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Guest Editorial

A New Way of Thinking Leads to Process Improvement

From bench-scale chemists to process engineers — industry professionals are increasingly aware of the need to improve the drug development process. We employ tools like biocatalysis, high-throughput screening, process simulation and streamlined chromatography. Yet one of the most important enablers is not new science and requires no additional capital investment, if done right. This enabler is a way of thinking, planning and organizing that recognizes that success and speed in drug development are achieved by making a conscious effort to manage uncertainty and risk at every stage of a project. It's an organizational commitment I like to call "Right-to-Left Thinking." To be most effective, it must be applied early in the planning process, and it must include the perspective of individuals who are downstream of the early development activities and who have a breadth of perspective.

Chemical engineers involved in process development and scale-up play an important role in successful drug development — and can be even more valuable when right-to-left thinking is applied. Faster drug development requires the right expertise in the complex interdependencies and the downstream implications of upstream activities, combined with ongoing communication as new information becomes available.

For instance, those who have built pilot and production-scale plants understand the "obsession with shiny." But shiny new equipment can reduce value if the chemical process takes one day per step while the cleaning process takes two days per step because form was considered over function. Design input at an early stage by someone who understands engineering, operational, quality and financial issues can ensure years of efficient operations.

We recently applied right-to-left thinking to expedite a company's development of a more-scalable route to a drug. A review pre-clinical safety data revealed that toxicology issues could be addressed with additional tests. We engaged a process chemist who recommended more work on the final form of the drug due to concerns about manufacturing scale-up. Finalizing the commercialized form of the drug early could eliminate repeated safety studies, which can cost $400,000–$600,000 and delay a program by six to nine months.

The number of compounds entering development is increasing at roughly 50% every 5 years. On top of that, the ability to efficiently progress drug candidates through Phase III and a launch relies on decisions made 1–3 years earlier. While early stages of a program determine much of the later risk, they have fewer manageable sources of risk. It's no wonder larger companies are seeking the ability of smaller ones for discovery and to take the compounds further into development. The experience and perspective resident in chemical engineering and process chemistry can prune whole branches of decision trees, if applied early, creating significant value for a relatively small investment.

Roughly 70% of pharmaceutical R&D is spent on projects that are ultimately terminated. Clearly, a right-to-left approach may help management focus resources on reaching clear go/no-go decision points for all projects in a portfolio. Things do go wrong in drug development. One of the keys to success is not simply moving forward with speed, but including a perspective that helps the organization look forward and backward at the same time.

Paul Woitach
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