Insider Tips for a Right-the-First-Time Tech Transfer

Driven by complex modalities, global supply chains, and strategic partnerships, increased outsourcing makes tech transfer a critical process for both CDMOs and sponsors.

Tech transfer is an intricate undertaking–often a "you don't know what you don't know" situation for newcomers, and even a demanding data-gathering trial for those with experience. Working with an experienced CDMO can clarify the path forward.

What's at Risk If Tech Transfer Goes Wrong

Every tech transfer is unique in some way, and the consequences of getting details wrong can be significant. The greatest risk would be the inability to produce a safe, high-quality product–something no sponsor or CDMO could accept as an outcome. On the path to ensuring safety, quality, and compliance, ineffective or inefficient tech transfers involve additional risks such as repeated development work, regulatory scrutiny, added time and expense, and increased stress on resources. All of the above can delay a programme's next steps or even postpone a product launch. Getting tech transfer right matters in the long run.

Knowledge Transfer

Tech transfer is not simply moving a product from one organisation to another. It is transferring the full depth of knowledge that underpins how that product is made. This is where the real challenge lies. Batch records, methods, material specifications, and equipment lists are essential, but they don't necessarily capture everything that is needed.

Just as important as formal documentation is the sponsor's tribal knowledge–critical information and know-how that is essential for successful process and product transfer. Tribal knowledge is based on a combination of experience, intuition, and practical insights from individuals who have worked extensively with the product. This knowledge fills gaps that official documents sometimes do not cover. How were parameters chosen? Which risks were explored or ruled out? What had to be adjusted during development? These details explain how the process evolved. Too often, formal documentation is solely relied upon, and the new CDMO must rediscover details on their own.

The Information Sweet-Spot

With documentation, there is also an information "sweet spot" for the receiving CDMO. Too little information forces the receiving team to make assumptions or do duplicate work. Conversely, too much detail, especially if it is not well-organised, leads to time lost sifting through documents to find the proverbial 'needle in the haystack'. It can also force reviewers who are less familiar with the programme to judge the relevance of vital details versus extraneous information.

Essential elements, which sponsors are sometimes surprised to find out are needed, are a target product profile (TPP) and the product's critical quality attributes (CQAs). To transfer a product, a CDMO needs to complete risk assessments based on this information. For example, risks can be very different when comparing something like acceptable particulate levels in a product that is administered via subcutaneous injection vs. an ophthalmic treatment that is injected into the eye.

Scale-Up Surprises

Often, the reason for a tech transfer is to scale up output in anticipation of a significant programme milestone. The optimism that sponsors begin with can shift to surprise once the realities of the required process steps come to light. Moving from bench scale to commercial scale is rarely as simple as 'bigger tanks and more product.'

Clinical & Commercial Alignment

One of the most impactful predictors of a smooth transfer is early collaboration between a sponsor's clinical and commercial teams. Typically, clinical teams prioritise speed and trial supply continuity, while commercial teams focus on long-term efficiency and cost of goods. Unfortunately, these goals can be at odds when it comes to process development and scale-up.

Since the Phase 3 process is typically carried forward into commercialisation, optimisation should occur at or before Phase 3. Once a process is locked in and regulatory filings are complete, changes become costly and difficult. For example, a clinical team included a specific brand and model of equipment in their regulatory submission. When the project reached commercial stage, that specific model was not appropriate for the scaled-up batch size. What they should have done is include details on functionality instead of calling out a specific make and model. That allows the commercial team to, if needed, move to different equipment that is appropriate for the batch size but maintains the same technical functionality.

Budget Blind Spots and Material Constraints

Early programmes frequently arrive with limited budgets and minimal supply of raw

material, along with the hope that fewer pilot runs will be sufficient. But robust development requires multiple batches to explore the design space and stress-test processes. Inefficiencies can occur if there's a lack of sufficient resources for thorough development work, including challenging the process repeatedly. In addition, understanding lot-to-lot variability enables the determination of raw material impact on the final product CQA.

Timelines Rarely Behave as Expected

Sponsors often underestimate the scope of work required to scale. Early-phase programmes move quickly, but later phases introduce layers of qualification, validation, equipment integration, and troubleshooting. Often, these steps are linear and a delay in one area affects others. Even with best-case planning, aggressive timelines leave little room for learning, iteration, or remediation. Programmes move faster and more reliably when they include a bit of breathing room for contingency plans.

Equipment – Not Always 'Plug and Play'

Early in tech transfer discussions, sponsors and CDMOs must determine what equipment is available, what can be transferred, and what must be acquired. An experienced CDMO brings the perspective of numerous past transfers – insights that can be especially valuable to sponsor teams navigating their first programme or those unfamiliar with equipment transfer between facilities.

