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### Backup Compound Strategies: Best Practices for Reducing Phase II Risk

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This report drives home real world experiences and best practices in backup compound strategies with:

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- Expert interviews with senior R&D managers who discuss the nuts and bolts of backup planning, and offer best practices and cautionary examples
- A proprietary survey of the views, practices, and plans of individuals in R&D involved with backup decision-making

This report details the strategic and tactical aspects of backup planning, examining organizational issues and business considerations such as:

- What organizational design, pure functional vs. pure project, with varying matrix forms in between, is best suited to backup planning
- What to do with backups once the prototype has entered the market
- Determining the level of resources available to a backup program

CHI's proprietary research shows that nearly 40% of companies surveyed do not have a clearly articulated way of thinking about backup compounds and an additional 14% employ a backup plan only at "some sites." This is not surprising in view of the daunting number of factors to be taken into account in the backup calculation.

**Backup Compound Strategies: Best Practices for Reducing Phase II Risk** is a trove of proven experience and sophisticated thinking about a critical but often neglected R&D decision.

To view a table of contents and executive summary, please visit [www.insightpharmareports.com](http://www.insightpharmareports.com)

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*Strategies for creating a leaner,  
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# **Strategic Management of Resources and Portfolios:**

## ***Structuring Risk to Maximize Opportunity in Pharmaceutical R&D***

**Hermann A.M. Mucke, PhD**

As a company develops its business, resources will always be limited and risk will always be involved. This is especially true for companies operating in the high-risk life science industry. To stay on top of the changing pharmaceutical R&D environment, certain measures must be implemented. This report analyzes:

- Types of risk that must be faced;
- Ways that various risks can be assessed and managed;
- How corporate resources can be allocated to meet the goals and create maximum value according to the corporate strategy.

*Continued on next page*

## Overview

Management of risks, resources, and portfolios are key challenges for any life science company that seeks to survive the difficult times through which the industry is now passing. There is ample evidence that the entire sector is in the process of restructuring, initially taking a defensive stance to defend earning streams but actually building momentum toward renewed initiatives on a broad front. The restructured industry that will come roaring back within the next few years will consist of leaner and more effective companies. Certainly, all of these survivors will have learned how to manage their risks and resources strategically.

For a life science company, risk comes in many forms, with compound attrition being the most obvious. **Strategic Management of Resources and Portfolios: Structuring Risk to Maximize Opportunity in Pharmaceutical R&D** examines the types of risks that must be faced (e.g., candidate failure, regulatory risk, legal risk, risk management for launched drugs, commercial and competitor risk, intellectual property risk, operational risk) and shows that these risks can be mitigated and managed if addressed proactively.

Intimately associated with the risk issue is the valuation of projects and portfolios. We outline the major approaches by which objective and quantitative valuation of drug development can be attempted.

Many resource-intensive corporate operations show extensive potential for streamlining. We present process optimization and quality control approaches that can result in remarkable savings. These include the "Lean" and "Six Sigma" concept, and the proactive management of laboratory equipment (including service contracts) and inventories.

On a strategic level, resource allocation management can largely be equated with portfolio management. We evaluate models and approaches for optimal portfolio planning and management, demonstrating that implementation of sound, data-driven, transparent decision processes is paramount. Also described are advanced software suites that are available to help manage the huge corporate data streams on the operational plane (i.e., enterprise resource management) and on the level of business intelligence, where internal data warehouses are analyzed to provide key figures and profiles that aid in decision-making.

Case studies illustrate how companies of various sizes and types (including Pfizer, Wyeth Pharmaceuticals, Bayer Schering Pharma, and Genzyme) have addressed their portfolio management issues. **Strategic Management of Resources and Portfolios: Structuring Risk to Maximize Opportunity in Pharmaceutical R&D** concludes by distilling our evaluation of this mission-critical function into actionable recommendations for sound project evaluation and portfolio management.

### Lean versus Six Sigma Approaches to Process Optimization



Source: Insight Pharma Reports

**About the Author:** Hermann A.M. Mucke, PhD, spent 17 years in academia and industry before he founded H.M. Pharma Consultancy ([www.hmpharmacon.com](http://www.hmpharmacon.com)) in 2000 to become an independent pharmaceutical consultant, analyst, and science author. His last industry position was Vice President R&D in a European pharmaceutical company, which he helped to take public on the Frankfurt Stock Exchange in 1999. Since then, Dr. Mucke, who holds a PhD in biochemistry from the University of Vienna (Austria), became a consultant and advisory board member for several European and American pharmaceutical companies and a regular reviewer of drugs and patents for Thomson Current Drugs and Ashley Publications. Dr. Mucke is based in Vienna.

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