

# Technology Transfer by Design™

## Pressures Mount for More Efficient Transfer

For many life sciences companies effective technology transfer has become a constantly recurring need – and significant challenge. Mergers, acquisitions, the rise of generics, new manufacturing strategies, licensing deals, all typically require the transfer of products and processes from one site to another. New products must often be moved from the development site to a manufacturing site for full commercialization.

Yet, despite the increasing frequency of technology transfer, many companies treat it as “something that will somehow get done,” rather than as a core competency that can make a real competitive difference.

We can help. Whether the transfer takes place between two sites, two companies, a company and a third-party manufacturer, or even from R&D to a pilot plant or commercial facility, Tunnell Consulting’s Technology Transfer by Design (TTbD™) ensures that you do it faster and more cost-effectively while acquiring the capabilities you need to maintain a reliable transfer capability.



## A Comprehensive Solution

Tunnell Consulting’s Technology Transfer by Design™ solution provides you with all of the critical elements for a comprehensive, proven framework for technology transfer that other approaches can’t match:

- GAP & RISK ANALYSIS
- A STRUCTURED APPROACH
- INDUSTRY & PROCESS EXPERTISE
- KNOWLEDGE TRANSFER
- BOTTOM-LINE FOCUS



## A Comprehensive Solution

Tunnell Consulting's **Technology Transfer by Design™** solution provides you with all of the critical elements for a comprehensive, proven approach to technology transfer (Fig. 1) that other approaches can't match:

**Gap and risk analysis** enables you to determine in advance what shortfalls for undertaking the project exist in plant capabilities and capacities, process understanding, documents, analytical methods, personnel at sending and receiving sites, project management capability, and understanding of regulatory and safety issues.

**A structured approach** provides a "by design" set of requirements, activities, decision points, and best practices including QbD. Transfer is timely, within budget, well-documented, and sustainable – with minimal impact on plant operations and sales of the product.

Our **industry and process expertise** provides pharmaceutical, scientific, and engineering knowledge as well as the process excellence understanding – two of the key skill-sets needed for a successful transfer.

**Knowledge transfer** leaves your organization with a core competency in technology transfer and with experienced personnel who can repeat the process rapidly, consistently, and at lower cost than before.

**Bottom-line focus** ensures that technology transfer is assessed, defined, designed, and managed from a comprehensive value perspective to capture the full benefits of the transfer. We also provide our proprietary TT Analyst™ application for project and portfolio management and risk analysis to help you make economically optimal decisions now and for future transfers (Fig. 2).

### Technology Transfer by Design™

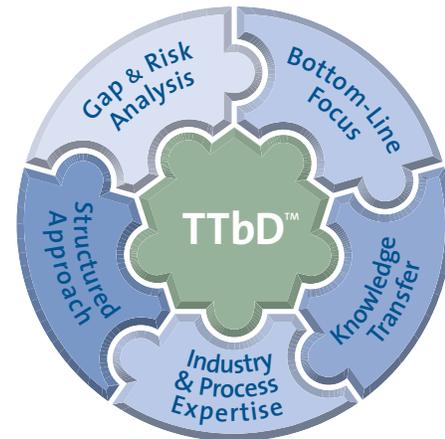


Figure 1:

