SPOT LIGHT

Tech transfer from clinical to commercial: a step-by-step approach to accelerating success

Julie Pagenaud and Elea Ney at CARBOGEN AMCIS outline a structured, strategic approach to tech transfer, offering practical insight into how biopharmaceutical companies can move from early-phase development to commercial manufacture with speed, quality and confidence

The transition from clinical to commercial production is one of the most pivotal – and high-stakes – moments in the pharmaceutical development life cycle. For companies bringing sterile drug products to market, the technology transfer process can either pave the way for regulatory and commercial success or introduce delays, inefficiencies and risk.

Why tech transfer matters

Tech transfer is far more than a procedural handover; it is a critical process for ensuring that development work performed in early clinical phases effectively translates into commercial-scale production. However, one of the most significant constraints is time. Companies aim to be first to market, but this pressure must be balanced with the need for product quality, regulatory compliance and cost-effectiveness. One major risk is misalignment between development efforts and the specific requirements of each phase. Overspending early, or underinvesting in critical data, can undermine project outcomes. The balance of success lies in applying resources appropriately at each stage.

Tech transfer often encounters obstacles when formulation knowledge is limited, or when there is no access to representative material. Relying on surrogates or placebos may not provide reliable data, especially with highly potent or novel compounds. For some products, surrogates are not viable for an efficient transfer, making it essential to have early access to drug substance batches manufactured using the intended process.

A step-by-step approach

A robust gap analysis and risk assessment form the foundation of a successful technology transfer. This early work involves evaluating the full transfer package across both process and analytical domains to identify discrepancies between the sending and receiving sites. From this, a technology transfer plan is developed to define the transfer strategy based on the available documentation, such as the number of engineering batches required, critical parameter settings and the expected outcomes depending on the foreseen process at the receiving site.

Clear documentation is critical at every step. This includes engineering batches, analytical method and process transfers, validation activities, and the creation of a regulatory file. Each stage is designed to accumulate evidence that the process is reliable, the product quality conforms to the acceptance criteria and the manufacturing approach is repeatable. This approach also supports regulatory preparation, with each stage generating essential documentation. During engineering batches, data is collected to demonstrate process consistency. Analytical method transfers are validated to ensure reproducibility at the commercial scale. As the transfer progresses, a full package of reports is compiled -– including the technology transfer report and validation master file – that will be key to fulfilling regulatory submission files. Also, those documents will be part of the package to be reviewed during the submission process and authorities' inspections later. Having this structured roadmap in place helps avoid rework and ensures alignment with evolving compliance standards throughout the process.

Transparent and open communication between partners is also vital. When customers share comprehensive data, documentation and expectations from the outset, potential issues can be identified and addressed early. This mutual visibility reduces the likelihood of late-stage surprises, strengthens trust between teams, and supports more predictable timelines and outcomes. Clear communication

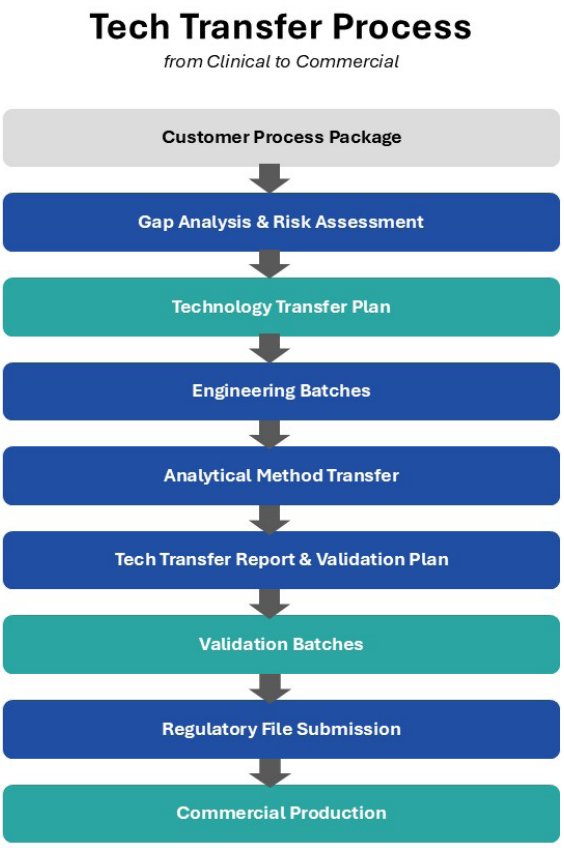

Figure 1: The step-by-step approach

also allows both parties to align on expectations and adjust plans proactively as challenges arise.

Accelerating success

With a well-defined roadmap in place, the next challenge is to execute it efficiently. This is where speed, planning and operational choices come into focus.

