

# Manufacturing Transfers for Medtech Innovators

## Part 2: Coordinating Transfer Planning with a Medtech Contract Manufacturing Organization

When creating plans for a manufacturing transfer, medtech original equipment manufacturers (OEMs) and contract manufacturing organizations (CMOs) should align their goals and processes so that neither side will encounter unpleasant surprises during the project. A careful planning process will help to structure the steps to be undertaken during the transfer project, while also ensuring that potential challenges are identified early on, when it's easiest to address them.



Eric King, chief technology officer, Flexan LLC.

To find out more about how a careful planning process can benefit the manufacturer and CMO engaged in a manufacturing transfer—and what they should expect to achieve through the planning process—we spoke with Eric King, chief technology officer at Flexan LLC (Lincolnshire, IL), a CMO specializing in product development and cleanroom manufacturing of silicone and thermoplastic components for medical technologies.

"In my experience the key to a successful transfer is transparency, so that neither side is surprised," says King. "And the foundation of that transparency is the planning process. Not just timelines, but actual work that's going to be done, what each party expects from the other, and what the end result will be."

A faulty planning process can lead to a variety of common pitfalls, with potentially disastrous effects on the project. One of the biggest pitfalls is delay, which can be generated by many things. An important cause in this regard is making and acting upon invalid assumptions.

"Although some engineering problems are not solvable unless assumptions can be used as a starting point, in the case of manufacturing transfer assumptions that aren't valid or aren't communicated properly between the two parties can lead to some pretty big gaps," says King. "Sometimes those gaps aren't found until later in the process, and they can devastate a project."

Using a careful planning process to align the partners' organizational goals and processes is an essential undertaking if the manufacturing transfer project is to be successful.

"This is the most important step," says King. "The planning phase is often where all of those different goals and processes are identified, established, and agreed upon, and it really is the key to a successful transfer. And this is true not only for the project timeline, but also for the partners' expectations for all of the project's deliverables."

### Defining the Project Scope

The specifications of the manufacturer's product are typically already defined, but there's a lot more to a manufacturing transfer project than that. Quality requirements, annual product volume expectations, and many other factors need to be established as part of the contract.

"Before a contract can be written, established, and agreed to, there really has to be a very specific and detailed statement of work," says King. "That's the document that explains what the expectations are for the project."

The statement of work can be generated by either party, but it has to be agreed to by both parties. Once the statement of work is established, a contract can be created that references the statement of work in contractual terms.

To refine the scope of the project and make the statement of work a reality, the partners need to answer a number of detailed questions about the project.

"That's where the specifications come into play. The statement of work typically incorporates a definition of the product being manufactured, as well as details about all of the product's manufacturing processes," says King. "The statement specifies all of the materials in use, outlines all of the supplies

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### Successful planning plays an important role in helping to avoid project failures.

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that are required to produce the device, and goes through all of the various manufacturing processes and subprocesses."

The statement of work is the document that is used to define annual production volumes; to provide analyses of the capabilities and capacity requirements for the project; and to formalize the project's quality requirements, including what types of testing will be required, and what types of training will be required. Those are the types of details that enable both the sending and receiving parties to get a better understanding of their respective capabilities, and to identify any gaps that may need to be addressed before moving forward.

It's also important for the statement of work to establish upfront any major elements that are not intended to be within the scope of the project.

"A lot of times, creating those boundaries from the very beginning can help to prevent 'scope creep,' which is the gradual inclusion of forgotten and often minor items that may cumulatively alter the scope of the project," says King.

Taken together, the inclusion of many such small changes can

## Seating Chart

*Creating the roster of a planning team requires forethought—and flexibility*

When developing a project proposal to transfer a medtech manufacturing operation to a contract manufacturing organization (CMO), creating a planning team is typically one of the first steps that the manufacturer and CMO perform together.

The best starting point for creating a planning team is the discussions that lead to creating a statement of work, establishing the scope of the project and detailing exactly what resources will be required. Those discussions will inevitably lead the core group to ask questions about whether the planning team will need to include any specialized talent in support of specific processes or capabilities.

If the project will involve the transfer of equipment for the extrusion or molding of components, for instance, the planning team will probably need a subject matter expert who can help with issues in that area. The same would be true for any kinds of specialized product testing that might be needed, or for validating the product's packaging and sterilization. Reviewing the scope of the project can often reveal areas for which specialized team members may be needed.