A comprehensive approach to Technology Transfer

### Bottom-Line Project, Portfolio Management and Risk Analysis

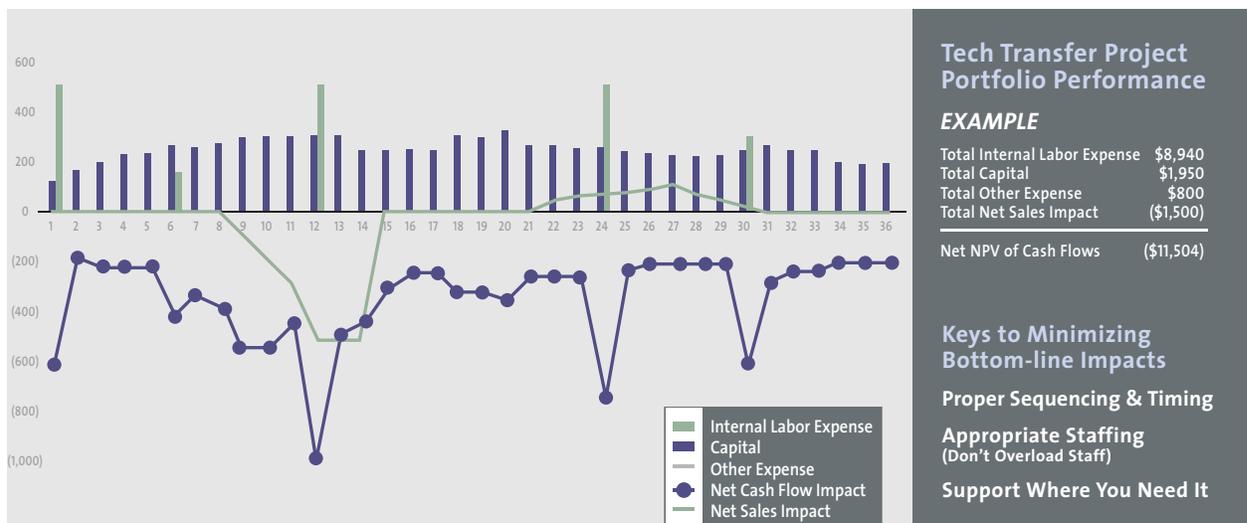


Figure 2: Tunnell's Analyst™

**Keys to Minimizing Bottom-line Impacts**

- Proper Sequencing & Timing
- Appropriate Staffing (Don't Overload Staff)
- Support Where You Need It

