

# PROJECT MANAGEMENT IN DRUG DEVELOPMENT: PHASE III TO COMMERCIALIZATION AND BEYOND

NORTH CAROLINA STATE UNIVERSITY'S BTEC

<http://www.btec.ncsu.edu/contact>

## Course Information

Room 123 at BTEC:  
7-8 DECEMBER 2009

Course Cost: \$990

Early Registration Discount:  
Save \$100 for registration prior to Nov 23, 2009

Multi-Attendee Discount (from same company):  
Save \$200 on each additional registration



An intensive two-day program for project managers or individuals with project management responsibilities in the pharma and biotech industries.

- Learn to use the fundamentals of project management for drug development projects
- Learn what skills are needed to implement, monitor, and control these types of projects
- Learn how to create a project team and develop project objectives, plans, and timelines
- Learn how to create a target product profile that highlights the key features of the end-product

## Why You Should Attend

As a new drug candidate enters late-stage clinical development, project managers must shift their focus from development to preparing to enter the marketplace. A few of the challenges associated with Phase III and Commercialization include regulatory submission, manufacturing scale-up, and promotional launch.

In order to successfully transfer from Phase III to Commercialization, project managers must learn how to apply the fundamentals of cross-functional project management to these later stages of drug development. Particular skills are needed to effectively implement, monitor, and control late stage projects.

By following the procedures and using the tools and templates provided, this course will allow you to successfully manage late-stage drug development projects and avoid costly delays during the shift from Phase III to Commercialization.

## Who Should Attend

Any individual who holds project or program management positions and/or individuals with project management responsibilities in the Pharmaceutical and Biotechnology industries, including but not limited to the following job functions:

- Project/Program Manager
- Clinical Operations Manager
- Clinical Trial Manager
- Clinical/Medical Affairs Director
- Regulatory Affairs Manager
- Portfolio Manager
- Project Coordinator
- Plant Manager

## How To Register

Email: [stephen.perry@kymanox.com](mailto:stephen.perry@kymanox.com)

Web: [www.kymanox.com/services/  
ProjectManagementCourse.php](http://www.kymanox.com/services/ProjectManagementCourse.php)

<http://store.kymanox.com/trco.html>

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## Course Outline

### Day 1 - Phase III

#### Lecture 1. Introduction

- Introduce course & key objectives
- Outline drug development process
- Define key project management concepts & terms

#### Lecture 2. The Project Team

- Determine which departments and/or disciplines should be represented
- Communicate with stakeholders

#### Lecture 3. Updating the Target Product Profile (TPP)

- Identify what has changed from the original TPP
- Identify what factors must be considered for the TPP

#### Lecture 4. Developing Project Objectives

- Understand importance of defining project objectives
- Develop & examine typical Phase III project objectives
- Understand relationships between project objectives

#### Lecture 5. Developing the Project Plan

- Develop the Work Breakdown Structure
- Identify critical path & develop sequence of activities
- Resource the plan & manage risks

#### Lecture 6. Developing the Timeline & Budget

- Create timeline & use timeline tracking tools
- Develop the budget & use budget tracking tools

#### Lecture 7. Project Implementation, Monitoring & Control

- Respond to risk & assure quality
- Outline decision making process
- Utilize monitoring tools & communicate progress

### Day 2 - Commercialization

#### Lecture 8. Transition from Phase III to Commercialization

- Identify the stakeholders
- Ensure a successful "hand off"

#### Lecture 9. Redefining Your Project Team

- Define the roles of Clinical Development, the Product Team, & Medical Affairs

#### Lecture 10. Updating the Target Product Profile (TPP)

- Identify changes from original TPP
- Identify what factors must be considered for updated TPP

#### Lecture 11. Developing Project Objectives

- Examine & define typical commercialization project objectives
- Prioritize objectives & identify strengths/opportunities

#### Lecture 12. Developing the Project Plan

- Develop the Work Breakdown Structure
- Identify critical path & develop sequence of activities
- Resource the plan & manage risks

#### Lecture 13. Developing the Timeline & Budget

- Create timeline & use timeline tracking tools
- Develop the budget & use budget tracking tools

#### Lecture 14. Project Implementation, Monitoring & Control

- Respond to risk & assure quality
- Outline decision making process
- Utilize monitoring tools & communicate progress

#### Lecture 15. Summing It All Up

- Analyze the state of project management
- Anticipate future trends in project management

### After this course you will be able to...

- Select the right cross-functional team to ensure project success
- Effectively communicate with internal and external stakeholders and prevent communication breakdowns
- Develop useful project objectives and project plans
- Apply risk management strategies when developing project objectives and making risk-based decisions
- Create and manage an achievable timeline and budget
- Successfully transition from Phase III to commercialization and avoid costly delays

### Attend and you will receive...

- 15 in-depth lectures on the specifics and mechanics of technology transfer
- Interactive discussions, quizzes, and activities to reinforce the course content
- Detailed list of documents and editable templates required for successful management of late-stage drug development projects
- Access to an instructor with first-hand project management and drug development experience
- Support of Kymanox capable staff for all of your technical project management needs

### About Your Instructor

Stephen M. Perry, PMP – President, Kymanox

### About Kymanox ([www.kymanox.com](http://www.kymanox.com))

**Kymanox is dedicated to assisting companies and individuals  
with knowledge transfer on a project-by-project basis.  
Serving the biotechnology, pharmaceutical, and medical device  
communities, we help get projects** 