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**Addressing the "Pipeline Problem":**  
Integrating Operations & Business Planning

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**The International Pharmaceutical Compliance Summit**  
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*Michael Mentasana, Director*  
PricewaterhouseCoopers LLP, Pharmaceutical R&D Operations Practice

*Vatsa Natarajan, Project Manager*  
Vertex Pharmaceuticals

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**The continually changing pharmaceutical/biotech paradigm**

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- ▶ Realization that "blockbuster" model cannot be only development model to ensure continued success
- ▶ Cost of research and development has increased dramatically
- ▶ Probability of success (POS) of compounds in development has decreased due to the pursuit of more difficult and complex targets and indications
- ▶ Increased pressure from the financial markets to demonstrate continued innovation, revenue growth, and shareholder value
- ▶ Increased pressure from political figures and patient lobbying groups to reduce pharmaceutical prices while outputting novel medicines through R&D
- ▶ Increased regulatory pressure to ensure safety and efficacy through numerous complex and costly clinical studies involving thousands of patients

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**Forces organizations to raise the bar on innovation**

- ▶ Increased consolidation of a fragmented pharmaceutical industry as firms pursue economies of scale in research
- ▶ Increased pressure to deliver more products through basic research and development with limited resources and budgets
- ▶ Increased focus on accountability to deliver projects on budget, while achieving product milestones
- ▶ Increased need to strike collaborative agreements to stay competitive (joint-ventures, licensing, strategic relationships, partnerships, alliances, etc)
- ▶ Increased willingness of bigger firms to license-in compounds and/or buy small firms, rather than relying solely on internal products

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**And seek new scientific and operational methods and strategies to maintain their competitive advantage and ensure long term success**

*The "current development path is becoming increasingly challenging, inefficient, and costly" as "the number of new drug and biologic applications submitted to FDA has declined significantly" while "the costs of product development have soared".*

US Food and Drug Administration (FDA)  
"Innovation/Stagnation" Critical Path Initiative White Paper [2004]

*More than innovative technologies are needed to deliver new treatments to patients. Productivity and quality improvements are also necessary to improve product pipelines. To do this, "drug developers must address big-picture issues such as creating more innovative R&D strategies....Firms will face growing pressure to improve R&D productivity to get new drugs to market sooner...and bolster return on investment".*

Tufts Center for the Study of Drug Development  
"Outlook 2005" Article [2005]

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**With a focus around portfolio and budget optimization, clinical decision making, resource allocation, external relationships, and risk management**

*"Many drug firms are focusing on ways to improve the efficiency and productivity of their R&D programs.... firms must improve management of their development portfolios.... improvements in R&D productivity will be tied to... enhanced risk management techniques..., better management of human resources, greater reliance on outsourcing and strategic relationships...."*

*"As companies seek ways to improve clinical decision-making efficiency.... the need to improve productivity and optimize resource allocation will impel greater use of risk assessment and management methodologies.... Firms will increase use of budgeting and portfolio optimization tools to reduce development times and out-of-pocket costs and improve attrition and clinical success rates."*

Tufts Center for the Study of Drug Development  
"Outlook 2004" Article [2004]

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**Which has created a new set of needs and trends that companies need to adapt to in order to remain competitive**

- ▶ Increased need to contain costs while implementing novel methods to increase the efficiency and productivity of the development chain
- ▶ Increased need for scenario/decision analysis and visualization tools to better understand organizational impact of options around key decision points to better optimize the development portfolio
- ▶ Increased need to incorporate risk assessment and risk management methodologies to portfolio and financial management to maximize value while mitigating the risks
- ▶ Increased need for tools to assist in optimizing budget and resource allocations
- ▶ Increased need to ensure that the organization as a whole is adhering to the same strategy and moving toward the same goals and objectives
- ▶ Increased need to terminate promising compounds earlier in the development cycle to reduce overall portfolio development costs
- ▶ Increased need to outsource programs or portions of programs to reduce overall development cost

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**Organizations are realizing they cannot comprehensively answer key questions about the operations of their development portfolio**

- ▶ Do we have the budget and internal resources to conduct the programs in our pipeline?
- ▶ How do we allocate / re-allocate budget and resources to meet our strategic objectives?
- ▶ If we modify one program, what effect does that have on other programs in the portfolio?
- ▶ If we modify budget/resources to a program, how will it affect the program timeline?
- ▶ How many people should we hire next year? What skills are needed and when do they need to be on board?
- ▶ How well are we executing on our development plans? What areas need improvement?
- ▶ Should we in-license or out-license a program? What are the associate costs and/or value?
- ▶ What programs will bring the most value to the organization? How do we value our products and technologies?
- ▶ Do we have defined and realistic project plans? How well are we executing on those plans?
- ▶ How accurate are our planning/forecasting assumptions? How well do they predict actuals?
- ▶ What metrics do we use to measure the throughput of our organization? Where do we stand relative to industry best practices?

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**One way to address these issues is to adopt the concepts of Integrated Operations & Business Planning (IOBP)**

IOBP can help firms to derive the maximum value from their research and development chain by increasing throughput and operational effectiveness.