Speed is the key driver for most customers, but attempts to cut corners to save money in the early phases often lead to downstream delays. Success is accelerated not by bypassing stages, but by front-loading planning and using established systems and materials wherever possible. One way to significantly reduce timelines is to use standard components or existing in-house equipment, which can eliminate the need for additional validation or procurement. Equally, on-site collaboration – such as visiting a customer's facility – can uncover subtle differences in processes or analytical handling that may not be captured in documentation and help to speed up the process. Accelerating success requires both operational efficiency and early alignment of project expectations, allowing technical teams to plan for known constraints and reduce uncertainty.

Scaling up with confidence

Efficient planning and reuse of standard tools can save time early on, but scaling up presents its own technical hurdles that require equally careful navigation. Shifts in equipment size, performance characteristics and process control can affect outcomes if not fully understood.

Freeze-drying (lyophilisation) is a clear example of where technical insight is essential. The process does not scale linearly, and parameters such as shelf temperature cannot be transferred directly from small to large systems. Understanding how the material behaves in each environment and how the equipment differs is critical to achieving a successful outcome. Organisations with integrated development and manufacturing capabilities are often better placed to manage this complexity. A development programme that considers commercial-scale equipment from the outset increases the likelihood of successful scale-up.

In more fragmented models, customers may conduct early development in one organisation and hand over to a contract development and manufacturing organisation (CDMO) at a much later stage. This can introduce variability, delay timelines and reduce opportunities for upstream optimisation. By contrast, integrated providers, such as CARBOGEN AMCIS, can develop formulations with commercial equipment in mind, run development and good manufacturing practice (GMP) batches under one roof and involve production teams earlier in the process – reducing both technical risk and administrative burden.

Expertise, collaboration and control

Navigating scale-up successfully also depends on the expertise behind the process, and the strength of collaboration between customer and CDMO. Early dialogue helps establish priorities – whether the focus is speed, cost, risk reduction or regulatory precision – and shapes the overall approach.

One thing to bear in mind is that customers may have different risk tolerances. Some require extensive

> *When development, transfer and manufacturing are aligned from the start, the outcome is faster, smoother, and more reliable*

> *A good tech transfer gets the job done. A great one is right first time – with no surprises at scale-up*

engineering batches to ensure confidence and completely minimise any risk, while others prioritise speed and are willing to proceed with fewer data sets. The critical factor is alignment and understanding your customer's needs; when both parties understand the constraints and goals, the process can be optimised accordingly.

Compliance must also be built into the process from the outset. Gap analysis includes the evaluation of GMP and Annex 1 requirements, and a proactive regulatory strategy ensures each stage is aligned with expectations. In-house regulatory affairs teams can further support dossier preparation and interactions with authorities, ensuring a smooth process.

A quality-by-design mindset underpins this approach. Designing formulations and processes with commercialisation in mind – from the earliest stages – helps avoid rework and builds a stronger foundation for long-term success.

From good to great

Strong collaboration and regulatory alignment lay the groundwork for a well-executed transfer. But what elevates a project beyond the expected? What separates a good tech transfer from a great one is the integration between development, tech transfer and production teams. When all functions are aligned from the beginning, projects benefit from clear expectations, consistent data and streamlined execution.

Organisations that engage their manufacturing partners early, ideally during the development of the drug product, enable better planning and reduce the risk of scale-up failures. Delays often occur when tech transfer is treated as a final step, rather than an integral part of the development journey.

From the customer side, preparation and mindset make a significant difference. Projects tend to run more smoothly when customers enter the transfer phase with a clear understanding of their own priorities – whether that is timeline, budget or risk mitigation – and have organised their documentation accordingly. Challenges often arise when a project reaches the manufacturing partner with limited data and unrealistic timelines. Treating tech transfer as a strategic workstream from day one improves the likelihood of first-time-right success.

By embedding tech transfer strategy from the outset, companies position themselves for success; not only in meeting regulatory milestones, but in delivering safe, effective products to market efficiently and reliably.

Elea Ney is a project management professional with experience in the pharmaceutical industry. She currently works as a technical transfer manager at **CARBOGEN AMCIS**, where she is responsible for the successful transfer of new products from customer or in-house development departments to GMP manufacturing. Trained as a process engineer (ENSAIA), she has led projects involving new process equipment and production area build-up for sterile and non-sterile manufacturing, notably for Sanofi, coordinating multidisciplinary teams to meet quality, cost and schedule goals.

Julie Pagenaud is an experienced pharmaceutical operations leader and currently director of Pharmaceutical Operations, Drug Products at **CARBOGEN AMCIS**, where she oversees sterile drug manufacturing, MS&T activities and technical aspects, as well as customer projects portfolio management. Prior to this, she held senior operational, technical and manufacturing roles in the pharmaceutical industry, including at Ipsen, and brings deep expertise in process engineering, production leadership and quality systems for several markets worldwide (US, Canada, Japan, and the EU).

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