

Industry's Largest and Most Comprehensive Event on Project Management for Research and Development!

Project Management for Research and Development

March 28 - 31, 2006 • Crowne Plaza Hotel at Union Square • San Francisco, CA

Hear from 20 Industry Project Management Experts from these companies

- Aradigm Corporation
- AstraZeneca
- Avecia Ltd.
- Baxter
- BD Diagnostic Systems
- Chiron Corporation
- CSSC, Inc.
- Equinox Consulting, LLC
- Harpum Consulting
- Hornbacher Associates
- IntraSphere Technologies
- Invitrogen Corporation
- Integrated Project Management Company, Inc.
- MannKind Biopharmaceuticals
- ORBee Consulting
- Rescentris, Ltd.
- Roche
- University of Iowa
- University of Pennsylvania

PDU CREDITS

PMPs attending the conference may be able to earn Category 4 PDU credits, but they should consult the Continuing Certification Requirements available on the PMI website (www.pmi.org) for information on the reporting process and documentation required.

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Special thank you to Technical Advisor:

TIM NOFFKE,
PMP, Vice President-Life
Sciences, Integrated Project
Management Co., Inc.



FEATURED TOPICS INCLUDE:

- Developing Realistic Drug Development Project Plans
 - Discovery Project Management
 - Decision Making
 - Cutting Development Time
 - Building and Developing Highly Successful Project Teams
 - Managing Research & Development Cost, Risk & Productivity through Globalization
 - Tools for Project Management
 - Uncertainty Management in Drug Development Projects
 - Strategies for the Validation of Biotechnology Methods
 - Projects, Portfolios & Programs (P³): Educational Options
 - The Clinical Trial Process
 - Applying Roadmap Processes to the Clinical Trials/Project Process
 - Simple vs. Complex Portfolio Valuation
- PLUS MANY MORE!

CREATE-
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34

INTERACTIVE
WORKSHOPS,
EXPANDED
SESSIONS AND
GENERAL
SESSIONS!

Project Management for
Research and Development • March 28 – 31, 2006



7:30 AM – Conference Registration and
Continental Breakfast

Interactive Workshop A 8:30 AM – 12:00 PM

Developing Realistic Drug Development Project Plans

Peter Harpum, MSc, MAPM, Life Sciences Practice Leader and Director, Harpum Consulting

I. The Theory of Project Planning and Control

- What makes drug development planning different to planning in other sectors?
- Developing and documenting drug project scope
- Estimating time, cost, and human resource requirements
- Scheduling the project
- Creating the project budget
- Assigning human resources to the work and assessing the impact on the schedule

II. Experiences from Industry on Implementing Realistic Planning Techniques

- How the need for realistic planning was recognized
- Implement new planning practices
- The impact on the projects and business of realistic planning

III. Developing a Project Plan: Case Study

- Using the case study supplied, working in teams
- Build a logic linked network diagram
- Document the schedule by creating a Gantt chart
- Build a cash flow curve
- Allocate resources to the schedule

IV. Interactive Exercise

- Compare the existing practices to the techniques learned in the workshop

Interactive Workshop B 8:30 AM – 12:00 PM

Improving Management of Discovery Stage R&D Projects

Jeff Spitzner, Ph.D., Chief Science Officer, Rescentris, Ltd.

I. Discovery Project Management – How is it Different from Managing Later Stage Pharma Projects?

- Discovery stage data: irregular and incomplete
- Discovery projects are unique
- Barriers between science and business

II. The Audit – What Do We Have and Where Is It?

- Evaluating and classifying discovery stage portfolios
- Mining reports, lab notebooks, information systems, and research teams
- Strategic business and portfolio goals

III. Protecting and Capitalizing on the Intellectual Assets of the Project

- Impact of record-keeping systems
- Managing knowledge, skills and expertise
- Proactive strategies for capture, analysis, and exploitation of intellectual property

IV. Discovery Stage R&D Activities and Strategies

- Tracking progress
- Project performance indicators and alternative options
- Product development projects versus platform technology projects (science, IT)

V. Increasing R&D Project Performance

- Collaboration of science and business strategies
- Using electronic lab notebooks
- Strategies for managing lower priority projects

VI. Evaluating Projects in Relation to R&D Portfolio Management Strategies

- Integrating strategic business needs and alignment
- Matching needs against licensing opportunities
- Auditing methodologies for portfolio review
- Rebalancing portfolios based on strategy, performance, and product concept
- Allocating resources and expertise

VII. Interactive Exercise: Evaluating a Discovery Stage Project

Participants will review a fictional discovery R&D project and make recommendations to improve performance.

Participants will take home the following Bonus Information:

- A scorecard to assess key parameters of the discovery stage R&D project management
- A problem-solution matrix to identify methods
- Tools to improve the communication between technology and business units in your organization

Interactive Workshop C 8:30 AM – 12:00 PM

Decision Making: How to Make Strategic Project Decisions Consistently

Eric Morfin, PMP, Director, Project Management Office, Chiron Corp.

