PIPMG - Pharmaceutical Industry Project Management Group

Autumn Meeting & AGM - 6th Nov 2002 – Renaissance Hotel, Heathrow

PLANNING FOR SUCCESS – HOW WELL DO WE PLAN ?

Chaired by Sarah Dawkins (GlaxoSmithKline)

Introduction

The first exercise of the day set a baseline for current practices in Pharma project management. With that established, speakers and delegates were invited to ask and answer these questions :

- Are the project management challenges in the pharmaceutical industry really different from those of other industries ?
- What can we learn from project managers working in construction, IT, manufacturing and distribution ?

Dynamic Session 1 : Current Practices in Pharma Project Management

All six groups were asked :

- How do you compile a plan and get buy-in from your team and key customers?

Each group discussed one of these questions :

- What are your measures of success or failure with a plan?
- What hurdles do you face with the planning process and how do you overcome them ?
- How do you build contingencies into your plans ?
- To what level of detail do you plan ?
- What are the competencies for successful planning?
- What drives the planning process ?
- Do you plan with an end date in mind or going forward from the start date?

(Sticklers for detail will notice that one group answered two questions !)

Output from this session is summarised in Appendix A

Project Management in the Construction Industry

Professor Peter Morris (UCL & INDECO)

The construction industry itself is not uniform, having at least three main branches : building; civil engineering; and process-engineering. Projects in these areas vary in the nature of activities, scale, organisational complexity and the division of labour between design & construction (a traditional schism exists between architects & engineers – maybe similar to research & development in Pharma).

Building & civil engineering projects tend to have inexperienced clients and constantly changing supply chains. Firms vary enormously in their degree of sophistication. Process Engineering is a younger industry with more standardisation of design & construction and more integration of engineering, procurement & construction (EPC).

Most construction projects are influenced by the weather and the state of the ground they are built on. They always involve physical components & products, and the deployment of resources follows an 'S-curve' concentrating logistics & effort in the middle of the project. Competitive procurement strategies, contracts & alliances lead to variations in the supply chain. The work force varies in speciality, quality and culture. Health & Safety is a big issue.

Modern PM techniques originated in the US defence industry and the construction industry added some scheduling network techniques. The basic gated project pattern is familiar (Concept-> Feasibility-> Development-> Execution->Operation). Construction-PM has fine-tuned the processes for critical path management, building-in value, and procurement. Amongst the strengths of Construction-PM are :

- Emphasis on front-end-loading symbolised by having a "milestone-zero" (planning time always saves more project-time)
- Integration of EPC and use of specialist contractors (parallels with Pharma CROs)
- Value Optimisation (Value Engineering & Value Management)
- Strong controls (estimating, resourcing, change-control, earned value)
- Tight contracts - Motivation by bonuses & avoidance of penalties (claims)
- Strong PM culture, team spirit, can-do attitude, 'robust' communication
- Leadership need not always be from the top (analogy of the military NCO)

Pharma, having a more repeatable process and uniform product is better able to manage a portfolio of programmes & projects and apply metrics. High-level strategy, project support & 'lessons-learned' are often done well – but not always.

The challenge is to articulate and implement the most appropriate PM practices - and demonstrate the benefits they bring to the business.

Project Management in the Information Technology Industry

Charles Willbe (GlaxoSmithKline)

Any supposition that we were to hear that IT-PM does it better was immediately dispelled by the statistic that, historically, 75% of IT projects failed on time, cost or benefit. We must all be honest about project performance – an improvement to 50% failure is achievable !

