**Small Molecule –**
Technical Insights Series

# Accelerating Molecules to Medicines: The importance of End to End CMC Service Provision.

## Introduction

As part of our technical insights series, we asked Tara Hope (Director – Business Development, Drug Product at Pharmaron) what are the key factors to consider when selecting organisations to support end to end CMC services.

**As Business Development Director for Drug Product at Pharmaron, Tara Hope brings strong commercial leadership and extensive experience across drug development and CDMO services. She has held senior roles spanning business development, commercial strategy, and client partnerships across the UK, Ireland, and Europe, supporting programmes from early formulation through to clinical and commercial manufacture.**

**Tara's understanding of integrated development pathways underpins her commitment to enhancing scientific continuity and accelerating progress from concept to clinic.**

## Setting the Scene

Biotech and pharmaceutical development teams operate in an environment where both scientific and operational pressures continue to intensify. Timelines are compressed, internal resources are stretched thin, and expectations from investors, regulators and patients demand a higher degree of predictability and technical accuracy than ever before. As programs move from discovery into preclinical development and later into CMC, each transition carries the risk of data discontinuities, shifting priorities or gaps in contextual understanding. Even small misalignments at this stage can develop into significant downstream delays.

Speed alone is insufficient. Organisations require confidence that each development stage is scientifically aligned to the next. This is where integrated service models provide an advantage. By linking discovery, safety assessment and CMC development under a unified framework, companies can streamline processes and facilitate continuity, build tacit knowledge and maintain a strong technical foundation that supports faster and more reliable program progression.

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## Current Industry Challenges

Conventional outsourced development models frequently involve multiple vendors, using different platforms, processes and quality systems. This introduces fragmentation. As a molecule moves from one vendor to the next, the receiving team often lacks visibility into earlier decisions, data justification or experimental conditions. As a result, context must be reconstructed and additional characterisation performed or assumptions re-evaluated.

Data silos compound these challenges. When analytical methods, pharmacology datasets or material specifications are generated in isolation, they may not translate easily into GLP studies or CMC workflows. Tech transfer becomes a resource intensive exercise in requalification or redevelopment. Such inefficiencies create genuine scientific and operational risk. A misaligned solubility profile, an incomplete impurity understanding or an analytical method that isn't sufficiently robust can trigger delays that affect both regulatory readiness and clinical supply.

## Evaluating the Value of End to End Service Providers versus Multi-Vendor models

The true cost of fragmented outsourcing emerges over the course of development. Technology transfers, duplicated activities, coordination overhead, and regulatory harmonization efforts can collectively add months to timelines and significant hidden costs to development programs. By contrast, integrated CMC partners reduce these structural inefficiencies by aligning strategy, infrastructure, and expertise across the product lifecycle.

**Comparing Fragmented and End-to-End CMC Models**

| Hidden Cost Category | How It Manifests in Multi-Vendor Models | Impact on Development Programs | How an End-to-End Partner Mitigates This |
|---|---|---|---|
| **Fragmented Pricing & Cumulative Costs** | Each vendor prices only their part of the workflow, leading to duplicated overhead, multiple project management charges, repeated documentation fees, and markups on tech transfer–related rework. | Higher total program cost, unpredictable budgeting, and cost escalations as additional vendors are added or timelines slip. | Integrated pricing structure with consolidated overhead, fewer repeat charges, reduced tech transfer-driven rework, and cost efficiencies gained from bundling development and manufacturing under one provider. |
| **Coordination Overhead** | Sponsors must manage multiple vendors, timelines, contracts, and communication channels. | Increased internal resource requirements and slower decision-making. | Centralised project management and single point of accountability. |
| **Timeline Inefficiencies** | Sequential handoffs between vendors create pauses while new teams onboard and understand the process. | Slower development timelines and potential delays to clinical milestones. | Continuous development workflow with aligned teams and infrastructure. |
| **Quality System Variability** | Vendors operate under different quality systems, procedures, and expectations. | Increased effort to reconcile data and ensure regulatory compliance across vendors. | Single quality framework across the entire development lifecycle. |

## A New Model for Drug Development – Pathfinder™ from Pharmaron

Pathfinder from Pharmaron brings discovery-enabling activities, preclinical insight, and all critical CMC functions into a single integrated operating model. In doing so Pathfinder removes traditional organisational barriers and creates a unified, cross functional approach. This alignment strengthens collaboration, accelerates progress, and ensures that every programme benefits from seamless scientific continuity - from initial concept through to clinical delivery.

Pathfinder eliminates unnecessary transitions and preserves the scientific rationale behind every decision. Early findings flow seamlessly into safety assessment, developability evaluation, process R&D and drug product strategy, strengthening data interpretation and providing clearer decision making towards first in human trials.

## Walking the Path from Discovery to Clinic

### Discovery

A unified discovery platform combines hit identification, medicinal chemistry, structural biology, in vitro and in vivo pharmacology and DMPK. This approach allows rapid design-make-test cycles and generates high quality datasets that can be directly leveraged by downstream teams. Early insights into compound stability, permeability, solubility and metabolic pathways help shape formulation and synthetic route decisions much earlier in development.

### Preclinical Development

Pharmaron integrates GLP and non GLP toxicology, safety pharmacology, PK/PD modelling and bioanalysis to develop strong IND enabling packages. Bioanalytical methods are developed with future clinical translation in mind, and toxicology formulations benefit from early CMC evaluation of solid-state characteristic, solubility and biorelevant dissolution. This ensures that safety studies generate data that is both regulatory compliant and technically aligned with eventual clinical dosing strategies.

### CMC: Drug Substance & Drug Product

Process R&D, GMP manufacturing, formulation development and clinical supply operate within a harmonised CMC framework. Pharmaron's teams consider scalability, impurity control, polymorphism, stability and process robustness from the outset. Drug product development integrates biopharmaceutics, preclinical exposure requirements and delivery considerations to ensure that clinical formulations achieve the product's intended performance.

Aligned quality systems and coordinated communication ensure that transitions between disciplines are seamless, reducing rework and accelerating movement into the clinic.

## Where Integration Makes the Difference

A fully coordinated model strengthens development programs by enabling:

- **Shorter timelines** through reduced duplication and more efficient transitions
- **Higher confidence in decision making** driven by consistent, traceable datasets
- **Lower development risk** due to continuity in scientific reasoning and quality oversight
- **Stronger regulatory submissions** built on harmonised methods and complete data provenance

Integration ensures that each stage of development is informed by the one before it and designed to support the one that follows.

# How Pharmaron Delivers End-to-End R&D Excellence

## The Success Behind the Science

With experience supporting thousands of global development programs, Pharmaron's integrated approach has helped clients overcome common blockages and maintain progress toward IND, CTA and first in human milestones. Our partners often highlight the operational continuity and seamless science achieved when discovery, preclinical and CMC work together as one connected service.

## The Future of Smarter, Faster Development

As drug modalities evolve and development pathways grow more complex, the value of finding a CDMO partner who can deliver both scientific excellence and operational consistency will increase. Integration is no longer optional; it's a strategic necessity. Pharmaron remains committed to empowering innovators with an end to end development model that accelerates progress, strengthens data integrity and ultimately helps deliver life changing therapies to patients.

Founded in 2004, Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.

**Find out more: www.pharmaron.com**