



CONSISTENT TECH TRANSFER PROCESSES ENABLE CDMO GROWTH

It's a good problem to have. A contract development and manufacturing organization (CDMO) found itself with a steep increase in demand thanks to a large pharmaceutical company acquiring the CDMO's largest competition. And it expects business to continue to rise as tariffs, most-favored-nation models, and geopolitical uncertainty prompt biopharma firms to reshore manufacturing.

The problem? The manufacturer didn't have the processes or resources to scale up, let alone do it quickly. Conducting technology transfer and achieving commercial production of a drug product is a complex endeavor. It requires coordinated contributions from a diverse group of functional stakeholders to achieve objectives in a reliable and predictable manner.

They turned to Integrated Project Management Company, Inc. (IPM) to define and implement process improvements and project management methodology. The CDMO wanted to execute tech transfers more quickly and reliably, enabling more rapid drug availability, improved customer satisfaction, and better profitability. They then had IPM lead the team through a client's onboarding and tech transfer for training and validation.

COUNTING ON HEROICS



IPM interviewed members from every functional team, including project management, business development, supply chain, manufacturing science and technology (MSAT), quality, operations, and finance. They sought to understand actual processes and pain points.

Consultants found that the organization was succeeding through heroic efforts rather than standard operating procedures. Business development would make promises to a client about clinical or engineering milestones without consulting operations. Without formal communication, 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.

Project managers, who were inexperienced and/or pharma manufacturing experts, used relationships and favors to get

information and make progress. While the CDMO was small, they could find the go-to expert in each function who could put out the next fire.

But when the company grew, these heroics were no longer sustainable. The lack of structure, processes, and defined roles cost them. Employee turnover was up, and kickoff meetings with clients were ineffective. More and more often, they had to purchase materials before the contracts were final, leading to waste—and wasted money. Making assumptions and rushing won't do for a company that built its reputation on quality. They used letters of intent as a stopgap until the work order was complete, but they became the norm rather than the exception.



INSTILLING END-TO-END DISCIPLINE



Working with leaders at the CDMO, IPM's consultant mapped the process steps and durations, handoffs, and roles and responsibilities. They held a workshop to validate what they learned and show the downstream impacts of others' pain points. It also helped generate ideas for improvement and gain buy-in from all the functions on recommendations.

IPM defined roles, responsibilities, and requirements for each step, so team members could see what they had to do or provide when. It also enabled them to hold individuals accountable and better track progress.

The team standardized kickoff meetings, preparing attendees in advance to align internally, have a positive impression on clients, and make meeting time more productive. They improved the room with better acoustics and conferencing software. All participants now wear nametags, and clients receive a short tour of the facility.

And client-facing staff received training in customer service and relationship building.

IPM trainers worked with project managers to improve their processes, from better meeting management and documenting decisions to proactive risk management and scenario planning. For the broader organization, an org chart and job descriptions clarify roles and help onboard new employees.

The company had been using Smartsheet, but not to its full potential. IPM developed intake forms for new projects, production plans, validation, quality control analytics, MSAT, etc., and incorporated them into Smartsheet. The tool was also refined to provide a portfolio view of all the work, so operations leaders can prioritize clients and products. An executive dashboard tracks and relays progress and helps to proactively identify and mitigate risks.

GETTING TECH TRANSFER PROCESSES UP TO SPEED



With a holistic, objective view of the business, IPM standardized processes and tools to ensure the CDMO and its clients are aligned on needs and expectations. To demonstrate the improvements, IPM's consultant led a client tech transfer from proposal to process performance qualification (PPQ).

Given the many challenges of tech transfer, the odds for successful outcomes are greatly improved with a consistent approach. 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.

