

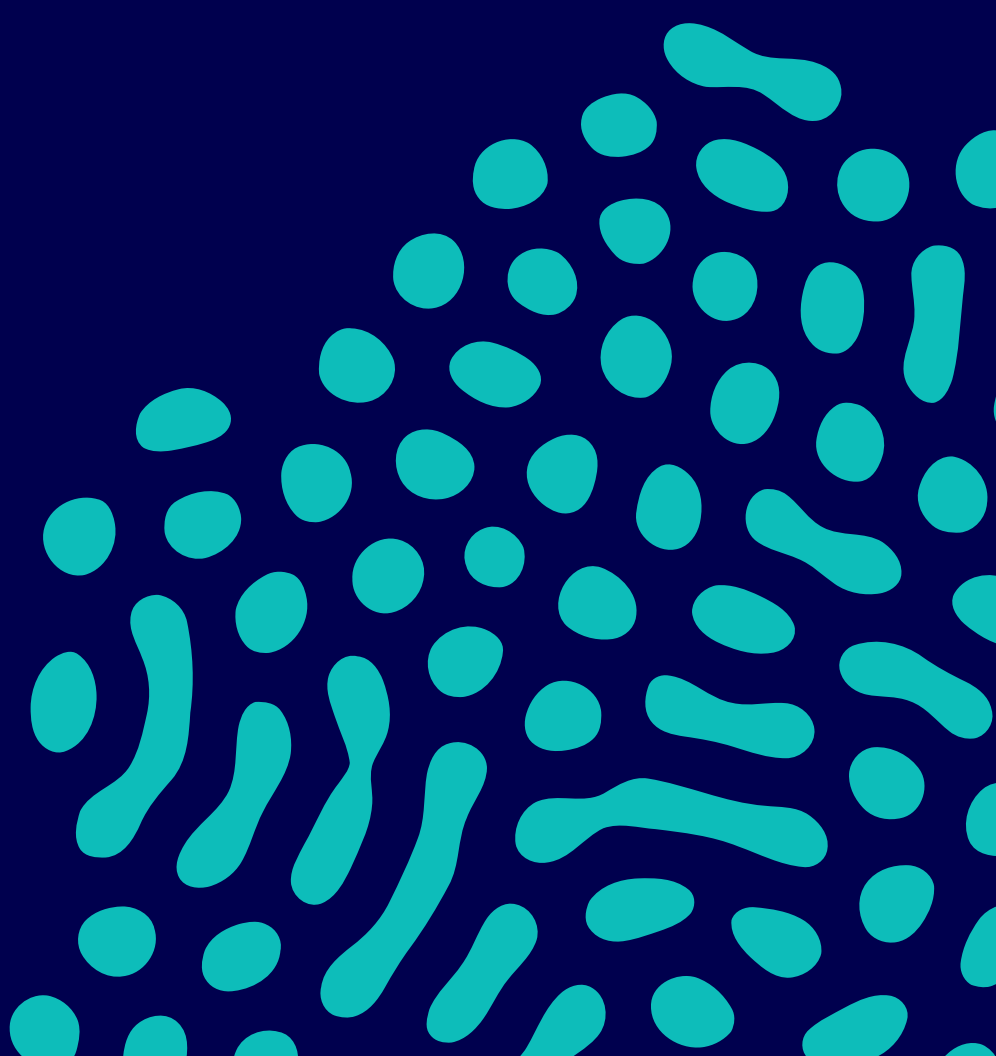


An altogether
different kind
of CDMO

Technology Transfers

A Beginner's Guide

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Pharmaceutical developers are increasingly relying on external manufacturing partners for expertise to develop and commercialize their products. In fact, contract development and manufacturing organizations (CDMOs) now process and manufacture approximately 28 percent of the world's prescription and non-prescription drugs.

Innovation is coming from all corners of pharma including independent labs, scientific consortia, academia and government programs. These emerging sources of drug innovation often have excellent science but few resources and a lack of experience in commercializing formulations and drug product concepts.

A priority for many sponsors, therefore, is finding partners with the specific scientific and technical capabilities to transfer their formulation chemistries from a source unit (SU) to the commercial-scale receiving unit (RU) in compliance with regulatory guidance.

At the beginning of any commercial relationship with a CDMO, there is a technology transfer. Over the product lifecycle this may occur with other external partners and a product's continued success can depend upon it. Whether you are a drug developer recruiting a CDMO for the first time, or in a new role, you may have questions or knowledge gaps on technology transfers. To help your understanding we've compiled a beginner's guide to technology transfer fundamentals.

A logical procedure, systematic in nature

According to Annex 7 of the World Health Organization (WHO) guidelines on the transfer of technology in pharmaceutical manufacturing, technology transfer is defined as "a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites."

It's a systematic procedure that transfers the documented knowledge and experience gained during chemistry and formulation development to an appropriate, responsible and authorized commercial manufacturing entity.

Technology transfer encompasses the transfer of documentation but also serves to demonstrate the ability of the RU to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and applicable regulatory bodies.

These systems can only be considered successful if there is documented evidence that the RU can routinely reproduce the transferred product, process or method against a predefined set of specifications as agreed with the SU.

Technology transfer: The basics

Technology transfers are the formalized and documented process to accomplish the knowledge and documentation transfers of a product. The event can occur at various stages and transitions in a product's lifecycle including:

- Development to clinical
- Initial launch and commercialization
- Post-market changes
- Market expansions
- Capacity expansions
- External supply

In the context of pharma manufacturing, technology transfers can occur intra-company and/or inter-company as well as to external CDMO partners. Regardless of where, technology transfers will always be a critical and necessary step to the commercialization or expansion of any drug product set for launch or already on the market.



Three Key Phases of Technology Transfers



Phase 1: Define/Scoping Phase

Phase 1 scopes the project and helps establish the project's organization and project charter. This is accompanied by knowledge gathering, encompassing the program's current status and future outcomes. Phase 1 also sets the stage for a gap analysis and failure modes and effect analysis (FMEA) risk assessment. Lastly, long lead time items are covered, as well as defining the transfer protocol.



Phase 2: Planning Phase

In the planning stage, your CDMO's technology transfer team will develop a work breakdown structure and outline critical milestones. The planning phase sees the development of the preliminary schedule, as well as generating resource estimates.

It's here that conversations can get interesting. Close, open collaboration can help to determine the most suitable course of transfer based on the outcome of risk assessment and understanding of process robustness at scale. It's at this juncture that the respective parties develop their risk management plans and refine transfer protocols establishing a clear schedule and laying the groundwork for the transition to the execution phase.



Phase 3: Execution Phase

Reaching the execution phase of a technology transfer is where the real work begins. In this phase, the program team tracks and manages the project and collects status data. As operational data arrives, the team is prepared to analyze variances and look for adaptive actions to assure quality and process optimization goals. Project status reporting is vital during this phase to ensure transparency and communication and it's important to partner with a CDMO that prioritizes this.

Focus on technology transfers for better outcomes

The eventual success of any program is likely to be prefaced by a robust technology transfer. To help realize the potential of your molecule, look for CDMO partners with a track-record of successful technology transfers relative to your program. Unlock your next breakthrough with the scientific backing of Pfizer and level up your next technology transfer with an altogether different kind of CDMO partner.

Discover how we're altogether different

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