"In the very beginning the core group may include only high-level individuals who are capable of evaluating the proposal from a broad multidisciplinary perspective," says Eric King, chief technology officer at Flexan LLC (Lincolnshire, IL), a contract manufacturing organization with a specialty in medical technologies. "The group will also likely include marketing people who can review the financial aspects of the proposal to ensure that it is going to have an upside for both partners."

## Additional Staffing

Only when the statement of work has been defined—so that the proposal can actually be considered a project—will more team members be added to cover key areas such as product development, engineering, regulatory affairs, and quality systems. If coverage for any specialized needs is found to be missing, team members and working groups can be added as necessary.

For the planning team, it's often wise to bring in staff such as production supervisors for similar project lines. Many staff



members can make valuable contributions to a new project, and it's a lot easier to elicit that information if they are involved in the planning process—even if they're not permanently on the team. There's great value in being able to reach out to someone who has relevant experience and get their take on a new project.

That's especially true when it comes to planning for the safety of the project, which is a very big concern.

"We always want to ensure that our work environments are safe, and that everyone goes home in the same shape as when they came to work," says King. "A significant amount of planning must be devoted to making sure that every aspect of the manufacturing transfer can be accomplished safely, and that the actual equipment and processes being moved are themselves safe. Drawing on the experience of existing staff members can be a good way of ensuring that a project can proceed safely."

## Implementation

Projects often include elements that are uncertain or contingent, for which planning may change over time. So it's a good idea to maintain a correspondingly fluid attitude toward the members of the planning team and their roles.

Different staff members may be brought into a project at various phases, as appropriate to their skills and roles. At certain points in the transfer process, for example, it may be useful to have the manufacturer's production staff work side-by-side with their counterparts from the CMO.

"In this way, employees of the sending facility can help to train employees of the receiving facility—sometimes even after the new production lines have been set up in the receiving facility," says King. "It just comes down to bringing people in at the right times, so that the right information is transferred when it needs to happen."

become significant, effectively resulting in large changes in the scope of the project. In some cases, late or on-the-fly changes to a project's scope can run completely counter to the purpose of the transfer, creating the opportunity for disagreements between the parties.

"A good statement of work does not need to be lengthy or wordy—the content can often be presented as a series of bullet points—but it does need to address all of the details that are essential for making the project successful," says King.

Because manufacturing transfer projects are complex, it is often useful to divide planning activities into manageable segments, each assigned to a specialized group (see sidebar).

"In my experience, dividing a project into manageable segments is a critical strategy for making the project successful," says King. "When planning for a manufacturing transfer, we typically employ a 'phase-gate' approach that takes on one activity at a time, and requires each activity to be completed before moving on to the next phase."

## Change Orders

*Making a formal plan for improvements can reduce downstream complications*

When a CMO is brought in to work on a manufacturing transfer project, company staff may become aware of weaknesses in the manufacturing process that could be improved. It can be tempting to try to address such concerns as part of the manufacturing transfer, perhaps greatly modernizing and improving a process that isn't what it should be. That can be a good outcome—but there are a couple things to watch out for.

One concern is that trying to make improvements to a process that is in the midst of being transferred can lead to scope creep and greatly slow down the entire project. Instead of focusing on the task of completing

### Step 1: Make a plan.

### Step 2: Stick to the plan.

the manufacturing transfer, company teams find themselves working on a myriad of interrelated issues that may have no defined endpoint. Even if the manufacturer agrees that such improvements are desirable, taking them on without a formal plan can make the original task of manufacturing transfer much more complex.

Another concern is that making improvements to an existing process may run afoul of critical factors whose importance might not be immediately apparent. In order to improve efficiency, for instance, someone might take it upon themselves to eliminate a waiting period that appears to be slowing down the manufacturing process. But if it turns out that the waiting period is essential for allowing an adhesive to cure between manufacturing steps, making such a change could cause significant production failures. So when the partners outline the scope of their project, defining what will be allowed to be changed or improved, it's important that they stick to that plan.

If the partners are currently engaged in the process validation phase of a transfer project, King explains, all of the pertinent activities related to that phase must be completed before taking on the next phase. Completing a phase typically involves a formal team review of all the bullet points outlined for that phase in the statement of work. Only when all of the team members have signed off can the phase be completed so that the gate to the next phase can be opened.

