MYCENAX

WhitePaper

The Tech Transfer Playbook: 6 Essential Steps for Lab-to-Market Success

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About Author

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Albert Liao is the head of the MSAT department at Mycenax, where he oversees the production of both biosimilars and new drug products. With over a decade of experience in the biopharmaceutical industry, he has developed extensive knowledge in GMP manufacturing and successfully led numerous tech transfer initiatives—from early-stage development to complex site-to-site transfers. Passionate about bridging lab-scale innovations with commercial-scale production, Albert has managed projects throughout the entire tech transfer lifecycle, ensuring seamless transitions and maintaining process integrity. His commitment to cross-functional collaboration, technical excellence, and continuous improvement consistently delivers lasting value to both clients and patients.

About Mycenax

Mycenax is a fully dedicated CDMO specializing in process development and cGMP manufacturing of biologics and biosimilar products. We leverage our expertise to optimize product development and market access for pharmaceutical and biotech partners. Our comprehensive solutions include mAbs, BsAbs/MsAbs, ADCs, plasmid DNA, cell therapies, vaccines, small peptides, and fusion proteins. With advanced platforms and PIC/S GMP-compliant facilities, we offer integrated DNA-to-Drug Product services globally. Our GMP facility has EMA, PMDA, Health Canada, and Taiwan FDA approvals and has passed 70+ global client audits, ensuring consistent GMP compliance.

Effective Biologic Tech Transfer for Quality and Compliance

Though some may assume tech transfer is a formulaic process, each is a unique journey between drug sponsor and CDMO, especially when it comes to biologic drug manufacturing. Tech transfer is the pivotal stage at which a lab-scale project will begin its journey to a GMP facility. As such, the processes and analytical methods leveraged at lab scale may not transfer easily to GMP production, making the tech transfer an ideal opportunity to optimize processes, mitigate risks, and identify adjustments to safeguard quality, compliance, and a continuous supply of therapeutics for patients.

To achieve a successful tech transfer and maximize the benefits for your therapeutic, work with a knowledgeable and experienced CDMO that can tailor their tech transfer approach to suit your needs. As you consider how this process should unfold with a tech transfer, and how an experienced CDMO ensures quality and compliance at every stage.

Biologic Tech Transfer: Development to Scale or Site Switch

Which Type Of Tech Transfer Are You Conducting?

When it comes to early relationships between drug sponsors and CDMOs, tech transfers generally fall into one of two categories: (1) development stage to manufacturing at scale or (2) moving from one manufacturing site to another. They each have different components to assess.

For the transition between the development stage and manufacturing at scale, key considerations include establishing process scalability and operability within a GMP-compliant facility, along with ensuring that analytical methods are robust, validated (or qualification-ready), and suitable for in-process control, release testing, and long-term quality monitoring. To meet aggressive timelines for critical milestones — including toxicology material supply, IND, and/or IMPD submissions — an integrated and adaptable platform strategy, reinforced by deep prior experience, will be used to compress development timelines, improve coordination, and secure readiness across all deliverables.

For the transition from one manufacturing site to another, key considerations include achieving comparable process performance and consistent product quality. A thorough understanding of the manufacturing process, with clearly defined process parameters and a robust control strategy, is essential. Executing process performance qualification (PPQ) is critical to demonstrate process robustness and to ensure comparability with the reference medicinal product (RMP) or the reference standard from the original site. In addition, strong technical expertise and well-documented evidence of process understanding and validation are crucial to support regulatory inspections and marketing approval.

To achieve a robust technology transfer and launch your product successfully, an experienced CDMO will work with your team to gain a clear understanding of your project scope, goals, and timeline to provide tailored advice on your tech transfer approach.

Streamlined Biologic Tech Transfer with Expert Oversight

Who Oversees The Tech Transfer Process?

