8 Tech Transfer Pitfalls and How to Avoid Them

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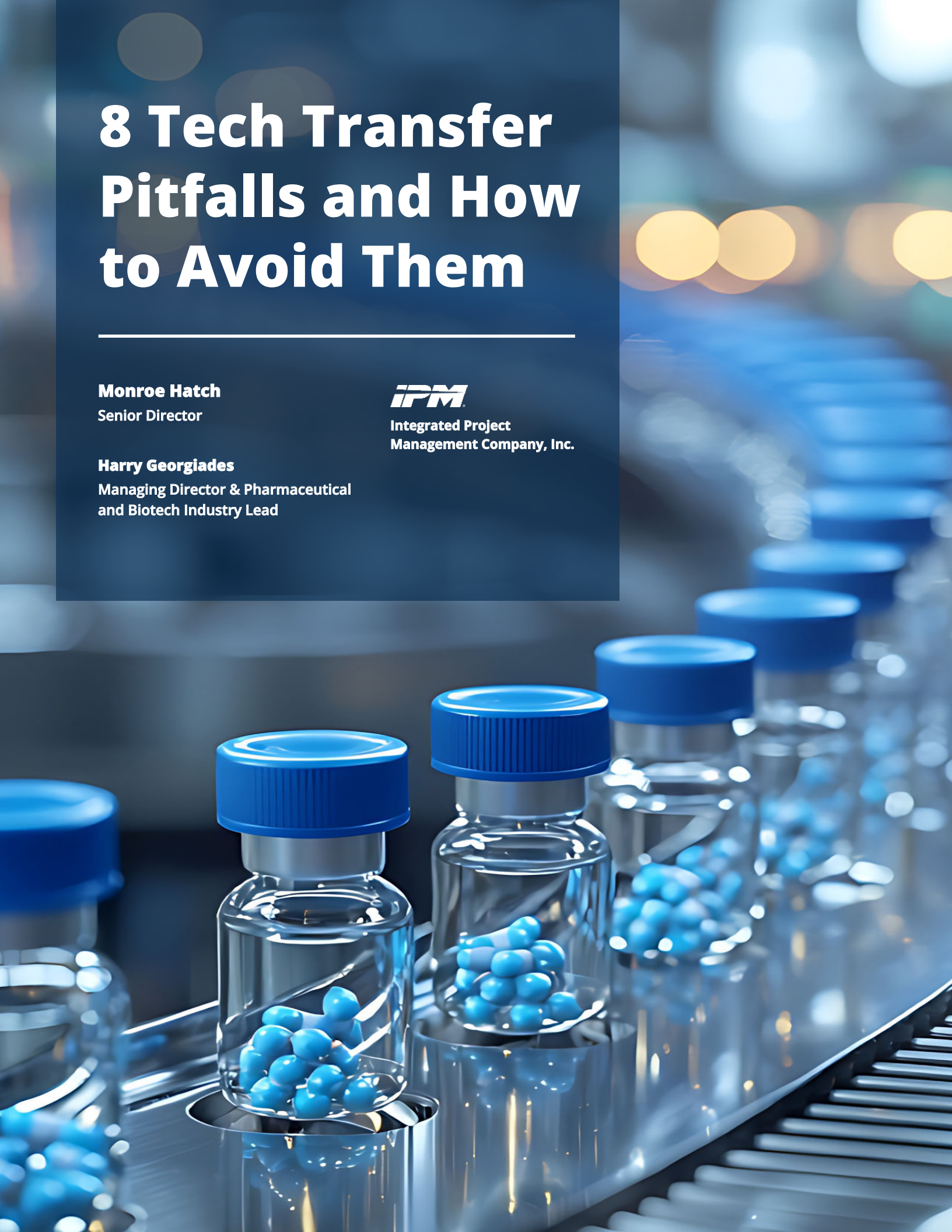

Tech transfer is one of the highest risk operations in pharmaceutical and biotech manufacturing. Moving from a lab or pilot scale to larger-scale clinical or full-scale commercial production requires precise knowledge and process transfer. Poorly executed tech transfer can lead to additional costs, deviations, product failures, and delays in getting products to market.

Adding complexity, more pharma companies are outsourcing manufacturing to contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs) due to increased demand and limited resources.

In its work with both pharma companies and CMOs/CDMOs on tech transfer projects, Integrated Project Management Company, Inc. (IPM) has encountered a number of inefficiencies. Here, IPM's tech transfer subject matter experts outline common pitfalls and preventive measures.

Operations, R&D, and manufacturing leaders will recognize many of these challenges. But even experienced teams can make missteps, especially as industry dynamics shift.

1 Not Clearly Scoping the Project

It's obvious that for a tech transfer to be successful, you need to thoroughly scope the work, capital investment, equipment, and other resource needs. However, far too often leaders make high-level assumptions or skip due diligence, which can introduce problems later. When project teams at the pharma company and the manufacturer dig into the details, they run up against budgets, deadlines, and resource shortages.