I. The Context of Our Observations and Research

- Concepts on pharmaceutical and biotech case studies
- Enhance project and new product launch success
- Risk analysis
- Schedule, cost, and compliance

II. Levels of Decision

- Key decision making processes
- Reduce completion and launch time
- Controversy in decision-making

III. SDM (Strategic Decision Method)

- Use information available
- Efficient way to make decisions
- Address typical weaknesses
- Provide a systematic framework

IV. Identification Phase

- Decision title
- Establish goals
- Needs versus desires
- Examine all your Goals
- Goals scale of performance

V. Analysis Phase

- Gather options information
- Options versus Needs
- Options versus Desires
- Potential Problems

VI. Interactive Activity

Exercises will range from selecting a drug package to selecting a CRO to work with. Practicing these concepts on pharmaceutical and biotech case studies

Interactive Workshop D 8:30 AM – 12:00 PM

Building and Developing Highly Successful Project Teams

Martin Jenkins, PMP - Project Manager, BD Diagnostic Systems

I. Identifying Team Strengths and Weaknesses

- Defining the Team Constitution
- Determining skill sets present or not present
- Selecting the best candidate(s) for the job(s)

- Learn the 4 Project Management Behavior Types

II. Optimal Utilization of Team Members Resources

- Determine who you really need
- How to effectively utilize team members
- Identifying researchers, developers, and discoverers

III. Team Motivation

- Concession vs. consensus
- Identifying wrath
- Planning vs. notification
- Prime motivators
- When to exclude and when to include
- Motivating, leading, and inspiring a team
- When to reward, award, acknowledge or ignore

IV Organizing Teamwork

- Identifying natural and needed sub-teams
- Defining divisions of labor
- Tracking team and individual progress

V. Developing Team Spirit: "Whose Team is This Anyway?"

- What does the team really look like?
- How does the team really perform?
- The team self perception
- The project stake holder's perception

VI. Training and Development

- Developing the team that you will need tomorrow
- Development of the individual
- Developing area experts
- When and why to cross-train
- Establishing feedback channels

VII. Team Member Management: Distinguishing Between Intellectual People and Intellectual Property

- Identifying individual team member's impact
- The role of ethical behavior
- Overcoming the difficulty of difficult people
- Accepting the objections
- Minding your mint
- Moving the dead

VIII. Interactive Activity

The class will be divided into groups of 4 to 5 people who are each secretly assigned team member roles and personality traits. Each team must identify their leader, and then determine how they will accomplish their assigned team project with the human resources available to them in their group.

Tuesday, March 28, 2006

Main Conference General Sessions

12:00 PM – Luncheon

1:00 PM General Sessions Chairperson's Welcome and Opening Remarks

Eric Morfin, PMP, PMO Director, Chiron Corp.,
Partner, Critical Skills, Inc.



1:15 PM - 2:00 PM

Cutting Product Development Time

Tim Noffke, PMP, Vice President – Life Sciences, Integrated Project
Management Company, Inc.

Project schedules, risk assessments and mitigation plans must be robust and provide a catalyst for heroic results. This session will guide the participants through practical insights into how to achieve and even accelerate complex pharmaceutical R&D schedules by:

- Relating current drug development PM practices to general industry performance
- Creating an aggressive baseline development schedule
- Creatively compressing the baseline
- Analyzing and proactively managing risks and opportunities
- Reviewing case studies illustrating good schedule management techniques.

2:00 PM - 2:45 PM

The Long Road From Molecule to Market

Randy Dunson, MBA, PMP, President and Principal, Equinox
Consulting, LLC

This session presents an overview of the critical decisions in the drug development and review process. It also addresses challenges faced by pharmaceutical companies today and suggests fundamental components for success.

- Understanding the basics of drug development process
- Recognizing challenges faced by the industry
- Identifying some of the fundamental success factors for R&D

3:00 PM - 3:45 PM

Critical Chain Project Management (CCPM): Integrating a Resource Management focus into Schedule Development

Joel Adler, Ph.D., University of Pennsylvania

The Theory of Constraints first popularized by Eliyahu Goldratt (The Goal) offers some valuable insights into the management of resources to achieve operational objectives. These concepts were first developed for production scheduling and subsequently extended to project management as CCPM. Critical chain concepts extend the benefits of classical critical path project management approaches by:

- Reducing the duration of projects
- Reducing the number of concurrent tasks for individuals (multi-tasking)
- Reducing "critical path jitter"
- Simplifying project monitoring and intervention
- Prioritizing project schedules to reflect resource constraints

3:45 PM - 4:30 PM

Software Vendor Due Diligence Selection Process Using a Pugh Matrix and Regression Analysis Tools.