**How is the value realized?**

- ▶ Through identifying and fixing gaps in four key capabilities (Project Management, Financial Management, Resource Management, and Portfolio Management),
- ▶ By integrating these four competencies and aligning the strategic goals of organization with the day-to-day project and portfolio decisions
- ▶ By utilizing a process-based methodology to manage R&D operations by integrating the three major stakeholders:



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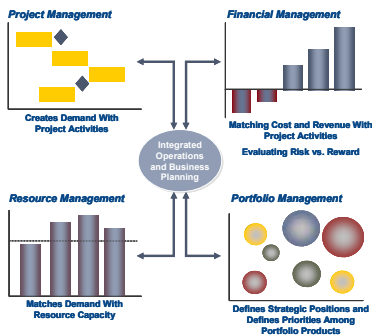
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**Organizations can more effectively execute their development pipeline and leverage the value of integrated development management**

**The Operating Framework**



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**IOBP Framework Key Principles**

- ▶ "One Set of Numbers"
- ▶ Activity-Based Costing and Resourcing
- ▶ Portfolio Visualization
- ▶ Data Transparency
- ▶ Development Chain Management
- ▶ Capacity Management
- ▶ Pipeline Throughput Metrics
- ▶ Integrated Data-Driven Analysis
- ▶ Sales and Operations Planning Models
- ▶ Resource Flexibility
- ▶ Variance Analysis
- ▶ Organizational Role Definition
- ▶ Risk Management
- ▶ Pipeline Utilization
- ▶ Organizational Alignment / Goal Deployment
- ▶ Standardized Project Plans and Multilevel Planning

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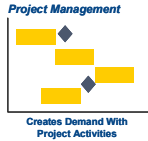
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## IOBP Conceptual Framework (Project Management)

### Key Capabilities:

- ▶ Ability to ensure that the entire organization understands project priorities and executes on the defined and agreed upon project plan and associated timeline and budget
- ▶ Ability to standardize project plans, activities, and milestones to allow for enterprise-wide multi-level planning
- ▶ Ability to identify an evolving critical path and key decision points for clinical, safety, process and formulation pathways
- ▶ Ability to model intra-project scenarios and understand implication on cost and timing (i.e. in-sourcing, out-sourcing, additional indications, additional study arms, scope changes)
- ▶ Ability to set a project budget and baseline and understand sensitivity to timeline acceleration or deceleration
- ▶ Ability to reduce project timelines and bring critical decision point milestones forward, with limited resources and budgets
- ▶ Ability to create standardized project-centric planning reports to set project baseline and track progress against plan



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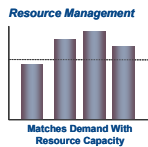
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## IOBP Conceptual Framework (Resource Management)

### Key Capabilities:

- ▶ Ability to translate prioritized activities into required development resources in a single, authoritative resource plan
- ▶ Ability to utilize parametric estimation to forecast future resource requirements over a defined planning horizon
- ▶ Ability to view available capacity by skill set and/or functional area
- ▶ Ability to summarize the resource requirements of all projects and compare against available capacity to ensure that sufficient resources are deployed onto all approved development programs
- ▶ Ability to translate resource requirements into hiring needs and facilities planning
- ▶ Ability to redeploy resources within a skill set or functional area in order to alleviate a resource bottleneck
- ▶ Ability to model cross-project scenarios and understand implication on resources (i.e. contract labor, cross-training, new facilities) and optimize resource deployment
- ▶ Ability to track actual effort against plan in order to improve resource requirements forecasting



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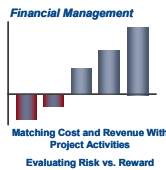
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## IOBP Conceptual Framework (Financial Management)

### Key Capabilities:

- ▶ Ability to appropriately define and allocate costs onto activities in the portfolio
- ▶ Ability to aggregate revenue and cost projections for all programs in development
- ▶ Ability to create an aggregated baseline budget/plan, capture actual costs and resources, and identify and track variances
- ▶ Ability to model project scenarios and understand implication on revenues and costs in order to maximize value (i.e. additional indications, shifting launch date, competitive forces)
- ▶ Ability to develop real-time NPV calculations based on marketing forecast inputs and real-time parametric forecasts of resources as portfolio parameters change



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## IOBP Conceptual Framework (Portfolio Management)

### Key Capabilities:

- ▶ Ability to establish one authoritative, transparent source of planning data and assumptions with associated costs, benefits, risks, and priorities assigned
- ▶ Ability to do what-if analysis to determine the impact of one program change on the resources, timelines, and budgets of all other components of the portfolio
- ▶ Ability to visualize all portfolio elements along key dimensions to better inform strategic business decisions and provide senior management with the "big picture"
- ▶ Ability to analyze pipeline gaps and assess strategies to remedy (in-licensing, out-licensing, merger/acquisition, strategic partnerships and alliances)
- ▶ Ability to perform optimization on portfolio elements in order to maximize value, minimize risk, and increase throughput
- ▶ Ability to qualitatively and quantitatively determine relative risk and value attributes of each project in the portfolio in order to make key decisions (i.e. terminating unpromising compounds earlier, accelerating high-value, low-risk projects)
- ▶ Ability to generate and compile the data necessary to apply risk assessment and risk management methodologies across the portfolio to maximize value while mitigating risk



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## About Vertex

Vertex Pharmaceuticals Incorporated is a Boston based pharmaceutical company focused on the discovery, development and commercialization of breakthrough drugs for a range of serious diseases.

