

Evolving Demands of Process Development Services

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Shifting demands from industry innovators is leading to an increased need for flexible and agile outsourcing partners offering broad and integrated models.

Over the years and in light of various industry trends, the demands for outsourced services have increased and evolved. In this interview, *Pharmaceutical Technology* discusses how process development demands have changed for service providers with Xiaoyong Fu, PhD, chief technology officer and head of API Business, WuXi STA.

Trends impacting process development services

PharmTech: How have process development demands evolved over the years for outsourcing partners?

Fu (WuXi STA): Molecules are getting more complex, pipelines more diverse, and at the same time, increasing numbers of targets are on accelerated pathways. Put these factors together and there is a need for contract development and manufacturing organizations (CDMOs) that can handle integrated and accelerated pathways with a full suite of technologies from biocatalysis and flow chemistry through to crystallization and spray drying. Integrated models provide much greater flexibility and enable API and formulation teams to work side by side.

Phase-appropriate development is also often asked of many CDMOs, and this usually means running pathways sequentially. Another way timelines can be accelerated is by developing an 'end-in-mind' process strategy to seamlessly connect discovery, development, and commercial API needs from milligram to metric ton scale. But the CDMOs will need a large R&D team with the right expertise and a broad technology platform to ensure the most appropriate chemistry at every scale.

The final trend that is being seen and, in some ways is linked to the challenges of the pandemic, is the requirement of a partner who can ensure supply chain stability with a robust continuity business plan including multiple facilities available, technologies to avoid or minimize the use of scarce material, or even the ability to manufacture them in the event of shortages. This means forward-looking innovators are seeking backing by a contract partner that has a solid network of vetted vendors and a large chemistry organization and a diverse manufacturing and technology platform that can react and adapt quickly.

PharmTech: What other trends have impacted outsourced process development in recent years?

Fu (WuXi STA): Undoubtedly, bioavailability and solubility are increasingly common challenges and process characteristics are, therefore, a must for any outsourcing partner—they need to have the

full suite of particle size engineering tools and expertise from crystallization, micronization, nano-suspension to amorphous solid dispersion. There has also been an increase in the need of highly potent APIs, which necessitates highly specialized facilities and expertise. And, more recently, there has been a high demand for the CDMOs that can handle oligos, peptides, and various complex conjugates. Novel conjugates involving combinations of oligos, peptides, high potency payloads, linkers, and specific carriers are increasing, but the resources required are lagging worldwide.

One of the other major trends is that innovators are seeing the benefits of integrated networks with R&D and manufacturing teams in one location and, taking this a step further, having drug product formulation and manufacturing within the same or nearby facility, especially, in the case of oligos, peptides, and conjugates, having an injectable formulation development and manufacturing capability to be paired with the API project. These obviously bring tremendous benefits in reducing transfers—of materials or knowledge—and enable formulators and chemists to work closer and reduce time to market or milestone.

About the Author

Felicity Thomas is the European editor for Pharmaceutical Technology Group.