The old simplistic approaches each have their own modes of failure. Commitment-planning (pre-agreed delivery) failed because scope was not defined and resources not committed, Top-down planning ('the big picture') led to under-estimation and slippage. Bottom-up (aggregation from detail) led to over-estimation and unproductive use of the time. Common problems were :

- Detailed plans but no big picture (key activities forgotten, no prioritisation)
- Tenuous link to value (no transparent link to the conclusion)
- The "unexpected" always happened (external factors, internal decisions re-visited)
- "Successful" projects failed (delivered on time & on budget - but didn't solve the business problem)

New approaches have had some success and demand further attention :

- Combine top-down (the basic pattern that you do know) and bottom-up (collect the data on what you don't know)
- Start at the end (from what you want to achieve – a benefits dependency network makes the reasons for activities transparent)
- Remember the user (manage the change and the resistance, involve the right people, plan for communication & training)
- Expect the unexpected (risk management, uncertainties, mitigation & contingency plans)
- Plan-in quality, don't bolt it on (be clear about what makes a task truly complete)
- Allow for change (include a change-control process for cost, schedule and value)
- Value-based scheduling (deliver maximum value in the minimum time)
- Statistical estimation (MonteCarlo simulation on best, most likely and worst cases then commit on desired level of certainty. For normally-distributed outcomes, "most-likely" fails half of the time)
- Treat the range of outcomes as risks and update the plan as risks are either released or mature into issues
- Share learnings with the Project Management community

Radiopharmaceuticals Distribution – the ultimate distribution challenge

Roger Heppleston (Amersham Health)

Radiopharmaceuticals, which can be either diagnostic or therapeutic agents, have short half-lives (6hrs-8days) and must be delivered rapidly & reliably – often just in time for a specific patient's appointment. The analogy of delivering water in a perforated bucket makes the problem more tangible. Unlike water, however, their potential hazards and eventual medical usage require the delivery of these agents to be highly regulated. They are also subject to the same stringent quality control as any other pharmaceutical.

Manufacture & analytical clearance is complete within 48hours. Analytical clearance can be half an hour after the test-result (envious, anyone ?). Air-freight timescales are shaved down by special negotiation with airlines. A typical check-in time for known dangerous goods is 6-8hours but less than an hour after manufacture, a radiopharmaceutical consignment can be checked in 2-4hours ahead of its flight with all the necessary documentation. Customs clearance is retrospective. Where airlines have targets of ~85% for 'flown-as-booked' - Amersham's target is 97% and aircraft may be chartered specially if necessary.

Key factors in achieving this performance are :

- Cultivation of good relationships with airlines, forwarders & carriers
- Well developed IT systems to expedite analysis & generate documentation
- A customer-first business culture coupled with highest standards of safety, quality & regulatory compliance

The rest of the industry, developing "cold" pharmaceuticals, has much to learn from this super-slick operation.

Dynamic Session 2 : Room for Improvement ?

Using the baseline from the first session : -

- What are the similarities and differences amongst the industries ?
- Has what you've heard from the other industries made you want to change the way that you plan ?
- How could we adopt different practices in pharma planning?

Output from this session is summarised in Appendix B

Next Meeting – 15th May 2003

Many organisations are familiar with the "Project Close-out Review" and know that useful lessons are learned which can be applied to other Projects at earlier stages of development - but unfortunately not to the Project under Review !

In this facilitated workshop, delegates will be asked to consider a number of diagnostic questions that can be asked of a Project at regular intervals - such as at routine milestones - to determine the Health of the Project in terms of both technical progress and team working.

Back at the workplace, the answers to these questions can be used to redirect and refocus individual Projects in order to maximize the chance of success.

Phil Dolamore **21st November 2002**

Appendix A - Dynamic Session 1

Current Practices in Pharma Project Management

How do you compile a plan and get buy-in from your team and key customers?

- Project Manager should shadow the late Research stage
- Establish a team-charter with roles and a responsibility-matrix
- Stakeholders are Investors, Champions, Managers, Resource-owners
- Appoint a Sponsor and Steering Group for strategic decisions
- Sponsor should get team's buy-in to the TPP at a start-up meeting
- Sponsor should clarify what constitutes success (maybe a quick kill ?)
- Sponsor's role should not include micro-management
- Agree (sign-off) objectives, time-frame & resource-allocation
- Map requirements, specify deliverables (benefits-dependency)
- Distinguish between stretch-targets & manageable dates
- Start-up meeting (Risk-workshop & lessons learnt from past projects)
- Risk register should include opportunities & scenario-plans
- Team dynamics - Respect the expertise brought by each team member
- It helps to have a template or checklist based on lessons learned
- Confirm & document components of the strategy
    - (commercial, preclinical, clinical, regulatory, manufacturing)
- Identify critical decision points & major triggers for payments
- Be aware of possible conflicts (resources, priorities)
- Big organisations need to work extra hard at communication
- There is an opportunity to be creative at this stage
- Effort at this stage saves time overall (Front-end loading)

What are your measures of success or failure with a plan?

