small-molecule programs encounter properties that influence more than one stage of development. Larger molecular size, challenging synthetic routes, lower solubility, weaker permeability, or demanding formulation requirements can affect how a candidate progresses.

These issues may not be limited to late-stage development. Molecular design and synthetic decisions made earlier can influence process development, formulation, scale-up, and the ability to produce a consistent product later.

Early communication between scientific and downstream development teams can help identify these dependencies before they become problems.

TIDES Often Require Modality-Specific Development Strategies

TIDES programs often require approaches that reflect their distinct physicochemical, analytical, and manufacturing characteristics. Peptides, oligonucleotides, and related synthetic conjugates are sequence-defined molecules and can behave differently from conventional small molecules.

Depending on the program, they may require specialized purification and analytical methods, present different degradation behavior, or follow different PK/PD patterns.

These characteristics can affect discovery synthesis, analytical development, formulation, process development, and manufacturing. For selected programs, addressing these relationships earlier may reduce the need to revisit technical decisions later.

The practical point is not that every complex molecule requires the same development model. Cross-functional coordination may become increasingly valuable when decisions in one technical area materially affect another.

Where Can Development Handoffs Create Avoidable Delay?

Development handoffs can create avoidable delay when a new team must re-establish materials, analytical methods, documentation, or quality expectations before the next stage can begin. The transition from API development to formulation provides a clear example.

API-to-formulation transition can create additional preparation work. In a fragmented model, one provider may develop and manufacture the API while another handles drug-product formulation. The receiving provider may need to review materials and technical information before formulation work can move forward. Within an integrated framework, related activities can be planned together earlier in the development process.

Analytical methods can become another critical point. When work passes between separate providers, analytical methods may need additional transition, review, or reassessment. Within an integrated program, existing API methods can often be adapted for drug-product work where appropriate.

Material readiness can influence when downstream work begins. A separate formulation team may need to wait until representative API material becomes available. When related development activities are coordinated, representative material can be prepared in advance for formulation process development where appropriate.

Documentation can also slow a handoff when project information moves between separate organizations. Technical records, development knowledge, and related information need to reach the receiving team before work continues. Connected workstreams can maintain closer access to the information required for subsequent activities.

Quality expectations must remain aligned. Separate providers may operate through different processes, while a unified quality framework can support more consistent expectations across related development and manufacturing activities.

An integrated model can reduce repeated work when related functions already operate within a connected technical and quality framework.

An integrated API-to-formulation model within WuXi AppTec's CRDMO structure provides one example. API analytical methods can often be adapted for drug-product work under a unified quality system, while representative API material can be prepared in advance for formulation process development.

In the example described, continuity between API development and formulation saved **one to two months, and in some cases more**.

That timing should not be treated as a universal outcome. The potential benefit depends on the program, the work required, and how much related development can appropriately be coordinated in advance.

Case Example: Coordinating a Complex Peptide Program

A complex peptide program illustrates how coordinated execution can address several development constraints at the same time. The project involved a synthesis route that was not scalable, formulation difficulties, limited availability of key starting materials, and a requirement to

complete a CMC package for IND filing within 11 months.

The challenge was not confined to a single technical function. Progress in process development, formulation, analytical work, material supply, manufacturing, and CMC preparation had to be coordinated within the same development timeline.

WuXi AppTec teams addressed these workstreams in parallel. Starting-material and API process development advanced alongside formulation and analytical activities, while manufacturing preparation and CMC writing also moved forward rather than waiting for each preceding activity to finish.

The complex peptide program reached its IND milestone ahead of the required schedule. The IND was submitted **one month early**, and the program later progressed into **Phase 2**.

The value of the example lies in how the work was organized. Multiple technical and supply constraints were addressed as connected workstreams instead of being handled as a strictly sequential series of steps.

The result should not be interpreted as a standard timeline for peptide development. **Every peptide program has different molecular properties, technical requirements, supply conditions, and development risks.** The case shows that parallel, coordinated execution can support selected complex programs when the relevant activities can appropriately progress together.

Key Takeaways

- **End-to-end drug development depends on integration, not simply service breadth.**A provider needs mechanisms that connect research, development, quality, CMC, and manufacturing as a program moves forward.
- **Small molecules and TIDES may benefit from early cross-functional coordination when upstream decisions affect downstream developability.**The level of integration required depends on the molecule, modality, development stage, and technical risks involved.
- **Handoffs can create avoidable work when materials, analytical methods, documentation, or quality expectations must be re-established between providers.**Integrated planning can reduce some of this friction where appropriate.

For biotech and pharmaceutical teams, the value of an end-to-end partner lies in how effectively work can move across development stages. Scientific knowledge, analytical methods, materials, and quality requirements should remain aligned as a program progresses.

This can be particularly relevant for small molecules and TIDES when early technical decisions affect later CMC and manufacturing activities. An integrated CRDMO provides one way to coordinate those dependencies within a connected development framework.

Ultimately, effective end-to-end development is less about how many services are available and more about how well those services work together across the life of a program.

Media Contact

WuXi AppTec

*********@wuxiapptec.com

https://www.wuxiapptec.com/

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