

# **PMPharma—Project Managers in Pharmaceuticals**

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*Business Development and Project  
Management:*

**Can't We All Just Get Along?**

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# Therapeutic Strategic Partnerships Will Continue to Be a Staple of the Industry

- ✓ While industry spending on R&D doubled from 1994 to 2003, NCE approvals declined 25%!
- ✓ 231 drugs representing approximately \$52 billion in revenue are going “off patent” in the five-year window 2003-07
- ✓ 75% of the aggregate cost of drug development is attributable to product attrition prior to registration
- ✓ Phase III deal value increased by 250-300% 1997-2002, while preclinical/phase I deal values declined

# Hypothetical Discussion Around a Therapeutics Corporate Partnership

## √ BioPharmaceutical, Inc.

- λ Large, publicly traded firm with substantial revenue base
- λ Typically acts as the “buyer” in strategic partnerships
- λ Accessing technology and potential products

## √ Gene Discovery, Inc.

- λ Small, privately held start-up with low revenue base
- λ Pursuing strategic partnership as #1 or #2 corporate objective
- λ Typically acts as the “seller” in such partnerships

## √ What role, if any, should project management play in the development of this deal?

# Strategic Considerations of BioPharmaceutical and Gene Discovery

## √ BioPharmaceutical, Inc.

- λ Interested in PRODUCTS—not TECHNOLOGY
- λ Wants a clear path to IND filing and/or clinical milestones
- λ Facing a shortage of in-licensing opportunities in a competitive field

## √ Gene Discovery, Inc.

- λ Rich in TECHNOLOGY—not PRODUCTS
- λ Board is bearing down on management—where's the beef?
- λ Needs to put some “lipstick on the pig” and get it sold

# Houston...Do We Have a Problem?

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- √ Strategic objectives of both companies militate toward getting a deal done ASAP
- √ BioCo has early-stage technology that must be validated in the form of a corporate partnership
- √ PharmCo has a strategic imperative to FILL THE PIPELINE
- √ Is this a good time to consider the hard realities of biological drug development (e.g., bring in PM)?

# Project Management Can Bring Value to the Deal Making Process

## √ BioPharmaceutical, Inc.

- λ Define time/resource implications of developing new products
- λ More in-depth understanding of the technology/product opportunity
- λ Strengthen diligence provisions
- λ Improve negotiating position

## √ Gene Discovery, Inc.

- λ Define time/resource implications of the product opportunity
- λ Prepare for negotiation of development-related provisions
- λ Build credibility and respect with the other side

# Get Real—You Want to Integrate PM Into the Deal Making Process?

- ✓ BioPharmaceutical, Inc.

- λ Already has too many cooks—trying to streamline the BD process
- λ Pressure from the top to get deals DONE!

- ✓ Gene Discovery, Inc.

- λ Even greater pressure to get the deal done
- λ Management not interested in hearing about the hurdles of drug development

# Integrating PM Into the Deal Making Process: How, Where, When

- ✓ Formal or de facto “deal team”—similar to the project team for drug development
- ✓ Active buy-in of top decision makers (CEO at BioCo) on PM participation is fundamental
- ✓ In one company, the PM can and will be highly visible
- ✓ In other companies, the PM will play a moderated role behind the scenes

# When It Doesn't Make Sense to Involve a PM in Deal Making

- ✓ When the PM can add value—bring them in!
- ✓ When the PM doesn't add value—they should stay out of the picture—as with any project team
- ✓ Deals in which PM input *may or may not* be necessary:
  - λ Out-licensing of technology or products
  - λ In-licensing of well-defined technology piece
  - λ Sponsored research agreements
  - λ Mergers and acquisitions

# When It Makes Tons of Sense to Involve a PM in Deal Making

- ✓ When the PM can add value—bring them in!
- ✓ When the PM doesn't add value—they should stay out of the picture—as with any project team
- ✓ Deals in which PM input *may* make sense:
  - λ In-licenses where successful product development is key to realizing deal value
  - λ TECHNOLOGY in-licensing with project milestones
  - λ Sponsored research agreements—project milestones
  - λ Mergers and acquisitions—project milestones

# How to Introduce the PM Function into the Deal Making Process

- ✓ CEO and/or key “deal” decision maker buy-in
- ✓ Personal touch with deal coordinator(s)
  - λ BD manager, inhouse counsel, R&D head, etc.
  - λ Title of this person differs across organizations
  - λ Actual responsibility may differ from what you hear
- ✓ Stay focused on the value add
  - λ Be very cognizant of the need and your contribution
  - λ Look for good fit with deal coordinator’s preferences