To minimize risk, create a scoping or work order template that includes input from technical operations, quality, manufacturing, supply chain, and other functions at the outset. This document should include all components necessary to complete the budget and schedule in the initial work order draft.

IPM led a tech transfer for a pharma company whose R&D leadership assumed that automatic visual inspection (AVI) equipment on the line didn't have to be in place until after process validation batches. But the quality team pointed out that it's a requirement prior to process validation, so waiting for the equipment delayed the project. If quality was consulted earlier, the oversight would have been prevented, and the timeline would have been more accurate.

You can't anticipate every issue. Plus, requirements or lead times can change, and assumptions or predictions can be wrong. You can and should document assumptions and decisions and reassess them regularly. Communicate changes to relevant functions. And capture lessons learned to identify trends over time and improve planning.

2 Making Everything a Priority

When everything is a priority, nothing is a priority. Trying to do too much or working without a sequence of steps causes mistakes in the tech transfer process, overcommitted teams, burnout, reactive prioritization, and missed deadlines.

When IPM arrived at a recent engagement at a CDMO, consultants found an "everything is a priority" mentality. Project leaders competed against each other for time on the line using past relationships and persuasive tactics. IPM encouraged a portfolio perspective to make proactive decisions and sequence production more effectively.

Leaders often focus on individual projects, but portfolio-level visibility is key to sustainable success. It offers an effective view of projects to drive objective prioritization. And it enables risk management and resource management of the personnel on both sides of the partnership who are devoted to tech transfers. A portfolio view also provides clarity for individuals who serve on many tech transfer teams and those who support the work alongside their day jobs. It also helps identify times when you need outsourced resources or specialized expertise.

3 Inhibiting Cross-Functional Collaboration

IPM has encountered a lack of transparency between the pharma company and CMO, unclear roles and responsibilities, and limited access to documentation and approval systems. During one engagement, IPM's project manager at the CDMO had to download information for the client to review, then upload it once it was approved. Often, changes were made in the system while the client was reviewing a document, so the client would have to approve amendments.

Anything that hinders communication and collaboration can cause confusion, delays, and poor decision-making. Define process steps, handoffs, and roles, and provide access to a single source of information to provide clarity on the plan and status.

Cross-functional cooperation and transparency are also important at each partner company. Ideally, this would go without saying. However, IPM recently worked with a CDMO whose business development team didn't confer with technicians to set expectations with clients. (See sidebar, "Reliable Technology Transfer Processes Enable CDMO to Scale Up," on Page 5.) Manufacturing was often behind schedule before they even started and had to look for ways to meet an unrealistic schedule. This led to mistrust between BD and manufacturing.

4 Neglecting Relationship-Building

Strong business partnerships are not simply transactional. The parties discuss and clarify differences as they work toward shared goals. And they build and maintain trust through open communication, transparency, and doing what they say they'll do.

Each partner brings something unique to the table: The biopharma company is the expert on the product, and the CMO is the expert on the manufacturing line. But those lines blur. IPM consultants have found it necessary to agree at the kickoff on roles and responsibilities and CMO processes. It has also been beneficial to bring client representatives to the production facility to tour the line, support knowledge transfer, resolve challenges, or just pitch in when resources are constrained.

In one instance, the CMO struggled with a quality issue that caused delays. They never covered up the problem, communicating often with their client about efforts and timing. While the CMO initially resisted help from the client, due to other customers' work in progress, when they asked the client's quality experts to come on-site, they were able to find a solution.

Transparency is important, but good relationships also recognize boundaries. Manufacturers must keep other clients' intellectual property confidential, and pharma companies protect their own proprietary information.

5 Not Recognizing Differences in Ways of Working

A pharma company wants to make sure it's bringing something life-enhancing to patients (and meet FDA regulations), and they trust that the third-party vendor will help them do that. But transferring a process to a site with different equipment or scale can introduce risk.

The pharma can't dictate the CMO's procedures. The CMO works with multiple clients, and their platform must perform for the majority. Even large customers have to work within their parameters.

That said, there is give and take. If the drug company has a non-negotiable requirement that is clearly defined, the CMO can usually accommodate it. When IPM recently led a tech transfer for a pharma company, there was a material used in the manufacturing process that the pharma wouldn't accept. The pharma had to pay for the alternate material and the time to switch it out in the manufacturing process. And it had to accept that the extra time would extend the project timeline. This is another reason to do extensive due diligence upfront and build the timeline to address material and other concerns.

In another instance, the pharma wanted stricter controls against particulates. The manufacturer cleaned the equipment when there was particulate, but the pharma wanted them to replace the equipment. It was non-negotiable for the pharma, so it accepted the additional cost.

Both partners must assess compatibility and be clear about processes, priorities, and non-negotiables early, so they can develop accurate scopes of work and make informed decisions. Even the partner that is larger or more experienced can't always dictate terms. Ongoing relationship-management efforts, like trust, transparency, open communication and focus on shared objectives, are key.