Fran Kennedy, PMP, Senior Manager, R&D, Invitrogen Corporation

This session focuses on the processes and tools used for assisting with the most appropriate vendor selection based on your company requirements. These tools will assist you with any software vendor due diligence process.

- Identify the company specific requirements
- Identify the system specific requirements
- Define your Pugh Matrix
- Identify the requirement weighting factors
- Complete the vendor rating
- Define regression analysis tools
- Determine final vendor selection

4:30 PM – Close of Day One

4:45 – 6:00 Networking Cocktail Reception



Wednesday, March 29, 2006
Main Conference Half-Day Workshops

7:30 AM – Continental Breakfast

Interactive Workshop E 8:30 AM – 12:00 PM
Managing R&D Cost, Risk and Productivity Through Globalization

Dr. Mani Subramanian, Professor, Department of Chemical and Biochemical Engineering, Director, Center for Biocatalysis and Bioprocessing, University of Iowa

I. The Problem of Escalating R&D Costs Coupled with Unsatisfactory Productivity.

- Quantifying the problem and its impact
- Defining the R&D value chain
- Building a case for change through illustrative real world examples

II. Outsourcing as a First Level Model for Enhancing Productivity

- Outsourcing models and cost issues the pros and cons
- Structuring outsourcing, both long and short term
- Project management issues and essentials

III. R&D Globalization and the Evolution of the Risk/Reward Model

- Companies with R&D centers in Asia
- Partnering with Asian companies in a risk/reward model
- Potential conflicts and issues requiring consideration and resolution

Interactive Workshop F 8:30 AM – 12:00 PM
Uncertainty Management in Drug Development Projects

Peter Harpum, M.Sc., MAPM, Life Sciences Practice Leader and Director, Harpum Consulting

I. The Theory of Uncertainty Management:

- Data supporting criticality of managing uncertainty
- Underlying theory of risk and opportunity management
- The approach to uncertainty management
- The uncertainty management process
- Timing of uncertainty workshops
- The register of uncertainty (risk and opportunity logs)
- Identifying uncertainty in drug development projects

II. Interactive Exercise 1

- Participants will use the case study provided, and identify project uncertainty for a drug development phase.

III. Assessing Risks and Opportunities

- The need to prioritize risks and opportunities
- Qualitative versus quantitative scoring
- Creating impact and probability score sheets
- Reporting information on drug project uncertainty

IV. Interactive Exercise 2

- Participants will score and report on the risks and opportunities identified from interactive exercise 1

V. Developing Action Plans for Risks and Opportunities

- Actions to take to control risk
- Actions to take to maximize opportunities
- Monitoring the impact of action plans on the project

VI. Interactive Exercise 3

- Develop action plans for the risks and opportunities identified in Workshop 1

VII. Integrating Uncertainty in Functional Sub-Teams with the Drug Project Team

- Managing the vertical integration process
- Setting up effective escalation procedures
- Horizontal integration
- Reporting on integrated uncertainty management activities

Interactive Workshop G 8:30 AM – 12:00 PM
Balancing Project Excellence with Speed to Market for Commercialization

Matthew Atwong, P.E., M.B.A., MSChE, BSChE, Executive Director, Start Up Consultants

I. Getting a Drug to Market Discovery to Commercialization

- Sequence of events from research to commercialization
- Magnitude costs
- Options for commercialization of new drug
- GLP to GMP
- In-house to outsourcing
- Pilot plant to manufacturing facilities

II. Select a Pilot Plant or Manufacturing Facility

- Mission of a pilot plant
- Pilot plant location, size and capacity considerations
- Single versus multiple products
- Mission of manufacturing plants
- Upstream and downstream integration
- Utilities

Wednesday, March 29, 2006 Main Conference Half-Day Workshops

- Validation and pre-approval inspection on PAI

III. Considering Strategic Inputs

- Impact of development and launch schedules
- Availability of capital
- Build or outsource
- Buy or grass-root
- Site selection
- Regulatory and tax concerns

IV. Ensure Technical Excellence

- Understanding GMP and validation requirements
- Evaluate process capability and process flexibility
- Assess the degree of process automation
- Utility integration
- Environmental health and safety considerations

V. Interactive Exercise

Participants will discuss the execution of a utility project and the tax, revenue and savings benefits on time delivery

Interactive Workshop **H** 8:30 AM – 12:00 PM Strategies for the Validation of Biotechnology Methods

Graham McPherson, Ph.D., Analytical Development Manager, Avecia Biotechnology, UK

I. Method Validation Documentation

- ICH 2A & ICH 2B guidelines
- Introduction, the objectives and guidance

II. Regulatory Guidance Documents

- FDA examples
- Understanding the implications

III. Regulatory Expectations

- Quality and quantity
- Safety, efficacy, and consistency in product manufacture
- Biochemical activity
- Purity, impurities and contaminants
- Immunochemical properties

IV. The Verification/Validation Process

- Qualification, verification and validation

V. When to Verify/When to Validate

- Evolution of the validation of assays
- Front-loaded, back-loaded and iterative approach
- Strengths and weaknesses of these approaches

VI. Specifications and Process Evolution

- The statistical basics
- Quantifying variability
- Analytical capability
- Setting specifications

12:00 PM – Luncheon

Wednesday, March 29, 2006 Main Conference General Sessions

1:00 PM – 1:45 PM

Tools for Project Management (What You Need to Know to be Successful)

Eric Morfin, PMP, Director, Project Management Office, Chiron Corp.

