International Technology Transfers: A Playbook for Success

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BACKGROUND

The BIOSECURE Act and the push for reshoring manufacturing to the US are driving complexities in pharmaceutical manufacturing. International technology transfers require effective coordination among cross-functional teams and become more complex across global sites due to evolving regulations and operational constraints, increasing the risk of misalignment and inefficiencies that can negatively affect time to market, product quality, and patient outcomes. To address these issues, Syner-G | Sequoia have developed a technology transfer playbook offering a strategic framework for effective planning and execution. Supported by proven case studies, this approach turns challenges into opportunities for effective implementation, improving outcomes for both organizations and patients.

METHODS

Where do Technology Transfers Happen in the Product Lifecycle?

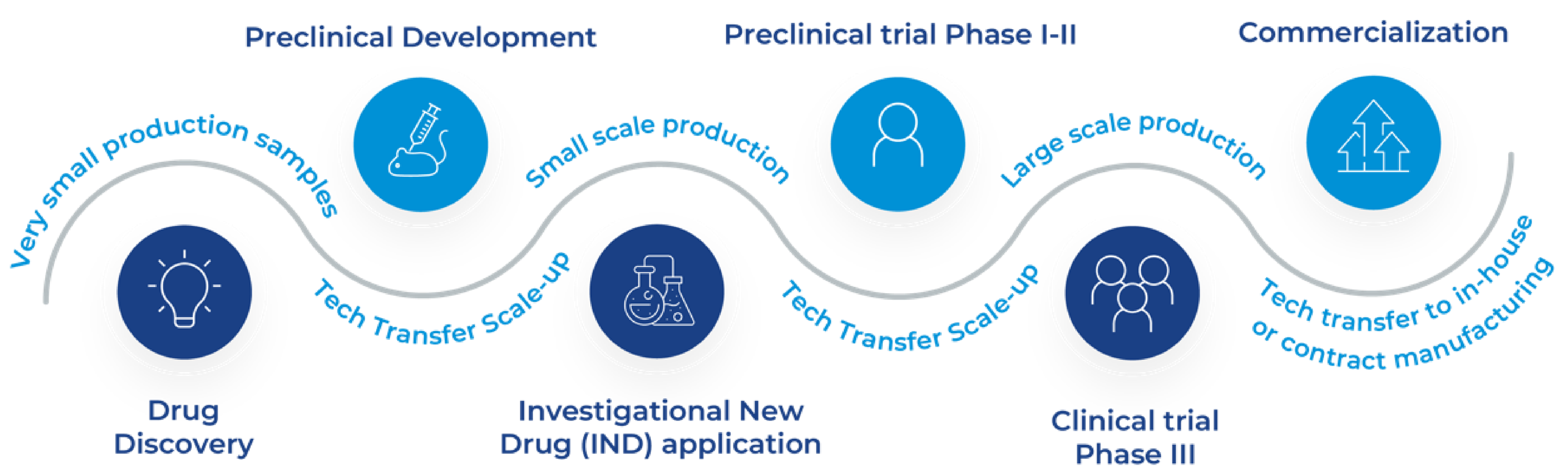

Figure 1. Critical Tech Transfer Milestones Across the Product Development Lifecycle

Technology transfers occur at different scale-up inflection points throughout the product lifecycle, each characterized by distinct drivers, requirements, and success criteria. As a product advances from preclinical to clinical phases and ultimately to commercialization, it is critical to employ a technology transfer framework that focuses on the effective transfer of product specifications and process knowledge, along with ensuring regulatory compliance.

Phase	Key Drivers	Technology Transfer & Regulatory Focus	Technical Considerations
Preclinical Development	• Establishing proof of concept • Preparing for IND/CTA submission • Early process feasibility	• Establish process • Document critical product specifications • Preparation for regulatory submission	• Small-scale, non-GMP production • Initial analytical assay development • Process scalability and reproducibility testing
Early Phase Clinical Trials	• First-in-human (FIH) trials • Demonstrating safety • Ensuring regulatory compliance (GMP readiness)	• Process knowledge transfer R&D to GMP manufacturing • Process refinement for clinical production • Approval requirements for clinical trials	• Transitioning to GMP manufacturing • Analytical method and process qualification. • Scaling processes for later-stage trials • Supply chain and raw material qualification
Later Phase Clinical Trials	• Pivotal trials for efficacy confirmation • Scaling up for broader patient access • Preparing for commercial launch	• Technology transfer to commercial-scale manufacturing • Process validation and regulatory submission readiness (BLA/NDA/MAA) • Establishing robust supply chain	• Process validation, optimization, and comparability studies • Analytical method validation • Site selection and qualification for large-scale production
Commercial / Post-Market Surveillance	• Routine, large-scale production • Consistency and cost efficiency • Post-market regulatory commitments	• Lifecycle technology transfer to ensure ongoing process improvements • Continued process verification (CPV) and regulatory compliance • Post-marketing surveillance and risk management	• Full-scale GMP manufacturing with validated processes • Continuous improvement initiatives • Long-term supply chain strategy

