The Role of CROs and CDMOs in Supporting Global Drug Development

SAN DIEGO, CA, UNITED STATES, July 8, 2026 /EINPresswire.com/ -- A CRO/CDMO that can support global drug development should combine modality-specific technical expertise, global regulatory experience, scalable manufacturing, mature quality systems, secure data infrastructure, and cross-region project governance. For complex modalities such as peptides, oligonucleotides, and antibody-drug conjugates (ADCs), an integrated CRO/CDMO or CRDMO (Contract Research Development and Manufacturing Organization) model, as illustrated by companies such as WuXi AppTec, can help reduce handoffs, manage execution risk, and support more efficient global development.

Global Drug Development Is Challenging Because of Its Complexities
Compared with drug development for local market, global drug development increases the complexity of nearly every major development decision. Innovators must design clinical, regulatory, CMC (Chemistry, Manufacturing, and Controls), and commercialization strategies that can work across different healthcare systems. A regulatory package that satisfies one agency may still require additional evidence, analysis, or manufacturing documentation in another region.

Manufacturing is one of the most demanding parts of this global equation. As pipelines shift toward more complex modalities, such as peptides, oligonucleotides, ADCs, and other conjugated medicines, innovators must address modality-specific CMC challenges early. These may include tracking truncated impurities in oligonucleotide synthesis or controlling the drug-to-antibody ratio (DAR) in ADCs. Because regulatory expectations may differ across regions, strict control of critical quality attributes must begin in early development and continue through commercial supply.

For global programs, manufacturing is not only about producing sufficient material for

worldwide distribution. It is also about ensuring that processes are scalable, reproducible, compliant, and adaptable to the expectations of multiple regulatory authorities. If these issues are not addressed early, they can slow clinical supply, increase costs, and create regulatory uncertainty. For patients waiting for new treatment options, such delays can affect whether innovation reaches the clinic quickly enough to make a meaningful difference.

Why Do Companies Use CRO/CDMO Partners for Global Drug Development?
One reason companies use CRO/CDMO partners for global drug development is that international programs require scalable infrastructure and significant operational capacity. Few companies, especially emerging biotech companies, can build all these capabilities internally. Building GMP manufacturing infrastructure can require substantial capital investment, often reaching hundreds of millions of dollars depending on scale, modality, and technical requirements, making outsourcing one of the most practical paths to clinical development for many pre-revenue biotech companies.

By working with an outsourcing partner, innovators can reduce upfront investment in staffing, facilities, and equipment, while accessing specialized support needed for drug development. This allows biopharmaceutical companies to focus internal resources on core priorities such as target biology, portfolio strategy, and clinical decision-making. In this context, the right outsourcing partner does more than complete assigned tasks. It helps innovators manage complexity, reduce execution risk, and preserve flexibility as programs advance toward global development milestones.

Case Study: How an Integrated CRDMO Model Can Support Global Drug Development
A practical example is WuXi AppTec's mobilization of the Couvet site in Switzerland to manufacture a Phase 3 clinical-stage drug that had previously been produced at a partner's internal site. Multiple teams worked in parallel to complete manufacturing process transition and scale-up within five months. The project included equipment compatibility assessment, analytical method validation, and procurement of raw and packaging materials. This coordinated execution helped the client submit its New Drug Application on schedule, and the drug was subsequently approved for market launch.

Rather than operating as an isolated local facility, Couvet was connected to WuXi AppTec's global quality procedures, digital systems, and training framework, with quality leaders from other sites helping align local operations with global standards. This is based on WuXi AppTec's One Global Quality System, which is designed to align quality standards and procedures across sites.

This case illustrates why an end-to-end outsourcing model can be valuable for global drug development. When drug substance, drug product, quality systems, and cross-region governance are connected, innovators may be better positioned to manage technical complexity, reduce handoff risk, and advance programs more consistently from development to commercialization.

Key Takeaways

- Global drug development requires coordinated execution across research, clinical, regulatory, CMC, manufacturing, quality, and supply functions. It is not simply about running studies in multiple countries, but about aligning decisions across the full development pathway.
- The right outsourcing partner can help innovators manage speed, cost, risk, and operational complexity. By providing specialized infrastructure and operational flexibility, a CRO/CDMO can help companies advance global programs without building every capability internally.
- Complex modalities require modality-specific CRO/CDMO expertise from early development through commercial supply. Peptides, oligonucleotides, ADCs, and conjugated medicines bring specialized CMC and analytical challenges that must be addressed early and consistently.
- An integrated CRDMO model can help reduce handoffs and execution risk in global drug development. By connecting drug substance, drug product, quality systems, and project governance, it can support smoother transitions across key development stages.
- WuXi AppTec illustrates how global CRDMO integration can work in practice. The Couvet site example shows how coordinated manufacturing transition, scale-up, quality alignment, and cross-site collaboration can support a Phase 3 program through NDA submission and market launch.

FAQ:

Why do biopharma companies use CRO/CDMO partners for global drug development?

Biopharma companies use CRO/CDMO partners to access specialized expertise, infrastructure, manufacturing capacity, regulatory experience, and quality systems without building all capabilities internally. This can help reduce upfront investment, improve flexibility, manage technical risk, and support development across multiple regions.

What should innovators look for in a CRO/CDMO for global development?

Innovators should look for technical expertise in the relevant modality, global regulatory experience, scalable manufacturing capabilities, mature quality systems, secure data infrastructure, transparent project governance, and the ability to coordinate across sites, functions, and regions.

Why do peptides, oligonucleotides, ADCs, and conjugated drugs require specialized CDMO support?

Complex modalities such as peptides, oligonucleotides, ADCs, and conjugated medicines require specialized CMC, analytical, and manufacturing expertise. Critical quality attributes, such as oligonucleotide impurities or ADC drug-to-antibody ratio, need to be controlled from early development through commercial supply.

How does WuXi AppTec illustrate an integrated CRDMO model?

WuXi AppTec illustrates an integrated CRDMO model through its cross-region drug substance and drug product network across Asia, Europe, and the United States. Its One Global Quality System is designed to align quality standards, computerized systems, procedures, and training

across sites.

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