Concepts in 
Pharmaceutical Development Project 
Management 
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Disclaimer
The views expressed in this talk represent my opinions and do not necessarily represent the views of the FDA.
Introduction

By way of …
Small
Medium and
Large Pharma

& the FDA
OND\CDER\DNP (Div Neurology Products)
Objectives
Clinical Development (CD) as a complex science and set of relationships
Review the concept of Clinical Development
Discuss the components of the clinical development team
The role of the CD Project Manager (PM) (CDPM)
Tools for the CDPM
How to succeed (and fail) as a CDPM
Recommended Reading
Book cover – Pharmaceutical Project Management edited by Tony Kennedy
Cartoon: Man & woman standing on a square that reads “Square One” and the caption “Well, here we go again.”
What is
Pharmaceutical Development
Chart showing the process of pharmaceutical development
Aim of Pharmaceutical Development

**CMC [21 CFR 312.23(a)(7)]:**
To assure the proper identification, quality, purity, and strength of the investigational drug.

**Nonclinical [21 CFR 312.23(a)(8)]:**
To assure that it is reasonably safe to conduct the proposed clinical investigations.

**Clinical [FD&C Act Sec. 505]:**
To establish efficacy and safety of a drug for use in humans, in a dose range and schedule that provides an acceptable risk benefit relationship.
Drug Development Process

Chart showing how a drug is developed
What is a Pharmaceutical Project Team

Graphic showing who makes up a pharmaceutical project team
The team at the first level
Graphics showing the first level teal of a pharmaceutical project team
What is a Clinical Development Project Team

Graphics showing the clinical development project team and their roles.
The Matrix Model for Project Teams

A graph sowing the matrix model for project teams
INTERNAL FORCES

Graphic showing internal forces

All of the components below are part of “Your Project”

Evaluation
Team
Turf
Strategic Intent
Marketing
Selection
Decision Making
Time
Quality
EXTERNAL FORCES

Graphic showing external forces that impact “your project”

Competition
Commercial Potential
FDA/BoH
Congress
Reimbursement
Activists
Time
“A second increase in the Health Care Financing Administration reimbursement rates for Epogen has aided in increasing the valuation of Amgen in the financial community.”

“On June 19, HCFA issued a program memorandum to payers that directed payment of claims for Epogen (erythropoietin alfa) in patients whose hematocrit levels reach as high as 37.5%”
Project Management
Value to the Development Process

Cartoon of boys arguing on the playground: “Oh yeah? Well my dad’s earned values is bigger than your dads!”
EXPANDED REIMBURSEMENT
“HCFA Reimbursement For Epogen, Takeover Talk Help Amgen Grow in June”

On June 24, Gruntal & Co. analyst David Saks predicted that the new reimbursement policy could result in a 10% increase in use; Epogen sales in 1997 were about $1.07 bil. And Amgen’s total revenues were $2.4 bil. Gruntal upgrades Amgen from “buy” to “strong buy.”

“The Pink Sheet” 7/6/98 page 20
Cost of Poor Management

$ 899 MM/Each New Drug
Opportunity Costs
Failed Drugs
Marketing & Sales Costs
The Patients are Still Waiting
• Benefit of Good Management
  Higher NPVs
  More Products per $
  Identify Losers Sooner
  More Successful Projects
  Faster Reviews
Shrinking time to second in class requires that you get out of the gates fast & hard

Graph showing years between drug launch and first competitor

Source: A.T. Kearney. The Economist 09/20/97
Pharmaceutical Project Management

Photos and cartoons of people in the project management field and of people working in a pharmacy.
What is Project Management?

PMBOK

“Project management is the application of knowledge, skills, tools, and techniques to project activities in order to meet or exceed stakeholder needs and expectations from a project.”
PM EVOLUTION
The Faces of Clinical Development Project Management
Duties of the Project Manager

Project Management of Business Process

- Portfolio Design, Planning & Management
- Planning
- Scheduling
- Resource Allocation
- Human Factors (Teams)
- Decision Making Process
- Process Leadership & Benchmarking

WHAT IS PROJECT MANAGEMENT?

1. PORTFOLIO
   - Design & Planning
   - Management

WHAT IS PROJECT MANAGEMENT?

PLANNING
   - Objectives
   - Strategy
   - Tactics
   - Go/No Go Criteria: Prespecified
   - Integration
   - Budgeting (Finance)

WHAT IS PROJECT MANAGEMENT?

SCHEDULING
   - Deadlines
   - Velocity
– Acceleration
– Tradeoffs

**WHAT IS PROJECT MANAGEMENT?**

• RESOURCE ALLOCATION
  – Capacity
  – Relative to timing needs?
  – Financial
    • Budget (Forecast)
    • Accounting (Status)

**WHAT IS PROJECT MANAGEMENT?**

• 6. HUMAN FACTORS
  – Leadership
  – Team Building
  – Matrix/Heavy-weight Teams
  – Communication
  – High Performance
  – Education

**WHAT IS PROJECT MANAGEMENT?**

• FACILITATING DECISIONS
  – Selecting Clinical Candidates
  – Implementing
  – Tracking
  – Reporting
  – Completing/Terminating

**WHAT IS PROJECT MANAGEMENT?**

**FACILITATING DECISIONS**

**WHAT IS PROJECT MANAGEMENT?**

• PROCESS LEADERSHIP AND BENCHMARKING
  – Knowledge of the Overall Process
  – Knowing What is Needed Next
  – Knowing How Long it Should Take & How Much It Costs
What is Project Management?:
Interpersonal Quotient

• Broad Knowledge
  – Experience
• Interpersonal Skills
• Ability to get the most out of tools / technology
  – Innate analytic
• Communication Techniques

What is Project Management?:
Knowledge

• Drug development process & benchmarking
• Science/Medicine (therapeutic area)
• Regulations
• Business
• Portfolio management
• Alliance Management

What is Project Management?:
Interpersonal Skills

• Network planning
• Strategic thinking
• Negotiation
• Meeting management

What is Project Management?:
Tools of the IQ

• Planning software
• PERT charts
• Gantt (bar) charts
• Dashboards

What is Project Management?:
Communication Techniques

• What if analyses
• Critical path analyses
• Brainstorming
• Challenging (devil’s advocate)

Tools for the Project Manager
Team Minutes Template
Team Meeting Minutes
Target Product Profile
Target Product Profile
Target Product Profiles
Product Labeling: New Format Highlights
Section
Why is Labeling Important
Product Labeling: New Format Full Prescribing Information

Strategic Development Plan

GANNT Chart
GANNT Chart

Probability Exercises for Project and Portfolio Planning
Summary