

Technology transfer: Best practices for optimizing success and mitigating risk in sterile drug manufacturing

Manufacturing drug substances and products demands a robust approach that ensures consistent quality and yield, regardless of production location. When relocating production for reasons such as enhancing operational redundancy, scaling up, transitioning to local manufacturing, or improving outsourcing support, efficient and effective technology transfer is essential for ensuring product integrity, optimizing outcomes, and mitigating risks. This article explores key strategies and considerations for effective technology transfer in sterile drug manufacturing.

A crucial aspect of this process is effective and early communication during project initiation, which can ensure a smooth transition, reducing timelines and costs. This process requires careful risk assessment, procurement of raw materials and equipment, and comprehensive training for operators, among other activities. Given these complexities, successful technology transfer necessitates collaboration with a manufacturing partner that has deep experience, a proven strategy for tech transfer, and a global network of capable sites.

Essential characteristics of effective project teams in technology transfer

Successful technology transfer hinges on an experienced team capable of crafting a tailored plan and integrating lessons learned from past projects. This proactive approach mitigates risks that could negatively influence project timelines and outcomes. Conversely, a lack of experience and insufficient planning can lead to numerous issues throughout the technology transfer process.

Key attributes of proficient technology transfer teams include:

- Customer-aligned approach to meet preferences and needs
- Clear roles and accountability ensuring seamless execution
- Synchronized scheduling to meet project deadlines and milestones
- Access to the right expertise, technology, and processes for success
- Application of lessons learned to enhance project outcomes
- Collaborative network leveraging broader company expertise
- Engaged vendors for addressing specialized needs and training
- Proactive risk management to mitigate potential challenges
- Consistent communication ensuring alignment with the customer
- Focused leadership providing clear direction and maintaining focus
- Cross-functional expertise driving innovation and problem-solving
- Strict adherence to regulatory standards and guidelines

Teams that embody these traits ensure the timely and within-budget completion of even the most complex technology transfer projects. This solid foundation enables well-coordinated transitions and adept operational management.

Critical importance of expertise and strategic planning

Successful technology transfer hinges on comprehensive planning that incorporates key business processes, regulatory standards, and precise timing requirements. This planning should clearly outline the interconnections between various essential activities and workstreams. It is essential for the planning process to be collaborative to ensure all parties are aligned on the technological components and operational procedures involved. Considering both immediate and long-term needs is crucial to prevent shortsighted decisions that could lead to significant issues later on.

A robust technology transfer plan features detailed task and timeline definitions, allowing for the simultaneous implementation of tasks as necessary. It includes the adoption of effective data-sharing tools and maintains flexibility to modify tasks in response to arising challenges. Utilization of flowcharts and process-specific checklists helps ensure timely task execution and accurate documentation. Ensuring that all team members have access to essential planning tools maintains alignment with the transfer strategy and continuously updates priorities as the project evolves. The implementation of a stage-gate process facilitates informed decision-making, the delivery of all project milestones, effective risk management, and comprehensive team commitment.

From the initiation and throughout the duration of a technology transfer project, it is critical for teams to thoughtfully develop each component of the process. This includes focusing on decisions that optimize the product's success and conducting comprehensive studies for validation, verification, feasibility testing, process parameters, quality control, and compliance with regulatory requirements. Such thorough preparation helps prevent setbacks, saving time and resources in the long run.

The 7M framework, a comprehensive approach used to identify and address factors that can affect production and quality, further enhances proactive planning in technology transfers and can help in root cause analysis and problem-solving.

This approach considers customer needs, market readiness, and market dynamics while integrating experiences from past projects. It addresses various aspects, such as adjusting lab and production staffing, capacity, and equipment needs (machines); managing lead times and ensuring material quality (materials); maintaining consistent visibility into financial considerations, including budgeting, cost control, investment in new technologies, and economic factors that can influence production efficiency (money); focusing on manufacturability and readiness for commercial production (manpower); gathering market intelligence, understanding demand, and navigating regulatory landscapes (market); implementing robust analytics and risk identification mechanisms (measurement); and preparing for product launch and proactive risk management (mitigation). This framework prioritizes foresight, ensuring all prerequisites for each task are met, potential risks are addressed early, and lessons from past projects are integrated from the outset to prevent recurrent problems.

