



Management
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Life Sciences

A fresh look at technology transfer: Are you getting the most from your data?



Transforming your approach to technology transfer

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The traditional approach to technology transfer has been perceived as a “throw-it-over-the-wall” activity. The research and development group designs a new product and then simply hands that information to the manufacturing unit for production. Not only is this approach outdated, it’s flawed. To be efficient and agile, and to reduce time to market, organizations must re-evaluate their technology transfer process.

Introduction: Addressing the knowledge gap

Manufacturing companies today, particularly in the pharmaceutical industry, are realizing that the enterprise is information rich but knowledge poor.

The problem, of course, is not a lack of tools. In fact, manufacturers have no shortage of technologies to capture information. Instead, the problem is finding a way to link these disparate systems, share the information effectively across the organization and make it easier to find in the future.

For many organizations, workforce trends fuel the urgency to retain institutional knowledge. Employee turnover through attrition and retirement often means immeasurable—and often irreplaceable—experience and know-how walks out the door every day. Add the influx of new talent, and the organizational knowledge gap widens even further.

In the pharmaceutical industry, effective knowledge management and technology transfer are crucial to a company’s performance on several levels, from product development to regulatory compliance to manufacturing and quality. Without sound, flexible technology transfer practices in place, chances are your business lacks the agility to respond to the shifting demands of the market—and seize new growth opportunities.

Taking a fresh look at technology transfer

Traditionally, technology transfer has been a “throw-it-over-the-wall” activity. The research and development (R&D) group designs a new product and associated manufacturing processes and then simply hands that information to the manufacturing unit for production.

Not only is this approach outdated, it’s flawed.

For a manufacturing organization to transform how it shares information, it must first look at how the enterprise views the role of its R&D function. To some, the output of R&D is the new product itself. But that’s only half the story. We believe the real output is information around how a product is developed and how it can be manufactured. Unfortunately, companies today struggle with poor linkage between manufacturing and R&D resulting in incomplete documentation of R&D activities and, at best, only a partial transfer of knowledge to manufacturing.

What’s more, these businesses don’t capture some of the most valuable knowledge gained during R&D: that of “failed” experiments. Today, data from unsuccessful experiments, if captured at all, might be found in a research report or in a lab notebook. However, the information likely is not consolidated, cross-referenced or indexed. These gaps in technology transfer can doom R&D and manufacturing to repeat the same mistakes time and again.

What is technology transfer in life sciences?

Technology transfer refers to the processes of successfully transitioning necessary knowledge and technology from drug discovery to clinical development and trials to full-scale commercial manufacturing.

Forward-thinking pharmaceutical companies are implementing leading practices—including the ANSI ISA S88 standard—to develop standardized operations that can be linked together to form an end-to-end process. And they are closely examining new methods for recording, storing and sharing key institutional knowledge.

Ultimately, this new approach will speed product transfer, reduce the chance of failure and accelerate time to market.

A leading-practice approach to technology transfer

The price of ineffective product technology transfers includes myriad areas of your business, such as labor, raw materials, equipment and disposal costs. By implementing leading practices, your manufacturing operations can move closer to the desired state for pharmaceutical production. In our experience, leading pharmaceutical manufacturers focus on three key dimensions to achieve effective technology transfer (Figure 1).

Process authoring. By creating processes using defined, discrete and reusable “pieces,” each of which is understood by both R&D and manufacturing, you can eliminate many potential problems in the technology transfer process and streamline the collection of the information around a specific product recipe.

Standardized recipe authoring. Establishing a process authoring methodology that is compliant with standards, such as ISA S88, can move the enterprise closer to the desired state (Figure 2). Recipe authoring tools such as those from JustSystems provide a visual, flowchart-style solution that integrates with leading enterprise solutions.