At Mycenax, a Taiwan-based CDMO, our Manufacturing Science and Technology (MSAT) team is the cornerstone of our technology transfer process, delivering unparalleled expertise and leadership throughout every stage. MSAT not only coordinates tech transfer but also drives scaleup, process characterization, control strategy establishment, process validation, and continuous monitoring—ensuring seamless integration from development to commercial manufacturing. MSAT experts conduct a rigorous pre-assessment to evaluate tech transfer feasibility based on a client's molecule type and process design alongside our equipment readiness and facility capabilities. This comprehensive review of raw materials, equipment, processes, and safety factors enables us to tailor the most effective and risk-mitigated transfer strategy for each project.

Throughout the tech transfer journey, MSAT acts as the central liaison with sponsors, providing continuous communication and transparency, to ensure alignment and rapid issue resolution. Our experts strive to mitigate risk throughout the process to implement a robust, GMP-compliant process that aligns with the stringent standards of our manufacturing, quality control, and quality assurance teams. Backed by years of hands-on experience in process development (PD) and GMP manufacturing for both drug substances and drug products, the Mycenax MSAT team is uniquely positioned to oversee the entire product lifecycle — from initial tech transfer through process performance qualification (PPQ) to ongoing process verification — providing clients with confidence and reliability at every step.

Strategic Biologic Tech Transfer: Collaborative Optimization and Risk Mitigation

What Are The Steps To An Effective Tech Transfer?

Mycenax views the tech transfer process not as a handoff, but as a strategic and collaborative process. Here's how we make sure every tech transfer is efficient, risk-mitigated, and built for long-term success.

1. Deeply Understand the Client's Process

Prior to initiating the tech transfer, our MSAT team works closely with clients to gain a thorough understanding of each process step, its purpose, and associated in-process controls (IPCs). We evaluate critical process parameters (CPPs), critical quality attributes (CQAs), and the design space of each step to define clear acceptance criteria and identify any necessary adaptations. This ensures we define the right acceptance criteria and identify necessary adjustments early — setting a strong foundation for a smooth transfer. Once the tech transfer plan has been reviewed and approved by the client, it is time to conduct a comprehensive gap analysis.

2. Assess facility and process gap analysis

At the gap analysis stage, we perform a rigorous and systematic risk and gap assessment that evaluates materials, equipment, and process compatibility. Risks are categorized (e.g., negligible, low, medium, or high), with mitigation strategies proposed for any area identified as medium or high risk. For example, if sourcing delays are identified, we proactively recommend qualified alternative materials. On the equipment side, if the client originally uses a benchtop bioreactor system with integrated advanced control, but our manufacturing site uses larger-scale stirred-tank bioreactors with a different control platform, we assess and align the control strategy to maintain cell growth and productivity. With this approach, we are able to stay ahead of potential issues rather than react to them. All findings are documented in a detailed report that is shared with the client for review and feedback before progressing.

3. Mitigate Risks Through Data-Driven Optimization

To effectively manage the medium- or high-risk gaps, we conduct bridge studies, when necessary, to assess the impact of proposed changes — whether in raw materials, equipment, or process conditions — on process performance and product quality. For example, when substituting analytical equipment used for key measurements such as cell counting, pH, or metabolite levels, differences in output values can arise. In such cases, a well-designed bridging study is essential to establish robust correlations and maintain data consistency between the new and original equipment, thereby safeguarding product integrity.

Moreover, to guarantee seamless integration with Mycenax's manufacturing environment, we conduct site-specific validation studies — including mixing and hold-time studies — that confirm process compatibility under actual facility conditions. In instances where variability is observed in CPPs, we undertake targeted investigations to define and implement controls that maintain CPPs firmly within their acceptable ranges. This proactive, data-driven approach minimizes risk, ensures process robustness, and ultimately supports a successful, reliable biopharmaceutical technology transfer.

4. Enable Process Optimization During Tech Transfer

At Mycenax, we recognize that clients may have specific considerations or opportunities for process optimization during the tech transfer phase. To accommodate this, our process development (PD) and MSAT teams collaborate closely with clients to evaluate and implement improvements where appropriate. The PD team focuses on key areas such as:

- Upstream Productivity enhancement
- Downstream recovery improvements and impurity reduction
- Analytical method development and validation
- Harvest process and filter-sizing optimization
- Formulation development and stability studies
- Drug product manufacturing process development

This partnership allows for a tailored approach where process optimization can be strategically integrated into the tech transfer activities — only when justified and agreed upon by the client —resulting in a process that is scalable, controllable, and optimized for GMP manufacturing. This collaborative and flexible framework helps clients achieve enhanced process performance without compromising transfer timelines or product quality.