Table 1. Technology Transfer Considerations Across Product Development Stages

Technology Transfer Playbook

Our technology transfer playbook facilitates a smooth transition of knowledge, processes, and technologies across sites and organizations through a comprehensive six-phase approach that aligns with best practices in project management for knowledge process groups. For complex technology transfers, implementing cross-functional stage gates and phase reviews is essential to maintain project organization, ensure proactive risk management, and secure alignment and support from stakeholders throughout the project's progression.

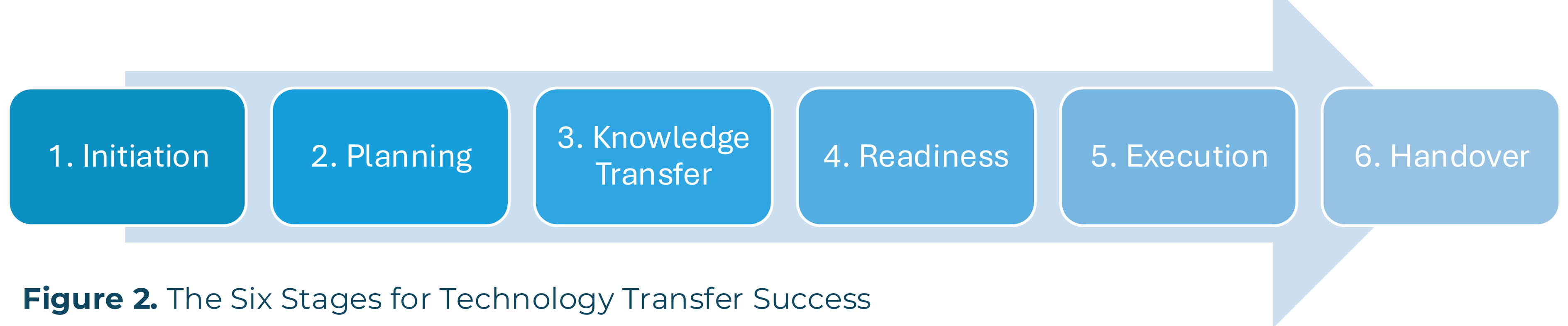

Figure 2. The Six Stages for Technology Transfer Success

Initiation: Define objectives, assess feasibility, and establish governance, risk, and communication plans.

Planning: Establish roadmap with milestones, timelines, and resources. Strong program management ensures coordination across cross-functional teams and effective risk management to maximize program efficiency.

Knowledge Transfer: Document handover, structured training and workshops, and gap identification/mitigation planning. A final punch list of site-specific modifications, quality system adaptations, and workflow harmonization is developed to ensure a seamless transition.

Readiness: Involves ensuring that the receiving site is fully prepared for execution of production runs. Punch list items from Knowledge Transfer are addressed, and equipment qualification, method validation, and regulatory compliance activities are finalized.

Execution: Focuses on product performance, ensuring phase appropriate validation. Pilot runs identify and resolve production challenges, enabling process refinement before formal validation.

Handover: Official transfer of the process ownership to the receiving unit. All documentation, including tech transfer reports, batch records, and validation summaries are in a final state.

CASE STUDY

A world leading supplier faced a serious challenge during critical vaccine development: they needed to rapidly scale up the production capacity of their animal-origin-free enzymes to meet the growing demand for raw materials. This initiative would require the construction and validation of two new US-based manufacturing sites and the international technology transfer of their manufacturing processes. Given the magnitude of scope and need for specialized expertise, this leading supplier partnered with Syner-G | Sequoia to successfully scope, staff, and execute the tech transfer.