Figure 1. Process, product and knowledge development

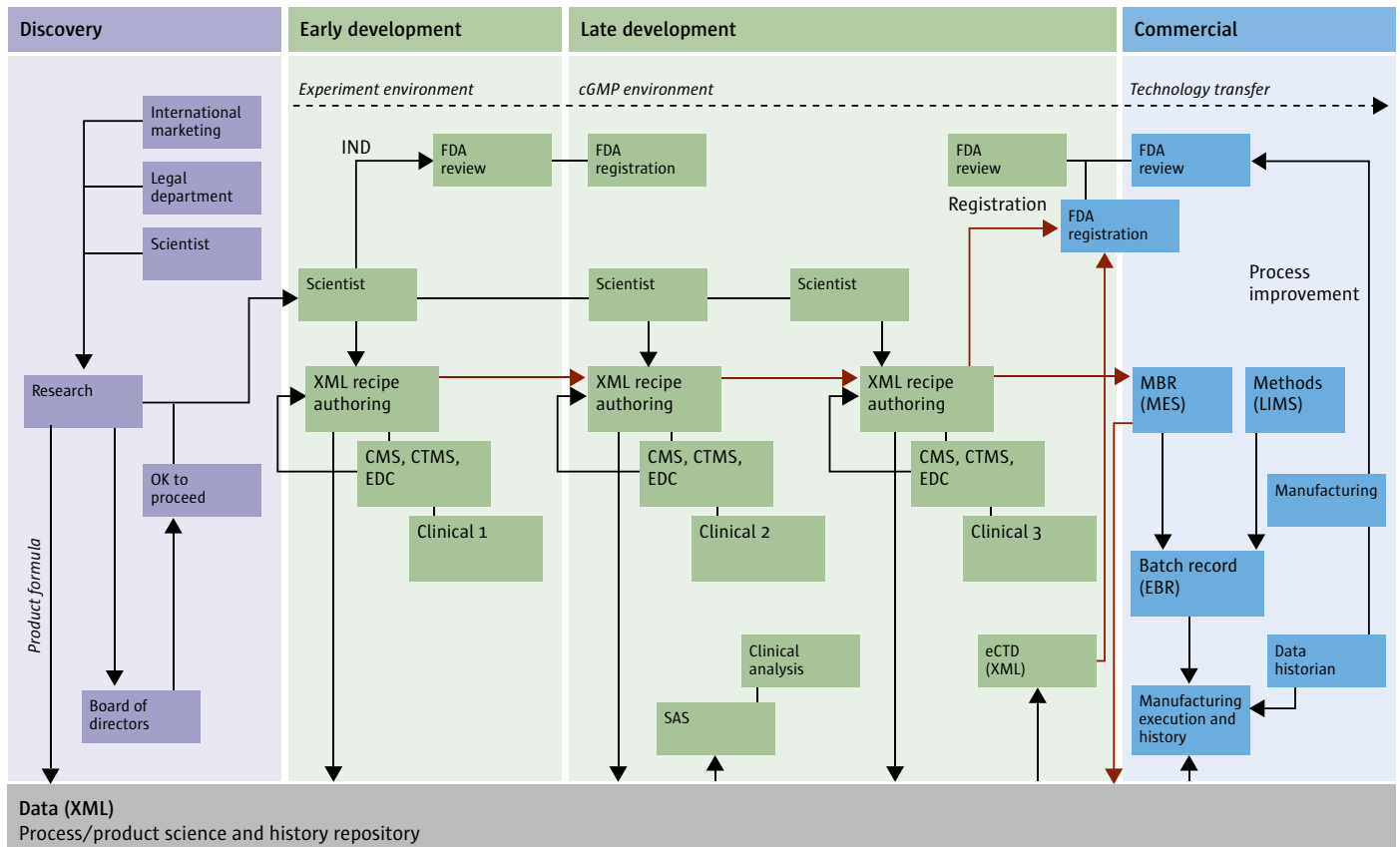
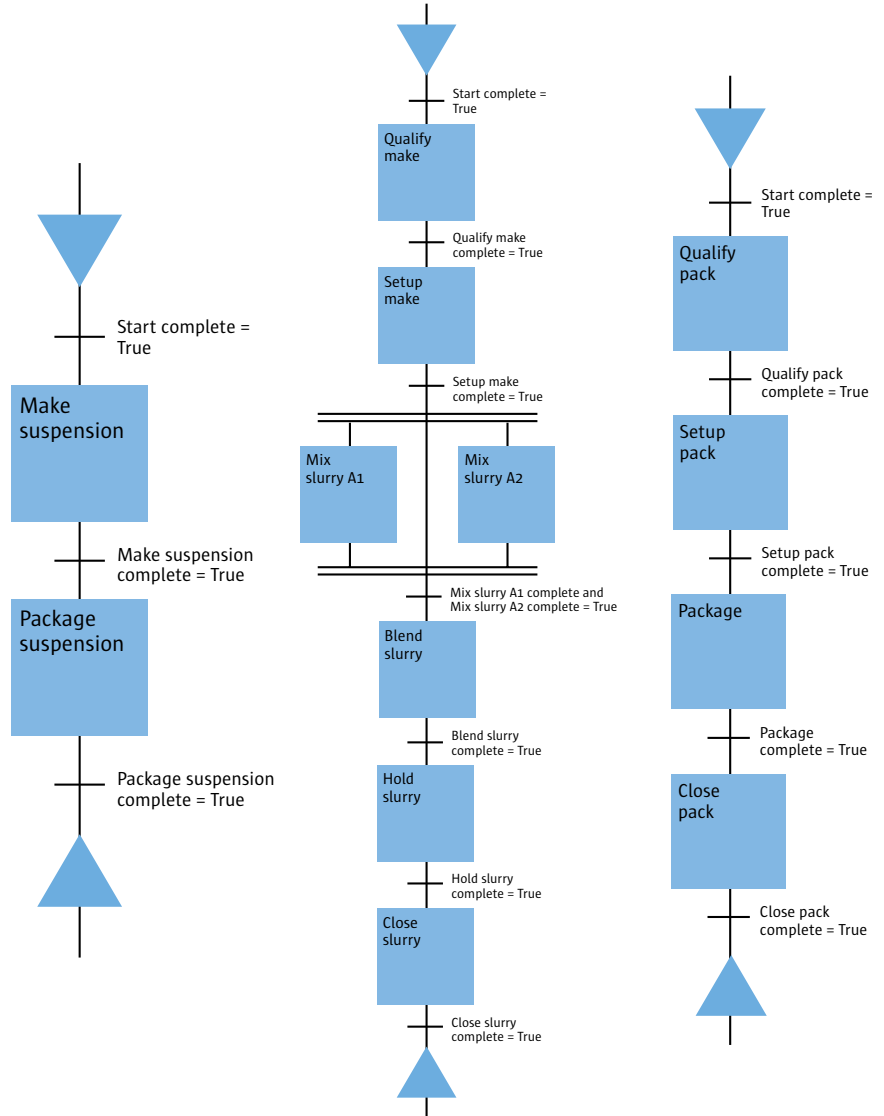


