



INSIGHTS

Increased Throughput: Optimizing R&D Deployment of Life Sciences Companies

By Kevin Heard

June 2004

Executive Summary

The successful introduction of new products is the life-blood of every for-profit enterprise. While some organizations are able to seemingly introduce dynamic new products easily, most struggle mightily with turning an idea into reality. Firms operating in FDA-regulated business environment are often rewarded with years of patent-protected revenue streams for successfully turning breakthrough ideas into commercially viable products. Effective leverage of research, and more importantly, development resources, are essential to the long-term success of medical device, pharmaceutical, and other FDA-regulated businesses. By applying the right combination of Portfolio Management, Constraint Theory, and disciplined resource allocation, life sciences concerns can drastically improve R&D pipeline throughput.

The Intersection of Life Sciences R&D and Constraint Theory

The Theory of Constraints has roots dating to the early 20th century and the Industrial Revolution. Resting upon several decades of manufacturing value, the basic premise of Constraint Theory states that in order to maximize throughput, one must exploit an identi-

fied constraint. Identifying the primary constraint (or constraints) in any value chain is a fundamental task to employing Constraint Theory.¹ For the life sciences value chain, the development portion is the notorious constraint in most organizations. The term “great idea, poor execution” seems to have been coined specifically for the much maligned development function of most companies relying upon Research & Development as a key enabler for new products and services.

What does constraint exploitation involve? To begin with, the exploitation of the development constraint requires that the majority of your variable investment be directed to your constraint. This means that your most talented human resources and best available physical resources, as well as an over-weighted proportion of capital investment, should be directed towards the development function. The ethical pharmaceutical space is awash with many more development opportunities than can possibly be developed. The investments in research technologies, combined with advances in automated methods of discovering new applications for compounds, as well as a plethora of micro-cap research organizations, have yielded unprecedented levels of product ideas, yet conversely has resulted in far too many opportunities to pursue.

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Effective leverage of research and development resources are essential to the long-term success of FDA-regulated businesses.

FDA-Regulated Industry Best Practices

The group of entities operating under Food and Drug Administration regulation is bridled with a burdensome approval process to bring new product to market. The ongoing process of maintaining continued operations requires substantially more effort than those manufacturers operating outside of the FDA-regulated arena. In terms of optimizing the Research & Development resources within the life sciences industry, focusing on the most promising opportunities is the absolute key to long-term prosperity. The following three cases represent the difference between merely using Research & Development resources well, and optimizing those resources to their realization potential.

Medrad

Medrad is a leading developer and manufacturer of medical imaging devices based in Indianola, PA. Their accolades include developing and delivering the most demanded product portfolio in the industry, and doing so with constantly improving efficiency over the past eight consecutive years. Medrad was recognized for this remarkable execution by winning the 2003 Malcom Baldrige National Quality Award.² Insight into Medrad's best practices reveals that their success is due, in large part, to the very effective deployment of Development resources on a select few opportunities collected from their new product research operation. Medrad has expressed that a defining moment in becoming a world-class operation in the FDA-regulated arena came when the management committee decided to focus its development efforts on no more than 12 opportunities at any one time. The very action of funneling a development pipeline from more than 180 opportunities to 12 exploited their constraint in getting new product introductions to the commercial marketplace. The improvement in Medrad's business results over the past eight years is reflected in receiving the aforementioned Malcom Baldrige National Quality Award.

Human Genome Sciences, Inc.

Human Genome Sciences, Inc. (HGSI) is a leading research group of mammalian strand compounds based on genomic research. The rampant discovery of compounds from this research placed HGSI in a position of possessing more opportunities than could be effectively cultivated by its development function. Aware of the need to improve performance of the development function, HGSI arrived at a decision to:

Sharpen its focus in preparation for the commercialization of the Company's most promising drug candidates. As part of the strategy, the Company plans to reduce the number of drugs in early development and to focus resources on its drugs that address the greatest unmet medical needs with substantial growth potential.³

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By reducing the number of projects, HGSI is exploiting the constraint in their new product development process and improving throughput. The move has been well received in the marketplace thus far, and has been followed by competitors.

Pfizer Global Research & Development

Pfizer is the world's largest ethical pharmaceutical company, and boasts the strongest portfolio of prescription drugs in the world. Pfizer Global Research & Development (PGRD) provides the fuel of new products that make Pfizer number one in the marketplace. Recently, Pfizer revealed that a promising new complementary drug to the world's number one prescription medicine, Lipitor, would receive unprecedented dedication of resources through development. PGRD recognized that the primary constraint for launching this new drug lay in the clinical trial process, and has since dedicated \$800M US to the continued development of Torcetrapid in order to bring it to market as expeditiously as possible.⁴ The investment of such sums reveals Pfizer's belief in exploitation of the development constraint and improving throughput of high-impact products.

