



PIPMG - Pharmaceutical Industry Project Management Group

Spring Meeting – 22nd/23rd May 2007 – Oxford

TURBOCHARGING PROJECT MANAGEMENT

Chaired by Stephen Clegg (GE Healthcare)

Introduction

Teams are at the heart of pharmaceutical discovery and development so this meeting set out to identify how they could best be selected, led, supported, & trained to achieve optimal performance. Special emphasis was placed on practices that have been shown to impact project-delivery. Interactive workshops collected a wide range of ideas on :

- competencies of Project Managers and Leaders
- starting, boosting and de-briefing Teams

The Successful Project Office – An Elusive Goal

Stephen Allport (SWA Consulting Ltd)

The Project Office is a common feature of organisations that manage Projects – but is not universal. A better and more general term is Project Management Office (PMO). Not all organisations see a need for a PMO, and where they do exist, they tend to have a short life-cycle through re-engineering of management structures. In fact, there is evidence of a “Boom & Bust” cycle where investment in a PMO results in better project delivery and the successful project-organisation, seeing the PMO as an unnecessary overhead, cuts spending on PM with a detrimental effect on delivery.

Their rôles vary, and they may be central to an organisation or de-centralised (e.g. in business units). PMOs are regarded as a support function much more often than they are seen as either accountable or in authority. Their place in the org-chart is best determined by the functions they support. The rôle is political so it's useful to have multiple sponsors, cultivate allies & identify opponents !

PMOs have been shown to generate measurable value from an investment that's typically less than 2% of budget. The most frequently reported benefits are improvements in : Reporting status or progress; Visibility of projects; Project management & control; Support of Project Managers; and Delivery. Areas where PMOs seem least successful are : Enforcement of procedures; Timesheets; and Resource management.

In Pharma, compared with other industry sectors, PMOs are more operationally focussed and less involved in : Supporting project start-up or close-down; Project-reviews; Mentoring team members. Our industry is particularly good at portfolio management and at handling the transition from research to development.



Best Practices can be identified :

Set-up	<ul style="list-style-type: none">• Wide Scope – across the enterprise or business unit• Clear accountabilities & matching authority• Direct responsibility for delivery• Consistent, overt management support
Personal Qualities	<ul style="list-style-type: none">• Experienced, respected staff• Impartiality & honesty• Networking
Impact on Delivery	<ul style="list-style-type: none">• Risk Management (reducing risk has a big impact)• Team Performance• Scoping & Change-control• Consistent time & cost performance
Measures of Success	<ul style="list-style-type: none">• Quantitative Metrics• Increases in Productivity & Value• Impact on Key Performance Indicators• Customer satisfaction

The future focus of PMOs is likely to evolve in response to the business environment. Top Pharma managers were asked what were their main concerns for the future and cited : the industry's image; cost of development; safety issues; and lack of novel candidates. Potential areas for change are :

- More external focus to deal with alliances & collaborations
- Supporting people and teams as well as tools & processes
- Driving process changes that reproducibly improve schedule & budget



High Performance Project Leadership

Harry Cannon (Grahame Robb Associates Ltd)

Some of the characteristics of the Pharma industry are familiar – long timescale, uncertainty, competitive pressure & regulatory constraint – but there are aspects of scientific management that are not so well recognised. One key factor is that the system is often geared to managing science rather than managing scientists. Projects are generally well managed but teams are not necessarily well led.

Insufficient attention to issues such as conflict, cultural differences or decision-making leads to poor project-performance. Plans often do not reflect hard facts (risks, costs & timelines), major risks are ignored like the "elephant in the room," and sponsors are not sufficiently involved. Time is wasted on "fire-fighting." The resulting low motivation reduces the amount of discretionary effort applied by team members who are keys to progress but not central to decision-making.

The difference between management and functional excellence is clear in the case of a good teacher promoted to head teacher without the skills necessary to manage people, finance or the education-authority. A similar difference exists between management and leadership. Skills like influencing, motivation, delegation, conflict-management, negotiation, team-building, giving/receiving feedback, and stakeholder-management require active development and training.

Leadership skills tend to be more abstract and less obvious than managerial techniques so improving leadership in an organisation requires a more subtle approach than a checklist of classes. Psychometric indicators & 360° feedback establish the *status quo* and enable a programme of relevant interventions. Case studies, exercises, rôle-play (using actors), coaching, discussion & feedback are valuable methods. Best results are obtained when the whole team is involved, in a relaxed off-site atmosphere, with a facilitator, and having prepared in advance. Suitably skilled individuals within the organisation can be identified & developed as coaches to maintain the programme and facilitate knowledge-sharing between teams.

