



## TECHNOLOGY TRANSFER

### TRENDS AND FRAMEWORK

Accelerating trends in the pharmaceutical industry have made successful technology transfer more critical than ever. Mergers, acquisitions, the rise of generics, the closing of plants and the construction of new ones - these trends and events typically entail the transfer of products and processes from one site to another. New products, too, must often be moved from the development site to a manufacturing site prior to launch.

Technology Transfer becomes **even more challenging** when several dozen products must be transferred at the same time and in parallel, as often happens following a merger, acquisition, or alliance, the closure of a facility, or the need to quickly develop and manufacture a large number of generic drugs. Cost pressures, market needs, government regulations, tax benefits, and logistic issues have also greatly magnified the importance of technology transfer.

The decision and plan for Technology Transfer is a direct result of several factors, such as corporate vision and business requirements, sourcing and manufacturing strategies, and the overall company strategy. All of these parameters together dictate the site and product transfer strategies and plans.



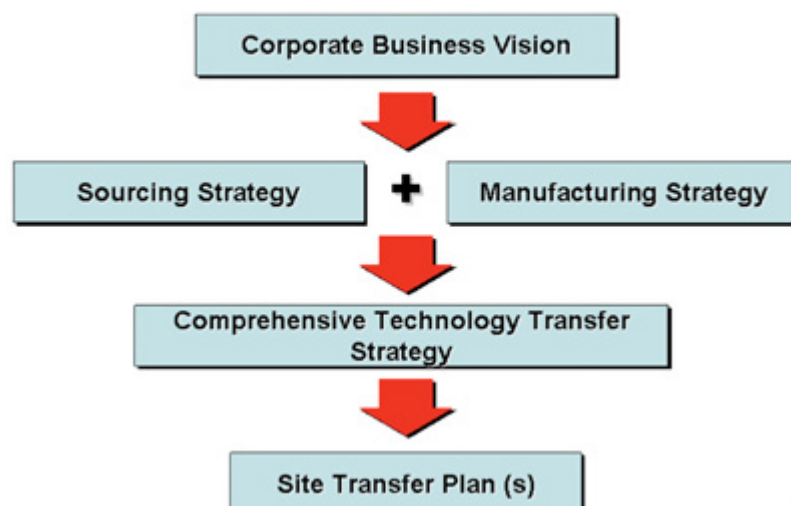
### TECHNOLOGY TRANSFER BY DESIGN

With these trends likely to continue for the foreseeable future, companies can no longer afford to treat Technology Transfer as something that "will get done anyway." Whether 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, the ability to do it faster, more compliantly, and less expensively can confer **significant competitive advantages**.

Successful companies will therefore make Technology Transfer a core competency to ensure that they can compete effectively today and in the future.

They can establish this critical core competency through Technology Transfer by Design (TTbD), based on the principle that Technology Transfer is a process that can be designed, improved, and controlled, much like other processes. Just as at the product level, where Quality by Design (QbD) depends upon an understanding of the interactions in manufacturing processes of multiple variables that keep the resulting product within specifications, TTbD at the portfolio level provides a systematic way to understand all of the elements that go into the design of the Tech Transfer process and ensure that they stay in synch to produce a successful transfer.

#### Technology Transfer Plan Hierarchy

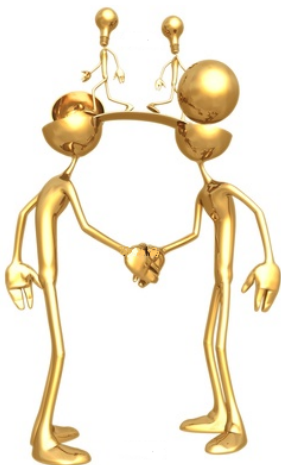


### A BETTER APPROCH TO TECHNOLOGY TRANSFER

TTbD provides a better way. By applying to the Technology Transfer process the advances made over the past 25 years in process and risk management, TTbD offers a uniform process for successfully transferring technology, whether for one product or many. TTbD is based on the assumption that, like any process, pharmaceutical technology transfer needs to be assessed, defined, designed, and managed from a comprehensive value perspective. Just as Quality by Design is employed to create the design space for the successful manufacture of a product, TTbD maps the "transfer space" within which Technology Transfer will succeed. It includes a structured set of requirements, activities, and decision points. And it provides an integrated approach to best practices to be systematically managed so that transfer is timely, effective, within budget, and well documented with minimal impact to current and future sales of the products involved.