5. Considerations During Tech Transfer Execution

Successful tech transfer extends beyond planning and optimization—it requires meticulous execution with careful attention to operational details. During the transfer, Mycenax ensures strict adherence to defined protocols while maintaining flexibility to address unforeseen challenges. Effective communication and coordination among the clients are prioritized to promptly resolve any issues that arise. Rigorous quality control measures are applied, with real-time monitoring of CPPs to drive process consistency. Additionally, adaptations to facility-specific constraints are made without compromising process integrity. Throughout the execution phase, robust change control procedures are implemented to document any deviations or improvements. By proactively managing these operational factors, Mycenax supports a smooth and controlled tech transfer, minimizing risks and laying the groundwork for commercial production.

6. Document all components of the tech transfer

A successful tech transfer relies on clear and complete documentation. At Mycenax, we create a high-quality tech transfer plan defining the key criteria of a project, including the scope, timeline, milestones, regulatory strategy, and judgment criteria. It also entails the designation of roles and responsibilities for both the sending unit (client) and the receiving unit (Mycenax) to ensure accountability and task tracking.

Throughout the process, we document all activities — including changes, key observations, and deviations with corrective actions. These are compiled into a final report shared with the client. Supporting documents such as gap analyses, study data, and process reports are securely managed via Mycenax's documentation system. This structured approach provides traceability, speeds regulatory preparation, and supports a smooth, compliant transition to GMP manufacturing.

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What Other Considerations Should Be Prioritized?

Beyond the standard steps of tech transfer, biologics require additional risk-based considerations to ensure product safety, quality, and compliance. At Mycenax, robust change control is triggered whenever a new product enters our GMP facility, with a strong focus on cross-contamination prevention. The following areas are critically assessed to mitigate the risk of product carryover:

- Molecular characteristics: As a multi-product facility, we must evaluate molecular properties — such as potency, immunogenicity, and toxicity — to assess the risk of cross-contact or residual impact on subsequent products.

- Cell Origin: Full characterization certifies the cell substrate is free from contamination and adventitious agents, reducing the risk of biological contamination spreading between processes.

- Raw Materials: We extensively use animal-derived component-free (ADCF) and single-use materials to mitigate safety concerns and eliminate cross-contamination between different products.

- Equipment and Facilities: All equipment is assessed for cleanability and segregation suitability. We implement validated cleaning procedures to ensure effective removal of product residues, supported by routine verification to prevent cross-contamination between batches.

In addition to preventing cross-contamination, strong supplier oversight is essential to ensuring product quality and manufacturing continuity. Mycenax works with our raw material vendors to help mitigate long lead times and secure continuous, high-quality supply. To assess supplier quality, we conduct site visits and test material upon receipt to confirm it meets our identity and quality specifications. We perform pharmacopoeia-compliance testing to verify that raw materials meet identity, purity, and quality standards and are suitable for their intended use.

How Does Mycenax Ensure Continuous Improvement From The Tech Transfer Exercise?

At Mycenax, tech transfer is not the end — it's the foundation for sustained, high-quality manufacturing. Our team assesses any challenges that came up along the way and develops mitigation strategies to help prevent similar obstacles going forward. These lessons learned are conveyed to the manufacturing team for future GMP production. We conduct PPQ to ensure the consistency and reliability of the manufacturing process, which helps guarantee process robustness. Throughout tech transfer, PPQ, and validation workflows, we maintain compliance with regulatory requirements, which helps facilitate a seamless transition to BLA submission, marketing authorization, and commercialization. Our commitment to continuous process verification and improvement helps minimize obstacles for our clients, which ultimately, helps guarantee that a high-quality biologics reaches patients efficiently and consistently.

References

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