- Did the team follow the plan that was set out originally ?
- How many unplanned tasks were added ?
- On time, on budget, and on target-profile (quality) ?
    - PRINCE methodology quantifies variance from the plan
- Were the contingency-plans sufficient and were they used ?
- Integration with a broader R&D-wide plan

What hurdles do you face with the planning process and how do you overcome them ?

- Micro-management – manage stakeholders
- The importance of planning is sometimes overlooked
- Difficult to get realistic target dates – manage stakeholders, use change-control

- Communication – maintain a strategy document and progress-reports

How do you build contingencies into your plans ?

- Use risk-management techniques – a risk workshop provides good team-building
- Plan contingencies for both time and cost
- Scenario planning allows the contingency to be anticipated
- A portfolio enables the contingency budget to be balanced across projects
- Small companies often have no room for manouevre
- Sponsors are sometimes unwilling to recognise the risks & provide for contingency

To what level of detail do you plan ?

- Depends on size and complexity of the project
- Time, Cost & Quality are treated differently at different levels of overview

	Portfolio	Programme	Project	Product	Phase	Study
Time	High level overview	High level overview	Milestones & decision-points	Tracking points Outputs, Inputs, Integration	Task Activity	Delegate
Quality	Not an issue	Not an issue	TPP	Management of Risks & Issues	Monitoring & review	Delegate
Cost	High level overview	High level overview	Costs v. Budget	Monitoring & review	Plan & Report	Delegate

What are the competencies for successful planning?

- Analytical thinking
- Pro-activity
- Intuition (understanding the team)
- Ability to see the big picture
- Negotiating skills
- Organisational skills
- Ability to say NO !

What drives the planning process ? - Do you plan with an end date in mind or go forward from the start date?

- Plans are often driven by a committed delivery date
- Distinguish between Business Drivers (B) and Project Drivers (P) ?
- Product Profile (P)(B)
- Risk Management is phased by milestones, gates & go/no-go decision points (P)
- Maximise remaining patent life (B)

- Competitor Intelligence (P)(B)
- Fund-raising depends on realising investors' expectations (B)
- Management of stakeholders and their expectations (B)
- Return on Investment (B)
- Portfolio management & changing priorities (B)

Appendix B - Dynamic Session 2
Room for Improvement ?

What are the similarities and differences amongst the industries ?

- PMs in other industries seem to have a better-defined role and more 'clout'
- The product is less tangible (less concrete !) during the execution of the project
- Construction & IT give more attention to change-control & identification of risks
    - but the PM is more accountable as a result
- In construction, bonuses & celebration of success are big motivators
- In Pharma, you can have a successful project without a product
- Pharma has more debate around business-benefit
- Small pharma companies see big companies as potential customers
- IT has well developed processes for estimation and documentation
- Construction is particularly good at procuring contracts
- The Value-management process in construction has a British Standard !

Has what you've heard from the other industries made you want to change the way that you plan ? - Could we adopt different practices in pharma planning ? The practices that Pharma PMs liked were -

- Seek more authority - Learn to say no – or at least gain acceptance of risks
- Can-do attitude, team spirit – which results from empowerment of the team
- Leadership is not necessarily from the top
- More thorough product definition
- "Milestone-zero" and front-end planning
- Benefits dependency network to link deliverable to activities
- Value management – add value early - eliminate risks as early as possible
- Better balance between top-down & bottom-up planning
- Better management of risk & contingency planning
- Statistical estimation – don't plan to fail
- Change-control – PM could adopt a 'client-representative' role (Sponsor<->Team)
- More priority for Knowledge Management (objectives, issues, learnings)
- Work harder to build partnerships and alliances (trust, reliability, shared risk)