These early assessments shape everything that follows. They help determine whether equipment needs to be ordered well in advance, or whether existing assets will suffice through later programme phases. Thoughtful planning can prevent issues such as attempting to scale clinical-phase equipment beyond its designed capacity, which can lead to inefficiencies, repeated deviations, or late-stage equipment failures.

Factors for Consideration

Seemingly simple decisions – batch frequency, anticipated demand, and longevity of the process – can drastically change equipment needs.

- The demand on equipment running three times a day will be very different from a campaign approach with batches every six months.
- Early manual or semi-manual operations may have worked for clinical needs, but later stages often require greater automation to ensure data integrity, reliability, throughput, and operator safety.

A well-defined manufacturing strategy also guides the CDMO's planning for facility space, utilities, environmental controls, and cleanroom requirements. These considerations can represent significant behind-the-scenes work and are foundational to integrating equipment successfully.

New Operational Environments

Once equipment arrives at the CDMO, the process may have to begin again. The first question is not whether the equipment worked elsewhere – it is whether it works as intended within its new location. Before manufacturing can begin, the equipment must undergo installation qualification (IQ) and operational qualification (OQ). These steps verify that it performs reliably across its full operating range in the new environment.

After confirming operational performance, focus shifts to safety and compatibility. Equipment must integrate seamlessly with the facility's cleaning, sterilisation, and containment practices and operate safely with all materials it will encounter. Only after these fundamentals are understood can the equipment be woven into the broader manufacturing workflow.

Equipment Documentation

Every piece of equipment must support well-defined, repeatable processes. Even a single batch can generate hundreds of pages of SOPs covering operation, cleaning, and maintenance. This may seem exhaustive, but it ensures that when the process is executed again – whether months or years later – it can be done with the same level of control. Going through these steps also helps guard against unknowns. It is common for a CDMO to bring in equipment, read the previous instructions, and have something go wrong because of unwritten rules that the previous manufacturer "just knew." Plus, regulators will expect detailed evidence that equipment is capable, consistent, and appropriate for its intended use.

Keeping In-Transit Testing Methods Intact

Analytical method transfer is the formal proof that a receiving laboratory can run a method reliably, reproducibly, and in alignment with the originating site. Method maturity directly determines how quickly a CDMO can scale, validate, and manufacture a GMP product. Analytical readiness is not optional; it dictates whether timelines hold, change controls multiply, or redevelopment emerges mid-programme. The earlier data, reports, and historical context are shared, the more smoothly the transfer proceeds.

CQAs First, or Everything Slows

Analytical methods define how a product is measured, controlled, and released. They establish how CQAs are assessed, how impurities are tracked, and how degradation and stability are interpreted. When CQAs are unclear or still evolving, methods tend to evolve alongside them, stretching timelines. While CDMOs bring execution expertise, sponsors remain the authority on what truly matters about their product.

What Transfer-Ready Actually Means

Transfer-ready methods are not perfect; they are clear, stable, and supported by sufficient historical data. Sponsors should be prepared to provide SOPs, development reports, validation or qualification documentation, representative chromatograms, forced degradation data, and records of trends or deviations. Together, these materials allow

assessment of method maturity and the appropriate transfer strategy.

A frequent pitfall is the assumption that a specification implies a standard method. In practice, many specifications mask non-compendial or heavily modified methods that emerge only after transfer begins. When the complete method surfaces later, project scope, cost, and timing may need to be reevaluated. Reviewing raw data – not just summary reports – often reveals issues that paper assessment alone fails to expose.

Analytics Drive Process, Not the Other Way Around

Analytical readiness directly shapes process transfer and scale-up. CQAs inform mixing strategies, hold times, filtration, and filling decisions. Methods such as assay, impurities, and viscosity provide critical feedback during engineering runs. If analytical precision is inadequate, process understanding inevitably suffers.

Process capability depends on method variability relative to specifications. Narrow limits combined with noisy methods increase the risk of ambiguous results. Early evaluation of variability helps determine appropriate testing strategies and whether a method requires refinement. Strong control strategies link CQAs, process parameters, and analytical performance into a coherent whole.

How A CDMO Can Help

It is important to select a CDMO that understands how to transfer a project smoothly across different stages of development. They should work with the sponsor to ensure that everyone is aligned on the process, the product, and the long-term goals. Oftentimes, that involves sharing honest, initial assessments of programme risks and potential impacts to schedules. For sponsors, having eyes wide open to important tech transfer considerations as well as trusting their CDMO's specific feedback can get everyone's expectations aligned before moving forward.

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