This session focuses on the critical tools needed to sustain a high performance project management environment. These tools have more to do with leadership than software, although high performance is hard to achieve without an EPM (Enterprise Project Management) solution. The session will cover the following tools:

- Strategic Decision Making Method "SDM"
- Root Cause Analysis Tool "PAM"
- Project Leadership Styles "MBM"
- Influencing Project Management Software, Microsoft Project and MS Project Server 2003 as an EPM solution

1:45 PM – 2:30 PM

Projects, Portfolios and Programs (P3) - Educational Options

Joel Adler, Ph.D., University of Pennsylvania

The nature of work is changing. There are fewer on-going operational tasks and more work with a beginning and end, i.e. projects. This is the inevitable result of automation, the information age and globalization. Therefore professionals must be prepared to engage more in new initiatives that launch programs that achieve objectives by developing portfolios of one or more projects. P3 skills are typically learned on the job but this learning can be augmented and accelerated through more formal educational.

- Formal education options:
- Objectives and expected outcomes of each option
- Criteria for deciding which option is best for you

2:30 PM – Refreshment Break

Wednesday, March 29, 2006
Main Conference General Sessions

2:45PM – 3:30 PM

Project Cost - Estimation, Prediction, and Analysis

Martin Jenkins, PMP - Project Manager, BD Diagnostic Systems

This session focuses on practical methods for identifying, accurately estimating, predicting, monitoring, and analyzing project cost. These techniques and methods are ideal for project managers who are not financial analysts:

- When and how to determine the project budget
- How to determine accurate cost estimates
- Applying Earned Value techniques to monitor and predict project cost
- Determine the real cost of the actual project performance
- How to keep your projects on the right financial track

3:30 PM – 4:15 PM

Project Management for Method Validation

Graham McPherson, Analytical Development Manager, Avecia Biotechnology, UK

- Understanding the issues
- Gathering verification data
- Phase of program (pre-clinical through to phase IV)
- Deciding the Priority Issues
- Planning the Validation Strategy
- Acceptance Criteria

4:15 PM – 5:00 PM

Most Common Project Management Obstacles

Harsukh Parmar, Ph.D., Director, Global Discovery Medicine, Respiratory & Inflammation Therapeutic Area, AstraZeneca

The four critical factors for success in Project Management revolve around: time or speed to market, a transparent cost management process, maintenance of high quality throughout, and a clear risk-management process. The most common obstacles to PM also revolve around these issues. Failure to develop a clear understanding of the interplay and impact of each of these 4 factors can and usually does lead to major obstacles:

- Poor communication
- Budget over-runs
- Poor leadership
- Technical scientific issues
- Lack of resources and people with appropriate technical skills to solve problems
- Poor team dynamics and lack of understanding of cross-cultural issues

5:00 PM – Close of Day Two

Thursday, March 30, 2006
Main Conference Half-Day Workshops

7:30 AM – Continental Breakfast

Interactive Workshop I 8:30 AM – 12:00 PM
Implementing Project Risk Management Processes that Work for You

Keith Hornbacher, MBA, Principal Consultant, Hornbacher Associates

I. Evaluate Your Organization's Project Risk Management Maturity

- Use assessment matrix developed by experienced practitioners
- Understand your project risk management culture

II. Discuss Risk Management Methods as Defined in the Project Management Standards: American National Standard (ANS) (ANSI/PMI 99-001-2004)

- Review the methods published by the Project Management Institute (PMBOK_ Guide, 3rd Ed.)
- Learn how to tailor six key processes for your specific needs

III. Removing Constraints to Be Effective

- How can these practices be applied in my organization?
- How are real project risks identified, analyzed, and handled?
- Does this method apply to programs, and portfolios?
- Is there a simple way to manage project risk?

IV. Interactive Exercise

- Work through examples in identification, qualitative and quantitative analysis
- Immediately add value by working with one of your real

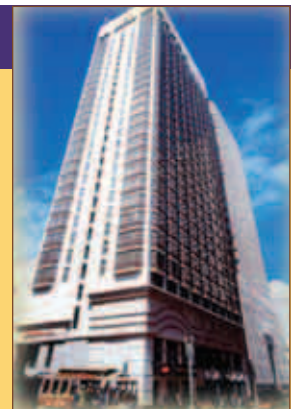
HOTEL INFORMATION

Crowne Plaza Hotel

San Francisco-Union Square
480 Sutter St., San Francisco, CA 94108
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Hotel Reservations – 800-980-6439
Hotel Front Desk – 415-398-8900

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A special room rate has been pre-arranged for conference participants. You must call the hotel directly by March 3, 2006 at the above number and mention IVT to receive the reduced room rate.