Critical success factors include:

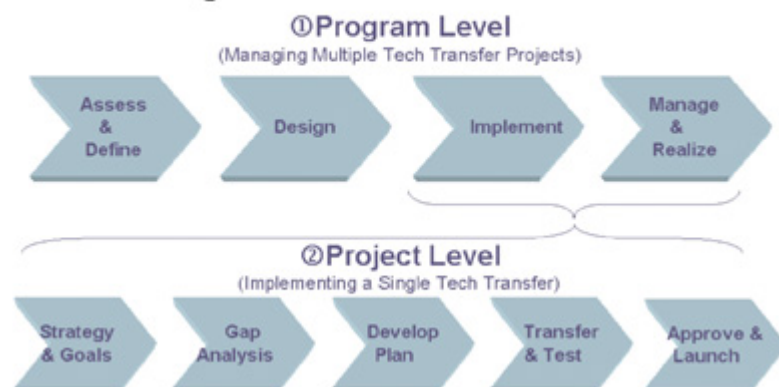
- ✿ Clear bottom-line financial focus
- ✿ Active senior management leadership
- ✿ A disciplined approach at the program and project levels
- ✿ Sequenced and linked tools
- ✿ Rapid project completion
- ✿ Clear definition of success
- ✿ Supporting infrastructure, including roles, responsibilities, and management systems, and adequate staffing
- ✿ Creation and use of process understanding
- ✿ Use of data and statistical modelling



The 10 steps constitute the focal points to be considered – both in creating the transfer process and investigating problems that might arise – when dealing with a multitude of product transfers.

1. Determine scope, strategy, and risks
2. Determine overall gaps
3. Develop governance body, champions, mentors
4. Determine communication and reporting channels
5. Determine performance measurements
6. Develop and train transfer teams
7. Determine responsibilities for each group and individual
8. Conduct gap analysis for each product
9. Determine Tech Transfer strategy for each product
10. Manage all activities, follow up, and keep at it

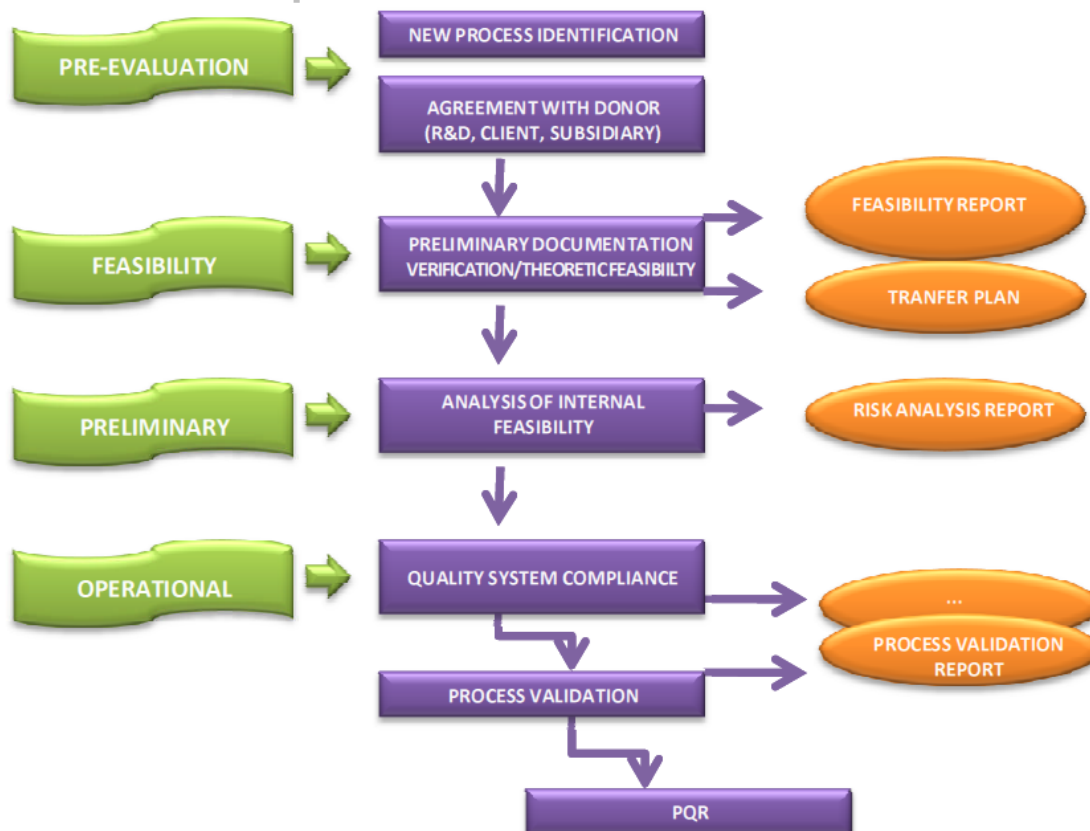
### Technology Transfers need to be managed at two levels