Results Oriented, Focused on Customer Demands

How did the preceding three cases choose the project on which to focus their efforts? All performed very concentrated and disciplined analyses of the very best opportunities to pursue. In the case of Medrad, the journey from more than 180 opportunities to only 12 also meant that of those precious dozen opportunities, only two could be internal in nature. Only those opportunities that are truly focused on the revenue-generating customer, and thus provide long-term business success, receive the majority of consideration when it comes to deployment of resources. Human Genome Science's decision to bring development focus to only a handful of promising compounds is another clear example of bringing the customer's demands to the forefront of the development process. Lastly, the same applies to Pfizer's Global Research & Development organization's decision to concentrate a very large portion of development resources on Torcetrapid, a complementary product to the world's best selling prescription drug, Lipitor.

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While most companies over the past decade have focused internally on reducing time to market and producing a vast network of research capabilities, only those that can increase throughput of the current constraint will achieve long-term commercial success. The examples above illustrate the need to focus on customer demands and to remain concentrated on results throughout the development process. Research & Development optimization is most effectively realized through operative portfolio management.

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The Enabler: Portfolio Management

Portfolio management as a discipline is mature and battle-tested by those in the financial marketplace. However, the practice has become increasingly necessary as a decision-support mechanism for executives in many businesses, life sciences notwithstanding. The effective use of portfolio management facilitates the “Top 12” opportunities for Medrad, the decision for HGSI to concentrate on a select few development projects, and, for Pfizer, the dedication of an estimated \$800M US to the development of a single prescription drug. While there is no single best practice, the discipline that effective portfolio management can bring to an organization has shown to effectively increase throughput of the Research & Development constraint, thus optimizing the physical, financial, and human resources of many life sciences organizations.

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Although portfolio management can assume many forms, the most effective are based upon improving Throughput⁵. The main vehicle to propel company-

wide improvement is selecting the right initiatives, and driving bottom line value from management of those initiatives. The throughput model has a great appeal to executive management, and provides an effective link between overall organizational strategy, specific strategies of each functional unit, and the projects these strategies drive. Balancing portfolio management with a driven throughput model provides many life sciences companies with an effective mix of projects to meet their goals.

Conclusion

For pharmaceutical companies, product development is the main constraint to revenue generation. Traditionally, pharmaceutical manufacturers have focused on decreasing cycle times and increasing cost efficiencies to maintain profitability. However, as margins continue to erode and companies try to do more with less, executives need to be acutely accurate on where they place their investments, both in terms of dollars and people. Pipeline growth will occur by way of increased throughput rather than through unsuccessful attempts to increase the efficiencies of the R&D process. Companies need to put more products through the process because there is a finite limit to the amount by which development time can be decreased. Thus, if a company can put more product through the rigors of R&D development, the greater the possibility of launching more products into the commercial marketplace.

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Notes

1. Smith, Debra A. *The Measurement Nightmare: How the Theory of Constraints Can Resolve Conflicting Strategies, Policies, and Measures*. Saint Luce Press, 1999.
2. 2003 Malcom Baldrige National Quality Award, http://www.quality.nist.gov/PDF_files/Medrad_Application_Summary.pdf.
3. Human Genome Sciences, Inc. Press Release, Thursday, March 25, 2004, 2:00 AM ET, www.hgsi.com.
4. "Pfizer Makes \$800 Million Bid To Reshape Heart-Care Market," *Wall Street Journal*, Page A1, April 8, 2004.
5. Kendall, Gerald I. and Steve Rollins. *Advanced Project Portfolio Management and the PMO: Multiplying ROI at Warp Speed*. J. Ross Publishing, Inc., 2003.

About Clarkston Consulting

Clarkston Consulting is a nationally recognized management and technology consulting firm that provide validation, compliance and implementation services to address issues that its clients face in FDA-regulated environments. Nearly half of the top 50 pharmaceutical companies in the world have worked with Clarkston's consultants, who deliver award winning expertise and exceptional customer satisfaction. Clarkston Consulting's approach focuses on the key business drivers aimed to improve productivity of product development pipelines; communications between sales, marketing, and customers; and business processes centered on new product launches. To learn more about Clarkston Consulting, visit www.clarkstonconsulting.com/whitepapers.



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