Thursday, March 30, 2006 Main Conference Half-Day Workshops

- projects
- Benefit from facilitated discussion with other professionals

V. Toolkit - The toolkit will include

- Organizational project risk management maturity assessment matrix
- Project Risk Management effectiveness metrics
- Glossary of terms

Interactive Workshop J 8:30 AM – 12:00 PM **The Clinical Trial Process**

Randy Dunson, MBA, PMP, President and Principal, Equinox Consulting, LLC

Clinical trials are research studies involving people. They seek to answer specific scientific questions to find better ways to prevent, detect, treat diseases, and to improve care for people with diseases. Clinical trials differ by type of trial and phase of trial. Each clinical trial follows a set of strict scientific guidelines called a protocol.

I. Clinical Trials Overview

- What Are Clinical Trials
- Clinical Trials - Types and Phases
- Treatment Trials
- Prevention Trials
- Other Types of Clinical Trials

II. Clinical Trials Protocols

- Participants assigning in Randomized Trials
- Dispelling Myths about How Clinical Trials Work
- Looking at a Clinical Trial Protocol

III. Interactive Exercise:

- Define clinical trials
- Name the different types and phases of clinical trials
- Describe how participants are assigned to groups in "randomized" clinical trials
- Review the purpose of a clinical trial protocol and its importance
- Dispel common myths about clinical trials

Interactive Workshop K 8:30 AM – 12:00 PM **Applying Roadmap Processes to the Clinical Trials/Project Process**

Joel Hoffman, Ph.D., Intrasphere Technologies

In technology projects, a good Roadmap will address the reality of project risks head-on by identifying the Who, What,

When, Where, Why, and How of a project as an essential component of project strategy and implementation planning. In this workshop, attendees will apply the techniques of technology Roadmaps to the clinical trial process.

I. Potential Critical Project Failure Points

- Exploring approaches for remediation
- Avoiding failure altogether through developing a project roadmap.

II. Identifying Potential Markets

- Technical and product information
- Resources to support development of the roadmap

III. Work Product and Summaries

- Current State Assessment - A review of the current state of the people, process and technology environments relevant to the initiative
- Visioning and Gap Analysis
- Governance
- Business Case

IV. Interactive Exercise:

- Participants will work with case studies and competing approaches to their resolution. Teams will develop Roadmaps reflecting their choices. Tools, materials and worksheets will be distributed during the session.

12:00 PM – Luncheon

Thursday, March 30, 2006 Post-Conference 90-Minute Sessions

Interactive Session 1 1:00 PM – 2:30 PM **When Worlds Collide: Maximizing Value in Alliance Projects**

John J. Turanin, Vice President, Corporate Planning & Program Management, Aradigm Corporation

I. Understanding Alliance Project Management

- What is it?
- How is it different?
- Why bother to learn about it?

II. Critical Success Factors for Alliance Project Management

- What are they?
- How should they be managed?
- How can I measure effectiveness?

III. Interactive Exercise

- Participants will apply these new skills in practical, real world scenarios.

Interactive Session 2 1:00 PM – 2:30 PM
Project Managing a Validated, Global Product Development Methodology Implementation

Fran Kennedy, PMP, Senior Manager, R&D, Invitrogen Corporation

I. 20 Global R&D Program Development Site Requirements

- Implementing a standard product development framework in an electronic software application.
- Identify requirements and processes for the standard program development methodology

II Defining the Scope

- Define process map for the stage gate program development methodology
- Define ISO/GMP standard operating procedures
- Define and execute functionality test cases
- Define and execute GMP Compliance Installation Qualification, Operational Qualification and Performance Qualification testing.
- Define training and Roll-out Strategy
- Review major challenges, issue resolution processes and lessons learned

Interactive Session 3 1:00 PM – 2:30 PM
Knowledge Management – and its Role in Project Management

Jeff Spitzner, Ph.D., Chief Science Officer, Rescentris, Ltd.

I. Knowledge Management (KM) Fundamentals

- Getting the right information to the right people at the right time
- Social not technical practice to improve business process
- Strategic process built on competencies and communication
- Leveraging intangible assets to solve problems, make decisions

II. Role of Knowledge Management in Project Management

- Utilizing knowledge assets for strategic planning, project assessment
- Increasing the visibility of project status and issues
- Matching resources with project priorities and skills needed

- Keep project on track and improve Project Management for the whole team

III. Implementing the Knowledge Management Process

- Disseminate KM best practices to improve performance
- Identify areas where KM can improve quality and timeliness of project data
- Identify bottlenecks in information flow - and the people involved in solving them
- Coaching team members to input data to KM systems & recognize benefits

IV. Interactive Exercise: Impact of Knowledge Management on Project Management

Participants will provide answers to a knowledge audit based on their own measures and experiences of information access, knowledge transfer, and decision-making processes, as well as existing KM tools and practices. The results will be discussed and applied to evaluate a fictional R&D project and its alignment with strategic business goals.