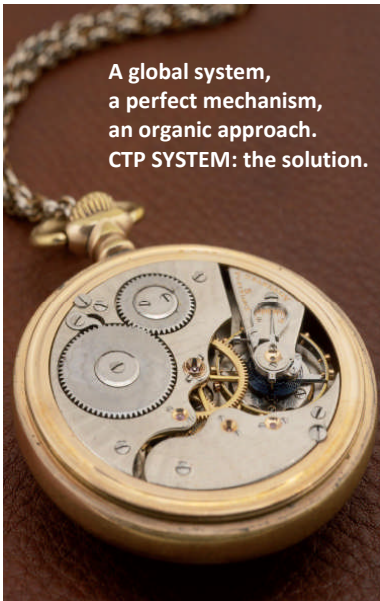


Our  
Skills

### CTP SYSTEM IS THE RIGH CHOICE

- Basic and Advanced Training
- OS and Change control Management Risk analysis based
- Equipment Validation Risk analysis based
- QC improvement Risk analysis based
- Technology Transfer consultant for all four steps (preliminary evaluation, feasibility, Transfer preparation, operative Technology Transfer)





A global system,  
a perfect mechanism,  
an organic approach.  
CTP SYSTEM: the solution.

## PLANNING FOR THE FUTURE

For the foreseeable future, the need to Transfer Technology is likely to continue to grow. Because speed to market, the ability to provide uninterrupted supply, and the drive to achieve ever greater efficiency and cut costs all affect the bottom line, effective Technology Transfer is all the more important. Organizations that view Technology Transfer as a core competency and adopt TTbD to design, control, and improve their approach to Technology Transfer, will enjoy a great advantage over companies that treat it in an ad hoc manner. Such organizations will have a ready framework for the increasingly crucial task of Technology Transfer. Just as importantly, they will also have a cadre of experienced personnel who can rapidly deploy TTbD to consistently achieve successful Technology Transfer more rapidly, consistently, and at lower cost.

[www.ctpsystem.com](http://www.ctpsystem.com)  
[info@ctpsystem.com](mailto:info@ctpsystem.com)

Località Salceto, 91/93  
53036 Poggibonsi (Siena)  
Tel. +39 0577 98481  
Fax +39 0577 980762

Via G. Stephenson, 94  
20157 Milano  
Tel. +39 02 49681311  
Fax +39 02 49681344

Via Campobello, 7  
00040 Pomezia (Roma)  
Tel. +39 06 9122873  
Fax +39 06 9120289