Identifying the milestones and deliverables for each phase of the transfer project is a major function of the statement of work (Figure 1). A statement can be structured in many ways, according

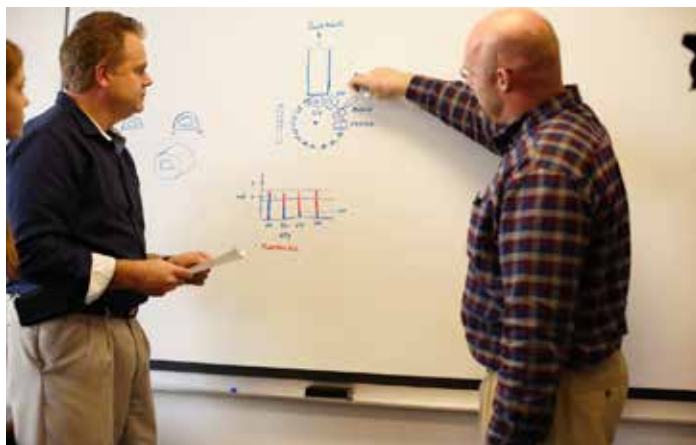


Figure 1. Eric King, Flexan chief technology officer (left), and Kevin Freestone, Flexan new product development engineer, discuss a design for manufacturability concept for a medical device customer.

to the shape of the project, but some structures may be more supportive or useful than others.

"Writing the statement of work so that it aligns with the phase-gates of the project is often a useful approach that can help to make for a successful outcome," says King.

"Accomplishing this requires the partners to agree upfront on all the work activities that must be executed for each phase of the project, before moving on to the next phase."

Creating and agreeing upon such a detailed list of activities can prevent a lot of ambiguities that lead to premature or false starts, repetitive activities, or even erroneous directions for new tasks. Such a list makes sure that both parties are in alignment before they move forward, and also provides a method for documenting the progress of the project (see sidebar).

"I think it's important to note that no two projects are identical, so there is a need for some flexibility," says King. "Even though manufacturing transfer projects are never identical, they typically consist of a similar set of phases that need to be addressed—and that's where the planning process comes into play."

## Team Building

Identifying the staffing needed to accomplish project goals also needs to be one of the partners' very first activities—even before starting negotiations or defining what will be required in terms of technical resources.

If the needs for staffing resources are not identified upfront, it can easily happen that a project will fall behind its intended schedule, simply because of the time required to identify and assign appropriate staff. Delays can be even more acute if it's necessary for the assigned staff to undergo any kind of specialized training.

To launch a project efficiently, the CMO needs to identify upfront what staffing will be required, and have all the needed resources ready to execute on day one. The CMO needs to know, for example, how many and what types of tests need to be performed on a product before it can be released. Understanding what processes will need to be performed is

Program manager  
 New product engineer  
 Process engineer  
 Quality systems (including product testing and analysis staff)  
 Marketing staff

Table 1. Typical members of an interdisciplinary core team for planning a manufacturing transfer from a medtech OEM to a CMO. Additional members may be recruited as necessary.

essential for determining what staff resources will be required. And assigning staff resources as early as possible is a very important factor in meeting the demands of the project's timeline.

"At Flexan, project transfers are typically guided by a program manager who is responsible for tracking and reporting all of the project's details," King explains. "In the case of transfers involving medical device manufacturing, the working team typically includes one or more project engineers, depending on the scope of the project.

"Medtech project teams also include quality assurance staff and technical staff with expertise in product testing and analysis, as well as staff who can provide input from a marketing perspective," says King.

**By performing a risk analysis and identifying all of things that could go wrong with a project, the partners can be better prepared to act when they do go wrong.**

Those staff members form essentially the core of an interdisciplinary 'tiger team' that brings together dedicated resources just for that particular medtech project, to ensure that all aspects of the project are executed properly and on time (table 1).

OEM and CMO partners typically find it useful to define important aspects of their working arrangements in advance. To begin, the partners should set out their plan for communications, defining how project data and related information will be transferred back and forth. Next, the partners should establish a meeting cadence for the project, so that everyone agrees that the team will meet at regular intervals of once a week, twice a week, or whatever the project requires.

"Both of those working patterns should be tied back to the project scope, as defined in the statement of work, so that it's clear who will be responsible for executing and tracking each specified task, and who will be responsible for reporting about the progress of those tasks," says King.

Taken together, these aspects of the project's planning can help to clarify how the partners' teams will work together, so that the sending facility can gather and transfer information seamlessly to the receiving facility.