Our business strategy is to commercialize major new drugs both independently and with pharmaceutical partners.

Vertex's product pipeline is principally focused on:

- ▶ viral diseases
- ▶ Inflammation
- ▶ autoimmune diseases
- ▶ cancer

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## The Business Need

During several Sr. Management team meetings the business need for an enterprise project management (EPM) tool and process was identified. The initial goal of this EPM tool was to address our inability to visualize the downstream impact of funding decisions on projects across the entire portfolio.

As a result, we began a process to understand the methods necessary to answer the following key questions:

- ▶ How do we automate the tools/process to identify & analyze optimal project/portfolio/franchise strategies so that we spend less time collecting data and more time analyzing it?
- ▶ How do our portfolio/franchise/project plans align with short-term and long-term company objectives?
- ▶ How do we optimize the budget and internal resources to conduct the development projects we have authorized?
- ▶ If we modify the resource allocations (\$ & FTEs) for one program, what effect does that have on other programs?
- ▶ If we modify budget/resources to a program, can we accelerate the timeline, what is the effect on the project value?
- ▶ What are the forecasted resourcing needs to implement the optimal project and portfolio plans?
- ▶ How accurate are our forecasting assumptions based on industry best practices? (e.g. Vertex Planned vs. Vertex Actual vs. CMR)
- ▶ How well are we executing on our development plans? What areas, if any, need improvement?
- ▶ Should we in-license or out-license a program? What are the associated costs/value to in/licensing or out-licensing? When is the right time to in/out-license?

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## Vertex Approach

The approach we took began with:

- ▶ Identified & clarified business need. Presented business case and secured support of IS, IT, Finance & Sr. Mgt.
- ▶ Identifying "as is" and "desired" state of data gathering, portfolio decision making tools & processes.
- ▶ Drafted an early version of the requirements for identifying and implementing a project and portfolio management tool.
- ▶ Evaluated a diverse set of market solutions to arrive at choice of optimal tool – Assessed feature sets, usability, scalability, feedback from other customers, customer base etc.

Identified & partnered with external consulting resources (Intendere Consulting...now part of PwC's Pharmaceutical Strategy Practice) to help Vertex to:

- ▶ Formulate a system and process implementation strategy,
- ▶ Map "as-is" & develop "desired" business processes and operating framework,
- ▶ Formulate and finalize system requirements, and
- ▶ Drive the implementation to successful completion.

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## ST and LT Objectives

Our implementation strategy was carefully segmented to achieve in the following key short-term & long-term objectives:

Short Term Objectives:

- ▶ Capability to provide project & portfolio level visibility of resource demands (\$ & FTE), supply and drivers (milestones and goals)
- ▶ Provide mechanism to view current/updated individual project timelines, internal (FTE) and external costs (actual & forecasts)
- ▶ Provide dynamic (real-time) scenario planning (What-If) capabilities for
  - Teams to identify optimal development strategy for each project within the resourcing constraints & parameters
  - Matrix side of the organization to identify resourcing gaps (\$ & FTEs) and formulate mitigating strategies

Long Term Objectives:

- ▶ Ability to perform strategic planning & probability modeling in the context of market opportunity, cost and risk balancing
- ▶ Ability to perform portfolio optimization including more robust capacity planning

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## Implementation Challenges / Lessons Learned

- ▶ Ensure top-down organizational buy-in
- ▶ Draft a business case with a clearly articulated business need and the ROI
- ▶ Identify/Map business processes prior to defining requirements
- ▶ Partner with outside expertise to facilitate identifying and implementing business process changes
- ▶ Clearly understand implications of choice at each stage of the project
- ▶ Determining the proper method to developing/changing process, culture and operating model
- ▶ Come up with a reasonably staged system implementation plan/evolution map
- ▶ Do not underestimate the time or effort involved!!! Get management to commit the resources (FTEs) needed to do this in a reasonable time frame.

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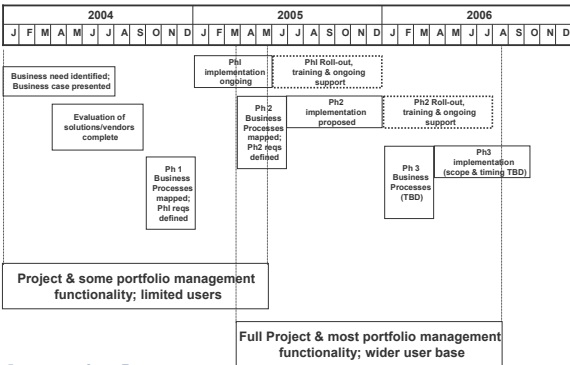
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## Project Status




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