A critical aspect of interpersonal relations is dealing with conversations (not necessarily interviews) when there are high stakes, opposing opinions and strong emotions. The process is like a decision-analysis but with the simultaneous distraction of primitive instincts. Maintaining mutual purpose & respect in these "Crucial Conversations™" is an invaluable skill.

Culture-change like this - where the criticality of leadership is properly recognised - has been shown to bring measurable improvements to team performance and confidence. Teams with these skills have ground-rules, and they negotiate & delegate better.



Implementing Risk Management in Pharmaceutical Projects

Stephen Clegg (GE Healthcare)

The activities and dependencies in pharmaceutical development tend to be fairly standardised – phases and milestones can be defined that apply to most projects. It seems surprising, then, that so many pharma projects appear to run late or over-budget. The weakness appears to be in the key PM technique of estimating and especially in the assessment of risk which is central to making sound estimates of schedule & budget. Risk is an uncertainty that could have either positive or negative consequences (i.e. the Opportunity or Threat from a SWOT analysis).

Comprehensive studies of the relationship between PM-practice & performance (Human Systems Ltd.) show that predictability of outcome improves with adequacy of risk-management practices. However, even when the range of variability has been narrowed, the interpretation of expectations can be flawed.

In the simplest terms, a graph of probability against outcome (e.g. activity-duration) might be bell-shaped with the most realistic schedule having the highest probability. Shorter or longer durations would have lower probabilities and ought to be interpreted as opportunities or threats, respectively. There is a strong tendency in our industry to set the "agreed" schedule at the most optimistic limit so that opportunity for improvement is almost impossible and the threat of slippage is almost certain. Agreed schedules are more realistic in the construction industry where contracts include penalties for lateness.

Risks can be identified in a team-workshop and they can be prioritised by multiplying probability (possible↔probable) by impact (annoyance↔catastrophe). Anything more than "possible annoyance" should be regarded by the team as important as the project's critical path. An action plan establishes owners (not scapegoats !) for the risks, and mitigation-strategies. This prioritised Risk Register forms part of the project's documentation alongside Target-profile, Project-plan & Budget - to be reviewed, updated and shared with strategic programme-managers.

It is a common experience that the process of risk-management alone is both educative and team-building. However, beware of the distinction between technical risk (properties intrinsic to the invention under development) and operational risk (activity being flawed or delayed) where risk management can be misinterpreted as intrusion into professional competence.

If expectations have been set realistically, the positive side of opportunity-management can be rewarding in terms of earlier, less costly projects achieving the "upside" of their target-profile.

"The nicest thing about not planning is that failure comes as a complete surprise and is not preceded by a period of worry and depression"

(John Preston, Boston College)



Deploying Lean Six Sigma in a Pharma Service Organisation

Alison Holland (Covance LSDS)

Lean Six Sigma is a marriage of two customer-focussed process-improvement methodologies. Six Sigma (developed by Motorola) addresses control of variation and elimination of defects. The concept of "Lean" (developed by Toyota) concentrates on identifying value and elimination of waste.

In statistical terms, sigma (σ) represents standard deviation. In a theoretical normally distributed graph of probability against process-outcome - if the mean outcome is separated by 6σ from the outer limit of the customer's specification, then there would be only 3.4 defects per million opportunities (equivalent to six seconds in a century). Thus, by tuning the process to centre on the target specification ($\text{mean}=\text{target}=\text{P}_{\text{max}}$), and minimising or eliminating the defects that would spread the performance-curve beyond 6σ , the customer's specification can almost always be met.

There is more to the Six Sigma methodology than a rigorous statistical approach to error-reduction – the concept extends to a management philosophy & culture with an almost religious fervour, as evidenced by the adoption of martial arts terminology for the exponents of the process. Importantly, individuals throughout the organisation are empowered to challenge the *status quo*.

The acronym DMAIC (Define, Measure, Analyse, Improve, Control) is used in describing the Six Sigma methodology. These activities are applied to a map of the process (f) which analyses inputs as "X" and outcomes as "Y" in the equation $Y=f(X)$ ("Y is a function of X"). If the Xs are controlled and the process (f) is streamlined then the desired Y can be achieved.

