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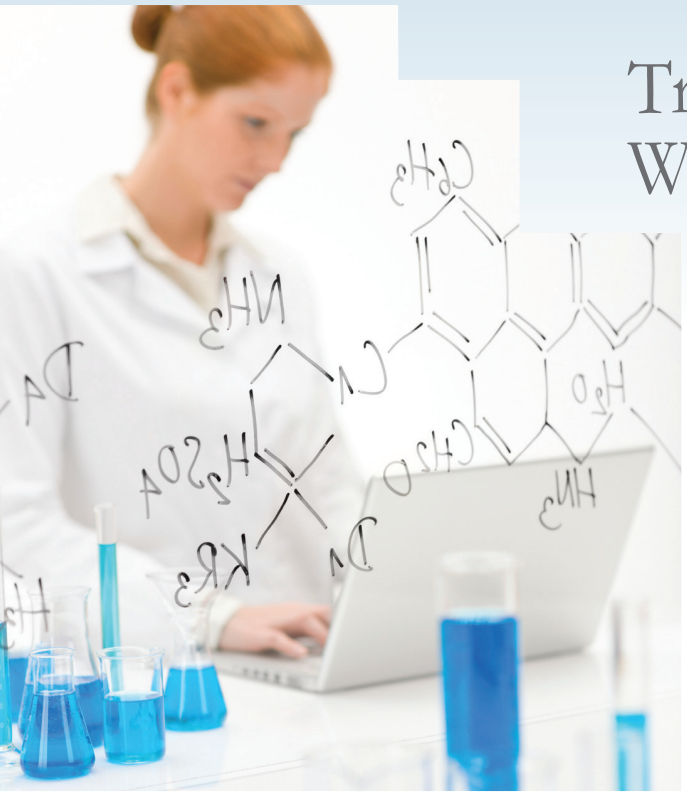


Trimming Technology Transfer With Automated Solutions

By Michalle Adkins & Robert Dvorak, Ph.D.

Taking a potential molecular or biological entity from research and development to market can be challenging for even the most experienced life sciences companies. In addition to the product development work, it requires collecting, organizing, and transferring the masses of information required to define a product, produce sufficient quantities, satisfy regulatory agencies, and obtain the necessary licenses. Simply satisfying the basic requirements is very costly and time-consuming.

The sheer volume of information can be daunting. Moving an ever-increasing amount of data from R&D through the various stages of testing, licensing, and commercialization is a huge responsibility where problems can derail even the most promising products. Frequently, this transfer is accomplished by means of written protocols, aggregated data, and reports that leave room for misinterpretation. However, by employing high-level knowledge management techniques and a common set of communication tools, transfers of technology can be accurate, effective, and efficient, thus reducing product development costs and shortening the time to market. According to a study by Tufts University Center for the Study of Drug Development (summarized in the Standard and Poor's Industry Surveys Biotechnology, Aug. 13, 2009), it can take as long as 15 years and as much as $1.2 billion to move a drug from pre-clinical development to biopharmaceutical product market launch. Even excluding the financial drain of drug development failures and associated time expended, the cost remains at $559 million per biologic.

Obviously, any viable method of efficiently pushing potential products through the maze of requirements, hastening the elimination of unacceptable candidates, and shortening elapsed time before a product is commercialized will have a dramatic impact on a company's R&D costs and bottom-line profitability.

CHALLENGES OF TECHNOLOGY TRANSFER

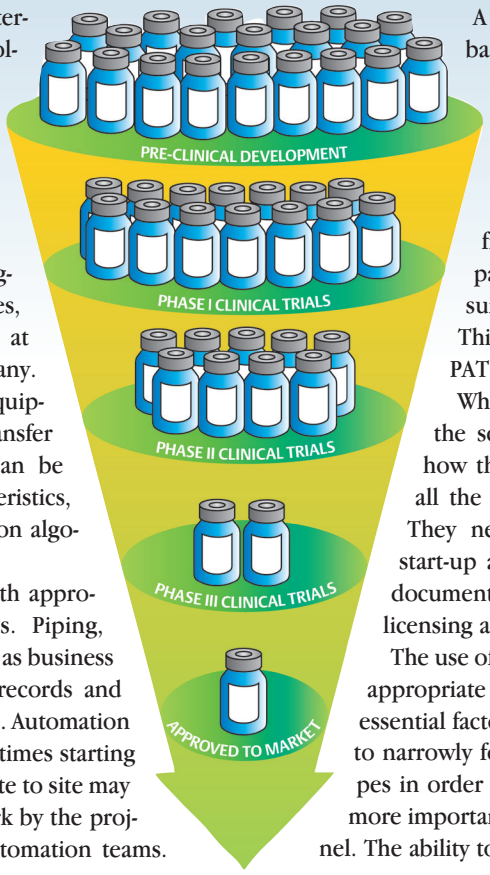
Technology transfer is an iterative process of moving information from development to manufacturing. This involves disseminating known information about the product and the anticipated process, collecting and analyzing test results, defining and executing experimental batches and campaigns, gathering process data, and providing summaries. Inputs consist of what is known about the product and the process at the time — data from prior similar products, research data from lab notebooks, characterization studies, batch instructions, set points, experimental data, and a campaign plan. Outputs consist of executed batch records, processing data, and test results, generally in the form of written reports — often hundreds of pages long. These huge, often repetitive, documents must be reviewed and understood in total.