Participants will take home the following Bonus Information:

Case study reports from knowledge audits conducted at life sciences R&D companies.

Interactive Session 4 1:00 PM – 2:30 PM
Techniques for Managing Vendor Projects to Budget: Case Study

Andy Walsh, Manager, Validation Engineering, Roche
Bruce Fieggen, PMP, Director of Project Management, CSSC, Inc.

I. Earned Value Project Management

- Vendors project reporting
- Vendor accountability for project risks and overruns.
- Calculating the overall costs of projects
- Determining what percent complete the project is at any time during the project execution

II. Predicting the Final Project Cost

- Calculating real project cost, including the cost of internal resources
- Prioritizing between projects and relieve overburdened resources
- Calculating percentage complete of the project at any stage
- Compare percentage complete with percentage of budget spent and be able to explain to management where the shortfalls occurred and why
- Accurately predict final project cost at 15% of the way through the project.

Interactive Session 5 3:00 PM – 4:30 PM
Building a Development and Validation Strategy for Setting a Product Specification
Graham McPherson, Ph.D., Analytical Development Manager, Avecia Ltd.

I. Linking Specification Evolution to Process Evolution?

- Specification changes between clinical phases?
- Acceptability in terms of product safety
- Evolution of validation status of assays

II. The Impact of Specification Change and the Importance of Specification Evolution

- Risk-based techniques to aid specification development
- The use of regulatory processes
- What should the specification for a product be and when should it be set?

Interactive Session 6 3:00 PM – 4:30 PM
Management Reporting of Clinical Trial Programs, Portfolios, and Studies: Managing Risks / Managing Projects
Joel Hoffman, VP of Pharmaceutical Practice, IntraSphere Technologies

I. Management and Outcomes of Clinical Trial Studies, Projects, and Portfolios

- The importance of actionable information
- Example displays and processes
- Identifying and implementing mission critical approaches to managing trials and the risks associated with them

II. Implementing Reporting and Risk Management Approaches in your Organization

- Uncovering risks associated with the following trial challenges:
 - Safety
 - Efficacy
 - Recruitment
 - Timelines (other than recruitment)
 - Budgets
 - Resources
 - Systems

Interactive Session 7 3:00 PM – 4:30 PM
Clinical Trials Supply Chain Optimization
Vladimir Shnaydman, Ph.D, ORBee Consulting, President

I. Optimization of Drug Delivery Supply Chain

- Multiple unique investigator sites distributed geographically with a variety of schedules
- Uncertainty of patients' accrual rate
- Expensive clinical materials of limited quantity
- Significant shipping costs
- Expiration date

II. The Presented Technique Based on Optimization Approach

- Minimizing production, storage and shipping costs
- Optimizing manufacturing and delivery schedule
- Optimizing inventory level for each site
- Optimizing shipment size
- Minimizing waste of clinical materials

4:30 PM – Close of Day Three



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7:30 AM – Continental Breakfast

Interactive Session 8 8:30 AM – 10:00 AM

Critical Paths: Identify and Manage the Real Ones

Keith Hornbacher, MBA, Principal Consultant, Hornbacher Associates

I. Seeking Root Causes of Scheduling “Mal-Practice” and Internalizing Good Practices

- How can project sensors be tuned to detect early signals?
- What are the strengths and weaknesses of the Critical Path Method (CPM) schedule network analysis technique?
- Can schedule models really be dynamic?

II. Classic Critical Path Analysis

- Fundamentals
- Technical critical path
- Dispelling illusions of estimating to the “nth decimal” place

III. Critical Resource Path Analysis

- How key resources drive the project
- Introduction to Critical Chain scheduling
- What is unique

IV. Managing Paths Likely to Become Critical

- Identifying variables
- Validation and credibility
- Why this type of project management is different – or is it?

Interactive Session 9 8:30 AM – 10:00 AM

Simple versus Complex Portfolio Valuation: What Works Best?

Joel Adler, Ph.D., President, University Informatics Associates, Inc.

I. Valuation Techniques: Strengths and Weaknesses

- Decision trees
- Ordered lists
- Systems Dynamics/Simulation/Monte Carlo analysis
- Optimization
- Assembling Hybrid Systems

II. Context of Valuations Operation

- How are decisions made and who makes them?
- Is good data really there?

- Is there a consistent decision process?
- Is there a system with a structured user interface?
- How does judgment fit in? Is it part of the process or does it fight the process?
- Is someone ultimately responsible for the process?