Figure 2. Standard recipe authoring



The desired state

The desired state of pharmaceutical manufacturing is one where pharmaceutical and biotechnology product development encompasses not only the creation of a high-quality final product to treat a disease state, but also a thorough knowledge base about the product and its manufacturing processes. This knowledge and understanding of the product and its characteristics will greatly improve scale-up and commercial manufacture of the product, reduce regulatory oversight, and facilitate continuous product and process improvements.

Knowledge management. Knowledge within an R&D function can exist in a variety of forms and locations, from lab notebooks and electronic document systems to lab information management systems and, more often as not, a chemist's head. By improving how the enterprise captures that information and catalogs it in a cross-referenced, indexed system, you avoid the loss of knowledge from staff changes and can realize value from it in the future.

Technology transfer and Quality by Design (QbD)

Quality by Design is a methodology for producing consistently high-quality products by embedding quality initiatives into development and manufacturing processes instead of testing for quality after products have already been made.* When bringing a product to market using QbD, pharmaceutical manufacturers identify critical sources of process variation up front. Then they continually monitor and update the process to facilitate more efficient development and delivery of future quality products.

By following QbD practices in developing new products, you will have a more thorough understanding of how the product behaves under various conditions, what process parameters will and will not affect product quality, as well as how process parameters affect it and by how much. QbD environments have more information available than has been available in the past. That is why it's critical to capture and transfer that knowledge.

Sound knowledge management principles not only can help you share information with your manufacturing organization, they can also facilitate a new drug application (NDA), particularly the chemistry and manufacturing controls (CMC) section.

By creating a product development history and following tested QbD tenets, Food and Drug Administration (FDA) review and approval of your submission can go much more quickly and smoothly. In fact, the FDA has committed to faster turnaround of QbD submissions.

Effective technology transfer also streamlines the post-NDA approval change process. In the past, depending on the nature of the change, the FDA required a submission to identify a product or process change. Then you waited for a response. Today, if following QbD processes, you may be allowed to make the change without asking for approval.

Tap powerful technology to enhance technology transfer

Until recently, few robust technologies existed to support an R&D environment in documenting the product and process development life cycle. Many pharmaceutical manufacturers looked to off-the-shelf product life cycle management (PLM) or manufacturing resource planning (MRP) tools to drive more rigorous technology transfer. Others used various enterprise resource planning (ERP) components, but discovered that scaled-down versions, designed primarily for production environments, didn't work well in R&D.