The need for transparent communication

Given the complex nature of tech transfer projects, maintaining effective communication is crucial to ensure alignment between the transferring and receiving teams to meet established timelines and effectively identify and mitigate risks. Regular updates and dedicated communication protocols for addressing issues as they arise are vital to prevent delays. By setting clear expectations, processes, and preferences at the beginning of the project, many common problems caused by misunderstandings can be avoided.

It's important that communication with customers and external parties is customized to suit their preferences or the specific needs of the project. Empowering all team members to voice their concerns and participate actively in technical and strategic discussions is essential for a collaborative environment. Moreover, employing digital project management platforms that integrate visual tools and analytics can significantly enhance the way teams communicate and monitor project needs, allowing for more efficient and effective management of the project.

Preparing for the unexpected

Tech transfer projects are complex and seldom proceed without unexpected challenges. A proactive approach is vital, involving comprehensive planning and foresight to anticipate potential issues such as raw material shortages, staff turnover, and equipment malfunctions. By preparing contingencies early, teams can prevent hasty decisions that could compromise risk management, disrupt process validations, and unnecessarily extend project timelines.

Sophisticated contingency plans and practical process improvement (PPI) enable teams to swiftly manage unforeseen problems, thus protecting the project's objectives, budget, and timeline. This strategic preparedness, bolstered by a global network, allows for creative problem-solving and the deployment of alternative solutions that maintain the integrity and momentum of projects despite potential setbacks.

Accelerating tech transfer with deep expertise and a global network

Tech transfer is a complex and costly endeavor that can span several months and incur significant expenses, both in terms of actual costs and opportunity costs. It's crucial to manage these transfers efficiently from the outset. Thermo Fisher Scientific leverages its vast experience in moving molecules from development to commercial production, including the transfer of

established processes—whether internally or from another CDMO—for both simple and complex products and processes, such as those sensitive to temperature or air. This extensive expertise across a global network enables us to significantly reduce the time, effort, and costs involved in transitions.

For example, our efforts to expedite the technology transfer of COVID-19 vaccines and therapeutics prompted a comprehensive overhaul of our processes, enhancing our efficiency substantially. Examples include new vendor/procurement management efforts, which helped with predictable lead times of equipment and components; internal and external tech transfer document generation model and harmonization; and enhanced utilization of risk-based regulatory principles. This newfound speed and agility not only improved our pandemic preparedness but also enhance our capacity to accelerate all tech transfer projects and swiftly adapt to market shifts and changes.

This agility is further amplified by our active participation across multiple pharmaceutical industry segments and our robust end-to-end capabilities. We support customer projects from early-phase development through commercialization and lifecycle management. As projects progress, internal tech transfers are conducted within our global network following a detailed, harmonized multi-site governance model and tech transfer framework. This framework expedites the transfer of information, analytical methods, and products/processes with increased efficiency, leveraging dedicated global tech transfer teams and enhanced internal project team support. Lessons learned throughout the project lifecycle within sending and receiving sites ensure efficient transfers and an improved customer experience. Additionally, our methodology is designed to meet regional regulatory requirements across North America, the EU, the UK, and Southeast Asia, further shortening overall cycle time and ensuring compliance across key markets.

Our commitment to optimizing the speed and agility of technology transfers has set new industry benchmarks. In a notable instance, we completed eight technology transfers as part of our COVID-19 pandemic response, utilizing an innovative mRNA platform for a single customer at our Greenville, North Carolina and Monza, Italy facilities, with each transfer taking approximately 8–12 weeks from initiation to the completion.

Focus on sterile manufacturing

The demand for sterile manufacturing capacity continues to rise as an increasing number of biologic drugs receive marketing authorizations from regulatory authorities worldwide. This includes a growing rate of approvals for biosimilars, antibody-based drugs,

and cell and gene therapies, particularly in the United States and Europe. Concurrently, there is mounting pressure from governments to boost local production of biopharmaceuticals.

With five sterile manufacturing sites around the world, including two in Italy, one in the United Kingdom, one in the United States, and one in Singapore, Thermo Fisher Scientific is well-positioned to support tech transfer for parenteral products. Many of these sites have similar production equipment, including filling lines. This consideration, combined with our comprehensive global framework for internal technology transfers and a highly experienced tech transfer team, facilitates smoother, quicker, and more cost-efficient transitions from one site to another.



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