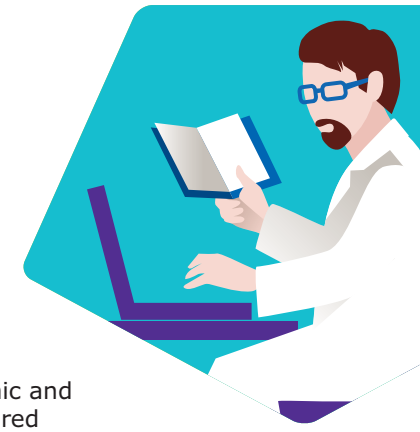
BioReliance®

Pharma & Biopharma Manufacturing & Testing Services

MERCK

Best Practices

Technology Transfer Considerations



Work with an Experienced Partner

Begin with a Transfer in Mind

Be Thorough to Reduce Risk

Flexibility and speed are key for development of a new drug, from the lab bench to the clinic and to the market. The ability to produce a batch at the right time and at the right size is required to support clinical trials and commercialization in a timely and cost-effective manner. A robust process is mandatory but scalability and tech transfer ultimately determine success.

Work with an Experienced Partner

It's inevitable. At some point, you will need to transfer a process either to another team for scale-up purposes or perhaps to another building, company or geography for manufacturing. Proactive planning for these events is essential as similar process conditions across different capacities and methods must be established.

One key to a successful tech transfer is experience. You need to know your equipment and set the tolerances and precisions of every operation and parameter in accordance with production capacities, leverage advanced tools for sizing and modeling and seamlessly manage people and planning. If this is your first tech transfer, don't go it alone – instead, partner with an expert who has done it many times and can optimize and accelerate the process while minimizing risk.

Begin with a Transfer in Mind

The ability to flawlessly execute and validate a tech transfer ensures robustness and applicability at higher scale. If problems arise, additional studies might be needed to understand and adapt the process, requiring extra time and money and putting key milestones in jeopardy.

As such, it is critical that every gap be managed as early as possible. Risks can be mitigated with use of pilot runs or via calculation tools for modeling and sizing. In a worst-case scenario, an unsuccessful tech transfer can result in loss of efficiency of the process such as a low titer or decrease of production yield, a loss of robustness in which GMP batches are not similar, or impact the quality of the molecule in terms of activity or charge profile.

Be Thorough to Reduce Risk

All data from development must be considered as potentially relevant and as key parameters for future tech transfer. A gap analysis should be completed between development and production and include methods, equipment, consumables and processes; everything that cannot be transferred directly "as is" must be assessed. This analysis details potential risks, the root cause, potential impact and informs the mitigation plan.

Keep in mind that every method and operation – even those considered the simplest – should be analyzed in detail as even a small difference can have a big impact. Any difference in methods, equipment performance and software represents a risk.

Download your full guidebook and learn from our experts about key considerations that biopharma executives need to make along the molecule's journey from laboratory to the clinic: **MerckMillipore.com/molecule-journey-clinical**

BioReliance® End-to-End Solutions

BioReliance® End-to-End Solutions is an adaptable CDMO partner for small biotechs and start-ups needing to develop and commercialize biologics. We do this by balancing speed, risk and cost through custom solutions, by leveraging our bioprocessing technologies and process development expertise, and by allowing our clients to transfer their process and knowledge to their end point at any step of their drug development. To learn more, please visit **MerckMillipore.com/adaptive-CDMO**

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