

Turning pipelines into profits

How drug discovery bottlenecks can be addressed, according to Grace.

Few people genuinely enjoy change, but the pressure is on for pharmaceutical companies to change the way they do R&D, to more efficiently produce new drugs in a post-blockbuster world. A visionary might approach bottlenecks in their process by developing a custom solution such as specialized software or equipment platforms. While the emphasis on new technologies and innovations is commendable, such custom solutions are often complex and risky, adding significant time and expense. Thankfully, ready-made commercial solutions, such as the Reveleris flash chromatography system, are available to address bottlenecks in the drug discovery and development process.

As discussed in a recent *Chemical and Engineering News* article, the days of feeling flush with cash are over, and the pharmaceutical industry must begin making simpler, more effective changes. Recent attempts to reduce overall drug development costs have included drastic cost cutting and 'merger mania'. However, the industry's attention has now shifted to examining and im-

“The pitfalls of customized solutions can be avoided by implementing commercially available solutions”

proving processes to shorten R&D time and fuel the pipeline. This is a critical time to consider the difference between customized and commercial solutions to productivity opportunities.

The productivity of the pharmaceutical industry is often measured by the quality and quantity of new drugs in the development pipeline. Those companies that commit to effective transformation will reap the benefits of a rejuvenated pipeline both short and long term.

There are many paths to strengthen a pipeline – diversifying with biologics, focusing on fewer disease targets, in-licensing more therapies



and adapting to offer other products (such as generics and other health products). However, pharmaceutical companies must focus on their core business – discovering and developing new molecular entities – to drive long-term, sustainable growth. In many cases, this requires an overhaul of their internal drug discovery processes.

Good operations management addresses bottlenecks to improve overall performance, quality and throughput. This new emphasis on 'process' means drug discovery must be streamlined to quickly deliver high quality NMEs without sacrificing quality. To address attrition concerns, companies must have more confidence that NMEs will perform better with less risk of failing in phase II. Leads must be advanced quickly, or failed early.

Adopting new technologies to achieve these process improvements is critical. For many years, the industry has chosen the path of customized solutions for these improvements, such as proprietary hardware or software developed internally or co-created in external collaborations. These projects may be born of an innovative spirit, but they can often fail.

Large teams, typically including the scientists in the affected labs, are chartered to develop and implement the customized technology 'efficiency project'. These projects take much of the scientists' time in designing, planning and testing. The

result can be a negative effect on drug discovery output since the scientists' time and energy, which should be focused on developing and testing NMEs, is instead focused on the efficiency project. The drive to continuously advance NMEs is diluted, and progress is slowed. Later, upon review of the new custom technology, the project may be deemed an expensive failure or abandoned due to a lack of measurable productivity improvement.

The pitfalls of customized solutions can be avoided by implementing commercially available solutions without the distraction of lengthy, complicated projects. Such solutions, whether instrumentation, software or consumables, are developed with productivity in mind and can be implemented quickly and cost-effectively.

As the world's leading supplier of silica gel to the pharmaceutical industry, Grace recognizes the challenges of NME purification. The Reveleris flash chromatography system was designed to address one of the most common bottlenecks in drug discovery: purification. Along with our solutions in process media, packing systems and column packing services, Grace can help pharmaceutical companies improve productivity throughout the R&D process. ■

This article was written through the collaborative efforts of Grace's Marketing, R&D and Six Sigma teams. Please see www.ngpharma.com to read our editorial on the purification bottleneck.