Without a common vocabulary and a shared set of tools, technology transfer can be particularly frustrating. Extra effort is

required to deal with variations across the enterprise and contracted sites, inconsistent terminology between groups, and disconnected sets of information needed to support licensing a marketable product. This can create costly delays due to inconsistencies, errors, and poor translation of data introduced by each successive group.

Each site often has unique methods for managing similar business and production processes, even for the same product manufactured at two commercial sites within the same company. Additionally, there are differences between equipment at the sites engaged in technology transfer through the development life cycle. This can be particularly trying when equipment characteristics, piping, valves, instrumentation, and automation algorithms differ at each step along the way.

Equipment differences may be overcome with appropriate engineering and scale-up techniques. Piping, valves, and instrumentation differences as well as business process differences are handled with batch records and standard operating procedures specific to a site. Automation is generally developed for a specific site, sometimes starting with a library of objects. So, differences from site to site may eventually be overcome with a lot of hard work by the project, quality, technology, engineering, and automation teams. Of course, this contributes to the ever-growing volume of information moving along the path from development to commercialization.



Business process efficiencies are needed to reduce overall drug development costs.

Whether technology transfer efforts are managed within a site or between sites, these efforts between groups share neither a common language nor a common set of tools. The need to translate the language and associated knowledge between groups creates an inefficient process that inherently introduces the opportunity for error. Since each group is working in a somewhat isolated domain with its own processes, the knowledge is situated in that domain rather than in a common expression.

The lack of shared tools only reinforces that sharp line between groups and emphasizes the need for data migration and the development of automated structures from scratch. In addition, due to these differences, a nonvalue-added review loop is required for the experts on each side to verify the accuracy of the knowledge transfer.

SOLUTIONS FOR REDUCING DEVELOPMENT AND APPROVAL TIMES

According to an economic study sponsored by the National Institute of Standards and Technology and reported in Standard and Poor's Industry Surveys Biotechnology, Aug. 13, 2009, between 25% and 48% of R&D expenses can be saved through improvements in technology infrastructure, standardization of data collection, and quality control for postmarket surveillance. Similarly, a significant reduction in development and approval time of biopharmaceuticals is also possible.

A shared set of tools can help break down those barriers by allowing the various groups to exist in a common authoring environment and, more importantly, provides the means to hand off knowledge, data, and design without the need to translate or transcribe. In addition, shared tools enable an organization to focus on the five or six things that are really important to a particular process. The end product can be measured against truly critical process parameters. This focus on critical parameters is fundamental to PAT (process analytical technology).

When a production process is under development, the scientists and engineers may not know exactly how they want a particular process to run (down to all the parameters) until they are actually underway. They need the flexibility to make changes through start-up and rapidly modify production records with a documented, understandable rationale that supports the licensing application.

The use of information technology to aid in the transfer of appropriate data, information, and recipes is becoming an essential factor in support of technology transfer. The ability to narrowly focus on control limits with parameterized recipes in order to transfer a recipe to production is becoming more important with every product moving through the channel. The ability to link to electronic lab notebooks, PAT (process analytical technology) systems, MES (manufacturing execution systems), control layers, and business systems is crucial to taking technology transfers into a new and improved reality.

Conventional technology transfer procedures are challenged by errors and site-to-site inconsistencies as large volumes of information are transferred manually in paper or electronic document format. These problems can be reduced or, in some cases, eliminated because advanced technologies and tools are now available to improve these practices. Companies that embrace these capabilities will be able to bring products to market more quickly with consistent, well-characterized, quality processes.

About the Authors

Michalle Adkins, a senior industry consultant at Emerson Process Management, has 20 years of pharmaceutical industry-related experience, including 13 years with Merck. In her consulting engagements, Michalle uses her varied experiences including project management, planning, manufacturing, automation, and engineering.

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