New product and process development life cycle management (PPLM) solutions are emerging and are designed with the R&D user in mind. One example, Conformia's Scale-Up Management System (SUMS), is designed to be more flexible, especially early on when you have yet to define processes or master batch records, for example. Also, Conformia's solution is designed to streamline your R&D operation as you get closer to commercial manufacturing. For example, as you move through phases one and two of development and, ultimately, phase three clinical trials, your processes become increasingly like what will occur in commercial manufacturing. And, Conformia's SUMS will communicate with SAP so that the PPLM data that you end up with in the system can transfer to an SAP® system at a later point.

For many organizations, workforce trends fuel the urgency to retain institutional knowledge. Employee turnover through attrition and retirement often means immeasurable—and often irreplaceable—experience and know-how walks out the door every day.

*For more information on Quality by Design read the BearingPoint white paper, "Quality by Design: Life sciences companies need to step up now," by Mike Power, available at www.bearingpoint.com/qbd.

Tangible benefits from technology transfer

Organizations that have implemented enhanced technology transfer practices see marked improvements in the product development. These breakthroughs include:

- **Increased speed to market.** Effective technology transfer reduces manufacturing scale-up problems. Additionally, by following a QbD methodology in your product and process filings, the FDA will give you priority review.
- **Lower costs.** Using standardized tools—paper or electronic—can help you virtually eliminate the chances of human error. Lower costs can mean reduced down time, which can result in reduced labor and resource needs.
- **Stronger knowledge management.** In an R&D organization, much of the information collected and stored must be retained indefinitely. Backed by a strong knowledge management system, the enterprise can access the information quickly, adding value and depth to the enterprise's intellectual property structure.
- **More efficient legal and regulatory responses.** By having a better knowledge management system in place, companies can respond more efficiently and completely to legal and regulatory requests for information. This reduces labor time and costs.
- **Continuous improvement.** New products based on existing formulas are commonplace in the pharmaceutical industry. By making past information—including failed experiments—more readily accessible, the enterprise can continually improve current and future products based on the entire knowledge base, not merely a portion of it.

Key considerations for upgrading your technology transfer methodology

New product and process development life cycle management (PPLM) solutions are emerging and are designed with the R&D user in mind.

As you begin to consider how your organization's technology transfer methodology can be upgraded to a leading-practice approach, BearingPoint recommends five key steps in preparing the organization for this change.

First, develop a governance structure between R&D and manufacturing to define a set of reusable process steps that both groups can agree on. Then define those steps and share them across the functions so that new processes use them consistently. Next, using the same governance structure, create the process for adding new modules. We believe strong governance is essential to charting a path to an effective and lasting technology transfer model.

As we've noted earlier in this paper, the organization's knowledge management platform is at the heart of your technology transfer methodology. Once you've established a governance structure, we recommend developing a strategy for the specific knowledge management of your newly created product- and process-related information.

Next, research how PPLM tools can improve your R&D operations. You may decide to extend solutions such as SAP into R&D. Or you may choose to deploy new tools designed for the R&D space, which can send data to existing PLM tools in the manufacturing area.

Another point to consider is a dual-reporting relationship for manufacturing and R&D. Typically, these functions are siloed, but the combined strengths could create a significantly more effective and innovative enterprise.

Finally, few practices can have as immediate—or as long lasting—an impact on your operations as QbD. While it's true that you can achieve most of the benefits of improved technology transfer without QbD, implementing a strategy centered on QbD can enhance your existing operations and processes dramatically.

The pace of change in the pharmaceutical and biotechnology industries now shows signs of slowing. You can be prepared for the next wave by taking a critical look at your R&D and manufacturing operations and sharpening your approach to technology transfer.

Conclusion: The time for change is now

The time for change in the pharmaceutical and biotechnology industries is now. You can begin by taking a critical look at your R&D and manufacturing operations and sharpening your approach to technology transfer. By doing so, you can cut waste, reduce rework and slash transfer-to-manufacturing time. And with a new reliance on QbD, you can get your submissions approved more quickly so that R&D can do what it does best: drive revenue growth for your business.

About the author

Ellen Reilly is a managing director with BearingPoint's Life Sciences practice. She is a seasoned professional with experience in delivery of large-scale, global projects. She has done work for large global pharmaceuticals, biotechnology organizations and medical device clients. Reilly's experience includes supply chain, manufacturing, logistics, order to cash, compliance and client relationship management business processes. She has been involved with business process management, client strategies, complex systems integration and testing, custom development, development methods and program management.

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