III. Interactive Exercise

How does your company do portfolio management? Would you change the process? The objective of the session will be to make non-analytically trained individuals who participate in portfolio management activities more comfortable with the analytical vocabulary and more confident in understanding both the power and limitations of analysis.

Interactive Session 10 8:30 AM – 10:00 AM

Computer Validation Project Management - Best Practices and Case Study

Mark Kropp, MD, MannKind BioPharmaceuticals
Bruce Fieggen, Director of Project Management, CSSC

I. Central Data Base Validation

- Project plan milestones and deliverables
- UFRS collecting user requirements and researching functional capabilities
- Testing measurement limitations

II. Local Equipment and Instruments System Validation

- Validation project plan and project management tools
- UFRS and how the clinic is using their equipment in conjunction with the functional requirements of the vendor software
- Testing and examining boundaries

III. Interactive Session

Participants will analyze a Clinical Study and associated software while developing a project plan and strategy for managing a validation effort for FDA approval

Interactive Session 11 8:30 AM – 10:00 AM
How to Handle Multiple Projects and Stay Above the Water

Eric Morfin, PMP, Director, PMO Drug Development Projects, Chiron Corp. & Partner, Critical Skills Inc.

I. Systematic, Integrated Approaches to Improving the Management of Multiple Projects

- Project portfolio performance
- The OPP approach (Optimal Project Portfolio) management helps companies select the best projects for their businesses.
- Decision Analysis: a proven tool is applied, incorporating consistent objectives, rigorous evaluation, risk analysis and database management to guide client decision making.
- Portfolio selection: skills for planning and managing
- The social and technological environment in the company

II. Interactive Session

Discuss and analyze the key factors to help you stay above water.

10:00 AM - 10:15 AM – Refreshment Break

Interactive Session 12 10:30 AM – 12:00 PM
Project Management in Planning

Bruce Fieggen, PMP, Director of Project Management, CSSC, Inc.

I. The Project Objective

- Reaching agreement with all team members and stakeholders
- Learning the NASA technique for reaching this consensus
- Understanding the tradeoffs one can make when the project cost, schedule and performance are included in one statement
- Realize what to do when trying to control scope creep

II. Project Scope

- Name the tangible deliverables for the project
- Add the supporting deliverables that will be required over the course of the project
- Determine what is excluded from the project scope but some people think are going to be done

III. Work Breakdown Structure

- Determine all the tasks required to reach each one of the above deliverables
- Learn rules of thumb for deciding if a task is broken down far enough
- Learn how to manage the discovery process at this point.

IV. Responsibility Matrix

- See how overall responsibility for the project can be distributed fairly from the project manager to the team members
- Watch people commit to tasks
- Understand essentials of initial and on-going testing

V. Schedule

- Take the tasks from above and convert them into an MS-Project Gantt chart.
- Include the responsible person for every task.
- Allow the responsible person to commit to the task duration and predecessors.
- Distinguish between duration and hours of effort

VI. Budget

- Use the Responsibility Matrix to determine how many hours of effort are required by each person on the task.
- Roll up the costs to achieve a bottom-up estimate of the project cost.
- Compare this estimate to a parametric estimate of project cost.

VII. Project Plan

- Combine all of the above activities into the overall project plan.

Interactive Session 13 10:30 AM – 12:00 PM
A Virtual Pharma Model and Project Management for the 21st Century

Harsukh Parmar, Executive Director, AstraZeneca

I. 3 Key Components of a Successful Integrated Pharma Company

- R & D, Manufacturing Marketing
- Subcomponents of specialist skills required to succeed in each phase

II. Is an Integrated Pharma Model Right for You?

- Long lead times (>12 years) from conception to products
- Life-cycle management

- Patent expiry (> 20 years)
- Contracting out certain activities.

III. A Virtual Pharma Model

- Living in a global economy
- Specialist skills that are required for successful delivery are also available somewhere in the world.
- Leveraging special skills at the exact moment when they are most required
- The key employees of the virtual pharma model need to be highly skilled in a broad range of different areas and have powerful project management skills as system integrators who are well connected and networked into the global economy

Interactive Session 14 10:30 AM – 12:00 PM
Optimal Resources Capacity Planning for Clinical Research

Vladimir Shnaydman, Ph.D., ORBee Consulting, President

I. Resource Capacity Planning for Multiple Clinical Trials

- Significant number of clinical trials running simultaneously
- Multiple employee categories in each clinical trial
- Multiple uncertain and/or undocumented parameters affecting an employee workload
- Uniqueness of each clinical study
- Dynamic nature of resources allocation
- Planning uncertainty associated with unpredictability of study results
- Budgeting limitations
- Variety of business rules

II. Optimal Resources Allocation Across Multiple Clinical Trials

- Workload demand prediction across different employee categories and clinical trials
- Foundations for optimal resources allocation – mini-tutorial
- Optimal balancing of workload & budget across multiple clinical trials
- Resource reallocation due to clinical trials failure, trials prioritization, etc