6 Inconsistent, Undefined Tech Transfer Processes

Whether pharma company or third-party manufacturer, poorly defined processes will lead to inefficiencies and project delays. Without consistent processes, you end up missing key components in the initiation of the project. You won't have a baseline to gauge or improve performance or present to your partner when negotiating changes.

IPM led tech transfer projects for a CDMO that didn't have well-defined processes. To get information or make progress, you had to know the right person. That person was always overworked and had to use heroics to accomplish anything. When the company grew, that wasn't sustainable. IPM worked alongside their team to improve and document processes from onboarding a client to process performance qualification.

Tribal knowledge and informal handoffs are persistent risks, especially with turnover or compressed timelines. Map processes, identify owners and approvers, and develop escalation governance. Invest in robust knowledge management and training. And enforce strict adherence to documented procedures.

It's worth noting that consistent processes and documentation enable standardized data, which are the foundation of digital control systems and AI/ML tools. In turn, these can support efficiency gains, scenario planning, and decision-making, and simplify regulatory submissions.

Reliable Technology Transfer Processes Enable CDMO to Scale Up

A contract development and manufacturing organization (CDMO) had a steep increase in demand, but it didn't have the processes or resources to scale up quickly. It turned to Integrated Project Management (IPM) to define a process to execute tech transfers more reliably.

Relying on Heroic Efforts

IPM consultants interviewed members across the organization, which relied on heroic efforts rather than standard operating procedures. Business development would make promises to clients about clinical or engineering milestones without consulting operations. Key contributors didn't know when a new client had signed on. Because the company didn't have a set workflow, they were always in react mode. Kickoff meetings with clients were ineffective. They often had to purchase materials before the contracts and specifications were finalized to meet required schedules, leading to waste.

While the CDMO was small, project managers could find the experts who could put out the next fire. But when the company grew, the lack of structure, processes, and defined roles was no longer sustainable.

Building Discipline

Working with leaders at the CDMO, IPM's consultant mapped the process steps and durations, handoffs, and roles and responsibilities. Team members could see what they had to do or provide when, and they were held accountable.

The team standardized kickoff meetings, preparing attendees in advance to align internally, have a positive impression on clients, and make meeting time more productive. IPM trainers worked with project managers to improve processes from documenting decisions to proactive risk management.

New project intake forms, production plans, validation, quality control analytics, MSAT, etc., were incorporated into Smartsheet. The tool enables a portfolio view of all the work, so operations leaders can prioritize clients and products.

Ready to Grow

The CDMO now has a toolbox to define and structure projects, assign responsible resources, coordinate interdependencies between functions, clearly communicate expectations and progress, and meet client demands as it grows.

7 Skipping Steps to Meet Compressed Timelines

The pressure to move quickly can lead even seasoned teams to skip steps or rely on informal agreements, like ordering materials based on sales proposals or letters or understanding. But a "just get it done" mentality can cause misunderstandings, high costs, and wasted resources. Not to mention product deviations.

On a recent engagement, IPM witnessed and called out a CDMO sidestepping GMP and its own best practices to solve an issue on the fly. Downstream impacts and systemic issues weren't considered.

Prevention is the best solution: Work in advance with your partner and relevant functions to understand the scope and identify potential risks, so you can avoid having to rush.

8 Production and Supply Chain Challenges

No matter how well you plan and prepare, unexpected challenges will occur. On tech transfer projects with pharma, biotech, and contract manufacturing organizations, IPM has encountered issues from equipment malfunctions to global trade restrictions, tariffs, and customs.

Building flexibility into supply chain planning and trying to identify and manage risk can go a long way. But often, you just have to handle things as they happen. The relationship you've built, good or bad, will impact the outcome. Communicate early and often about changes to the timeline, budget, and other expectations. Bring relevant information and expertise together. Consider downstream impacts and keep those stakeholders in the loop. And collect lessons learned and apply them to future projects.

Dig into the Details

While many pitfalls are well-known, the real challenge lies in the details, especially as industry pressures and relationships evolve. Revisit your own tech transfer processes, assumptions, and cross-functional practices, and seek out lessons learned from others' experience.

The biggest factors overall are making sure you have strong cross-functional and cross-company engagement and participation, and an experienced project manager leading the team and tying all the pieces together.

Integrated Project Management Company, Inc.

is a business consulting firm focused on planning and implementing strategically critical initiatives across multiple industries, including life sciences, healthcare, consumer products, and industrial products. Since its inception in 1988, IPM has served more than 600 clients and completed more than 5,000 projects. Headquartered in Chicago, IPM has regional offices in Boston, St. Louis, Los Angeles, San Francisco, Minneapolis, and Parsippany. IPM was a recipient of the 2018 Malcolm Baldrige National Quality Award. To learn more about IPM and its services, visit *www.ipmcinc.com* or call 630-789-8600.