Decisions about when meetings are necessary often fall to the judgment of the program manager, who should have a



Figure 2. Project management tools enable the partners to review project data in real time, and to identify weaknesses or interdependencies that might create problems. Photo: Andrey Popov courtesy Dreamstime (ID267635961).

detailed understanding of what's required at any given point in the project timeline. For example, when discussions are needed to define what types of tooling the project may require, the program manager may call for more frequent or longer meetings so that those issues can be dealt with. But during the time when that tooling is being manufactured, the program manager may judge that the team members involved in that task do not need to meet with the full team at all. Instead, those team members are brought back into full meetings when the newly manufactured tooling is undergoing validation, so that they are engaged when they are needed for that part of the project.

In effect, the program manager's judgment about team meetings means that the composition of the team may vary as the project goes on.

One of the pitfalls that partners often encounter is the mistake of requiring meeting attendance from multiple people who are important to the project, but not to the specific phase or to the decisions to be discussed at that particular meeting, King explains. Team meetings are all too often cluttered and flooded with a large number of people whose attendance is not really required at that time.

"We're all busy—and meetings cost money—so it's important that the program manager keeps that in mind and invites only the team members who are necessary to participate in meetings related to a particular phase of the project," says King.

**Step-by-Step Thinking**

Project planning teams often follow a predefined process for identifying the working steps that will be needed to accomplish the manufacturing transfer. "Flexan follows an established planning process that is based on the company's extensive experience with medtech manufacturing projects and also takes into account the pertinent regulatory requirements," says King. "This process is repeatable, and the lessons learned from previous applications can be distributed and used for all kinds of new projects."

With such a process already in place, it becomes very easy for the partners to make necessary adjustments and apply them to the project in hand. Having such a process established up front

makes the entire planning process flow much more smoothly.

It is often useful to establish segment-by-segment goals and timing for the project, so that the entire project can be tackled in a step-by-step fashion. If the phase in question involves the validation of a process, for instance, there will be several steps to be performed before the validation can be completed. First, the designated equipment must be purchased and installed, and the installation itself must be validated through installation qualification (IQ). Next, the team will need to perform operational qualification (OQ), which is the challenging and optimizing of the process's parameters. And only then can the team move on to formal process validation activities, during which the process is actually used to produce testable components.

"Each of these steps represents a series of interactions among team members for which the sequencing and timing can be critical," says King. "Unquestionably, with so many interactions required during the course of a project, it really does help the overall flow to establish the project's step-by-step goals and timing from the outset."

When various departments and specialized teams have been working apart from one another, it takes a special planning effort to bring their work together. Those types of issues fall directly under the control of the program manager, often with the use of project management tools such as software that can generate Gantt charts and other tracking resources (Figure 2). Using such tools enables the partners to review project data in real time, and to identify weaknesses or interdependencies that might create problems for the project.

This is where having an experienced program manager becomes vitally important to the success of the project. The program manager is uniquely situated to be tracking all of the interactions and data that characterize the progress of the project. It is the program manager's role to evaluate all of this

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information and remind team members when particular deliverables are required, so that delays in executing a single step don't prevent other steps from starting on time.

## Conclusion

Advance planning is essentially a method for identifying all of the risks and issues that a project could encounter. By performing a risk analysis and identifying all of things that could go wrong with a project, the partners can be better prepared to act when they do go wrong. Successful planning plays an important role in helping to avoid project failures.

"Planning is the tool for anticipating potential issues, and for creating a path that is ready for use if things go wrong," says King.

A truly experienced CMO should be able to demonstrate not only that it understands in the abstract what is needed to plan for a manufacturing transfer, but that it has a planning process and detailed procedures already in place for this purpose.

"Having such a structured framework enables the CMO to stockpile the lessons it has learned along the way, so that they can be applied to avoid the pitfalls that are common to projects as they go through this process," says King.

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Unquestionably, says King, the planning process often becomes the genesis of close working relationships between the manufacturer and the CMO. "Some of our most successful long-term customer relationships got their start in planning activities that worked so well and so seamlessly that our two teams seemed to merge into one," says King.

"When the customer is holding project meetings in the CMO's building, and vice versa, that's a pretty sure signal that the planning process has created a single merged team with the common goal of executing a successful project." 🎯

## Next Up

*Medtech manufacturers may have a variety of goals when transferring operations to a contract manufacturing partner. Part 3 of this series examines how such goals create unique demands that must be addressed as the partners begin to actualize their project. Stay tuned!*