# Establishing the Right Support Structure

## TTbD™ Governance Structure

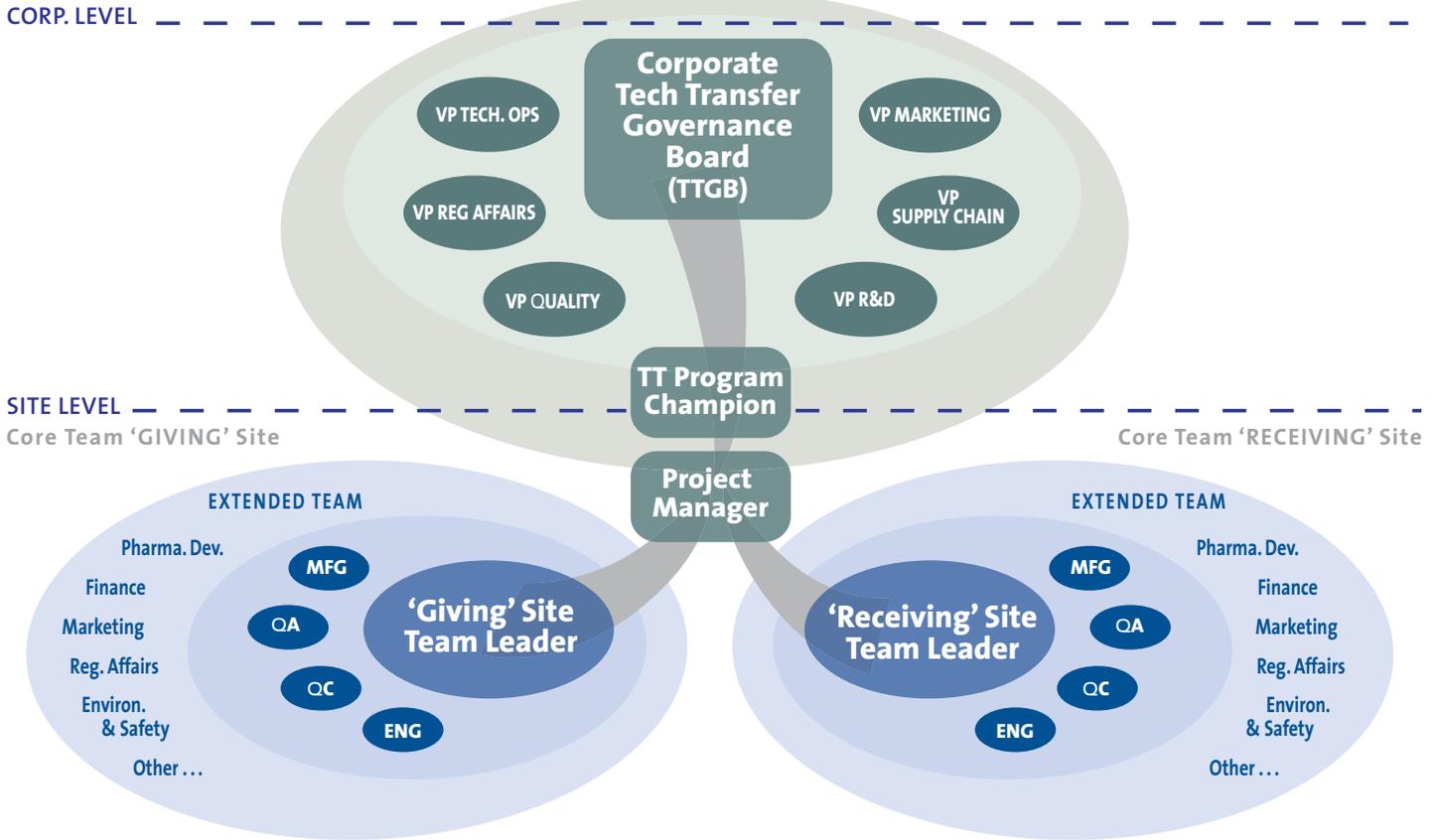


Figure 3: Governance and Reporting Structure

Reaping the benefits of those capabilities requires the right organizational infrastructure to support them. Tunnell's TTbD™ helps you rapidly design a governance structure consisting of senior management from all departments – operations, supply chain, quality, regulatory, marketing, and any other functions that have a stake in the transfer at both the sending and receiving sites (Fig. 3).

Because inadequate communication remains one of the most frequent causes of costly delays in technology transfer, our approach clarifies at the outset the

communication and reporting channels in the governance structure. You establish clear and unambiguous channels, including the relationships among receiving and transferring sites, the reporting structure to senior management, and communication modes and intervals with all parties involved.

Like the other elements of TTbD™, this supporting structure, once established, provides you with a template and experience that can be repeated, with increasing efficiency, with every technology transfer you execute in the future.

## Delivering Business Benefits

Based on the assumption that technology transfer, like any process, should be efficient, cost-effective, sustainable, and repeatable, TTbD™ delivers significant business benefits, including:

- ◇ Faster, **in-budget transfer** of products and processes
- ◇ **Cost-effective** filling of resource gaps
- ◇ **Timely compliance**, right-the-first-time validation
- ◇ **Uninterrupted supply** of products to customers
- ◇ **Core competency** in technology transfer
- ◇ Speed, **agility**, and effectiveness in technology transfer that competitors can't match
- ◇ Ability to **optimize** the tech transfer project portfolio
- ◇ Continued business **focus** despite disruption of a transfer
- ◇ **Greater speed** to market
- ◇ Manufacturing **flexibility**
- ◇ **Product rationalization**
- ◇ Ability to achieve **in-licensing** and **out-licensing** objectives

## Profiting from Competitive Advantage in Technology Transfer

Depending on your needs and organizational capabilities, we can provide carefully targeted assistance or fully deploy a multi-disciplinary team of formulation scientists, process engineers, and life science process excellence consultants. But no matter the size of the challenge, we apply to the technology transfer process the advances made over the past 25 years in process understanding and risk management as well as our deep industry expertise.

Because successful technology transfer has become more

important than ever, organizations that adopt TTbD™ and create a core competency in technology transfer will enjoy great advantages. They will have a ready framework for transferring technology. They will have a cadre of experienced personnel who can rapidly deploy TTbD.™ And unlike organizations that treat technology transfer in an ad hoc manner, these forward-looking organizations will be able to consistently achieve successful technology transfer more rapidly, more reliably, at lower cost, and with maximum strategic impact.

### Discover the Value

Founded in 1962 and serving many of the world's leading life science firms, Tunnell Consulting integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific credentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve.



For more information about how Tunnell's TTbD™ can help your organization achieve successful technology transfer, please contact:

**Headquarters**

900 East Eighth Avenue, Suite 106 • King of Prussia, PA 19406 • ph 610.337.0820 • [www.tunnellconsulting.com](http://www.tunnellconsulting.com)

King of Prussia, PA

Washington, DC

San Diego, CA

San Juan, PR