Applying the Tech Transfer Playbook

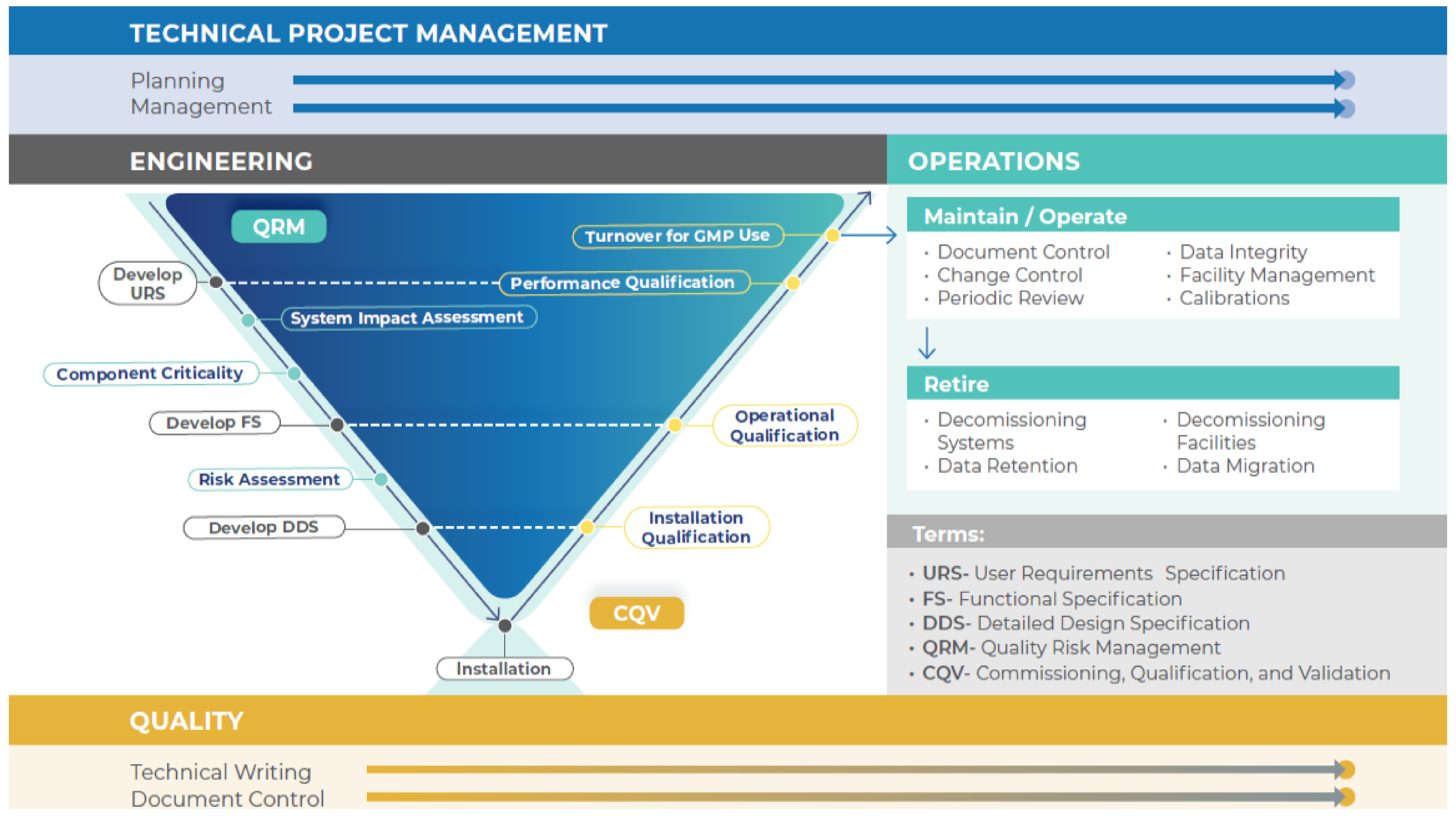

Figure 3. Engineering V-Model

We assembled a specialized team of quality, engineering, and project management experts to create a cross-functional core team and governance structure for defining project objectives, scope, and success criteria. During the planning phase, we identified CQAs and CPPs and developed a compliant tech transfer roadmap while designing new facilities aligned with these objectives. Our team collaborated closely with the client to develop tailored strategies utilizing the Engineering V-Model for manufacturing scale-up. In knowledge transfer, we refined facility designs, revised quality documents to meet North American standards, developed a phase-appropriate QMS, authored SOPs, and planned for CQV. Once the facility was constructed and operational infrastructure established, we implemented a PM program and successfully completed CQV. During execution, we performed engineering runs to establish process confidence, followed by PPQs to ensure reliable production. After the successful startup, we ensured the client could manage ongoing operations by addressing outstanding items, preparing final reports, conducting training, and resolving deviations and CAPAs.

CONCLUSION

While technology transfers are inherently complex and further complicated by changing regulatory environments and operational constraints, fostering consensus and collaboration within a strong cross-functional team can effectively minimize disruptions and ensure compliance. By forming the right partnerships and utilizing proven strategies, organizations can transform the challenges of technology transfer into opportunities for efficient execution and successful implementation, ultimately leading to better outcomes for both organizations and patients.