12:00 PM – Close of Conference

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Project Management for Research & Development

Event-At-A-Glance - March 28-31, 2006

TUESDAY, MARCH 28, 2006

7:30 AM – Registration and Continental Breakfast

Pre-Conference Half-Day Workshops A - D
8:30 AM – 12:00 PM

WORKSHOP A

Developing Realistic Drug Development Project Plans

WORKSHOP B

Improving Management of Discovery Stage R&D Projects

WORKSHOP C

Decision Making: How to Make Strategic Project Decisions Consistently

WORKSHOP D

Building and Developing Highly Successful Project Teams

12:00 PM – Lunch for Conference Workshop Participants

Main Conference General Session

1:00 PM – Chairperson's Welcome and Opening Remarks

1:15 PM
Cutting Product Developing Time

2:00 PM
Long Road from Molecule to Market

2:45 PM – Refreshment Break

3:00 PM
Critical Chain Project Management

3:45 PM
Software Due Diligence

4:30 PM – Close of Day One

4:45 PM - 6:00 PM Networking Cocktail Reception



WEDNESDAY, MARCH 29, 2006

7:30 AM – Continental Breakfast

Main Conference Half-Day Workshops E - H
8:30 AM – 12:00 PM

WORKSHOP E

Managing R & D Cost and Productivity Through Globalization

WORKSHOP F

Uncertainty Management in Drug Development

WORKSHOP G

Balancing Project Excellence: Applying Speed to Market

WORKSHOP H

Strategies for Validation of Bio Methods

12:00 PM – Lunch for Conference Workshop Participants

Main Conference General Sessions

1:00 PM
Tools for Project Management

1:45 PM
Projects, Portfolios and Programs P³ Educational Options

2:30 PM – Refreshment Break

2:45 PM
Project Cost Estimating, Prediction and Analysis

3:30 PM
Project Management For Method Validation

4:15 PM
Most Common Project Management Obstacles

5:00 PM – Close of Day Two

THURSDAY, MARCH 30, 2006

7:30 AM – Continental Breakfast

Main Conference Half-Day Workshops I - K
8:30 AM – 12:00 PM

WORKSHOP I

Project Risk Management Processes

WORKSHOP J

Clinical Trial Process

WORKSHOP K

Roadmap Processes to the Clinical Trials / Project Process.

12:00 PM – Lunch for Conference Workshop Participants

Post-Conference 90-Minute Sessions 1 - 4
1:00 PM – 2:30 PM

SESSION 1

Maximizing Value in Alliance Projects

SESSION 2

Global Product Development Methodology

SESSION 3

Knowledge Management

SESSION 4

Techniques for Managing Vendor Projects: Case Study

2:30 PM – Refreshment Break

Post-Conference 90-Minute Sessions 5 - 7
3:00 PM – 4:30 PM

SESSION 5

Building Development and Validation Strategy for Product specifications

SESSION 6

Management Reporting of Clinical Trial Programs

SESSION 7

Clinical Trials Supply Chain Optimization

4:30 PM Close of Day Three

FRIDAY, MARCH 31, 2006

7:30 AM – Continental Breakfast

Post-Conference 90-Minute Sessions 8 - 11
8:30 AM – 10:00 AM

SESSION 8

Identify and Manage Critical Paths

SESSION 9

Simple versus Complex Portfolio Valuation

SESSION 10

Computer Validation PM and Case Study

SESSION 11

Handling Multiple Projects

10:00 AM – Refreshment Break

Post-Conference 90-Minute Sessions 12-14
10:30 AM – 12:00 PM

SESSION 12

Project Management Planning

SESSION 13

Virtual Pharma Model

SESSION 14

Resource Capacity Planning for Clinical Research

12:00 PM – Close of Conference

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 A B C D (Choose one)

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Please choose one breakout session in each timeframe.

Wednesday Interactive Half-Day Workshops:

8:30 AM – 12:00 PM
 E F G H (Choose one)

Thursday Interactive Half-Day Workshops:

8:30 AM – 12:00 PM
 I J K (Choose one)

THURSDAY, MARCH 30, 2006

Post-Conference 90-Minute Sessions

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 1 2 3 4 (Choose one)

3:00 PM – 4:30 PM\$495 USD
 5 6 7 (Choose one)

FRIDAY, MARCH 31, 2006

Post-Conference 90-Minute Sessions

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Tuesday – Thursday, March 28-30, 2006

Main Conference including Workshops E – K \$1995 USD \$ _____

Thursday, March 30, 2006

Post-Conference 90-Minute Sessions 1 – 7 _____ X \$495 USD \$ _____

Friday, March 31, 2006

Post-Conference 90-Minute Sessions 8 – 14 _____ X \$495 USD \$ _____

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