LEAN is complementary to Six Sigma, eliminating waste by identifying what is needed, when, & how much - and the sequence of events that follows value through the process. The process is tuned so that value flows without interruptions.

Deployment of Lean Six Sigma requires courage, commitment and passion from all levels in the organisation. Like any process-improvement, there are phases of introduction, implementation and maintenance with training & sponsorship as keys to success. It is not a "quick fix" but can result in a lasting culture that maintains & improves quality & value.

*"Insanity is doing the same thing over and over again
and expecting the result to be different "*

Albert Einstein



Table Workshop 1 - Project Team Core Competencies

Knowledge and Experience of the Business and Projects

- Problem-solving
- Communication skills – presenting and listening
- Global market understanding, portfolio-awareness
- Therapeutic area knowledge, patient-needs
- Industry knowledge, commercial & business development
- Understanding of the organisational structure & governance
- Facilitation and meeting-management
- Relevant Technical knowledge
- Competent with audiovisual & telecommunication equipment
- Awareness of personality, (Myers-Briggs, Belbin)

Personality Traits & Attitude

- Positive, Motivating, Can-do attitude, (Driven ??)
- Using past experience, Realistic
- Realistic view of planning horizon
- Open, Collaborative, sufficient humility with experts
- Good networking and facilitation
- Organised, logical, able to analyse problems, creative
- Diplomatic and politically aware
- Balanced; able to be devil's advocate
- Responsible, taking ownership, decisive
- Charismatic, confident, influential
- Trusting and able to delegate

Project Leader/Manager Job specification

- Project Planning, Critical path, Estimating
- Budgeting and Negotiating contracts
- Facilitating Target Profile and Risk Register
- Delivery planning, Gap analysis
- Track record of delivering to Time, Cost, Quality
- Meeting Management

Key skills & traits for small companies

- Budgeting & negotiation
- Business Development
- Intellectual Property
- Networking within a virtual team
- Responsible and decisive



Table Workshop 2 – Team Performance Meetings

There was general agreement that all meetings like these should be facilitated and face-to-face - especially if the team is virtual or distributed. PL/PM performance in these aspects should be part of their job specification. This is not wasted time because it will be repaid by smoother conduct of projects in the future.

Team start-up meeting

Content of a 2½d meeting – and what to leave out if reduced by 1d (*) ?

- Introductions & possibly profiling
- Include the wider team – level playing-field for all
- Exchange views on cultural differences & styles (national, functional)
- Include Physical & Social aspects (e.g. Rock-climbing & Dinner)
- Motivation - the bigger picture – therapeutic (patient's view) & business
- Sponsor presents expectations in person
- Team's view on projected timelines & senior management response *
- Roles, Responsibilities, Expectations, Deliverables, Ownership *
- Understand governance & reporting/escalation structure *
- Planning *

Project Boost – bringing new life to an existing project

- What has gone well and "not so well"
- If a change of focus - Invite specialists (Research, medical, commercial)
- Senior management or sponsor to communicate any change of direction
- Rebuild the Target Profile and Business case
- Interactively "brainstorm" the new scope
- Revisit rôles and responsibilities – still the right team ?
- Set expectations ahead of critical outcomes
- Motivation - the bigger picture – therapeutic (patient's view) & business

Learnings from a successfully completed project

- Similar events at milestones – not just at closure
- Wider team and past team members – all should be heard
- Acknowledgement and recognition by PL, Sponsor, Senior Management
- Fun & celebration – "Oscars"
- What went well and "not so well" (metrics may help)
- Did we rise to challenges ? Would we have acted differently in hindsight ?
- Share learnings actively – story-telling, not a passive repository
- Emphasise behaviour & process much more than science & technical practice
- Retrospective Risk Management – Review the Issues-log
- Did the scope change ? Were there unforeseen constraints ?
- What did members get from being on the project ?
- Deal with moving on



Closure of an unsuccessful project

- Most activities from a successful closure are still valid
- Drawing a line – manage expectations of project revival
- Deal carefully with the sense of bereavement
- Needs a competent facilitator – a possible PMO rôle
- Often doesn't happen because :
 - end is ill-defined
 - team disperses rapidly
 - no budget, low priority
- Concern that positive aspects & achievements won't be communicated
- Other teams may benefit from the learnings

Next Meeting

“Project Management Fit for Purpose” – 20th/21st November 2007

Sunningdale Park, Ascot

Efficient, cost-effective Project Management linked to corporate strategy is critical to the success of pharmaceutical projects, whether the company is an academic research spin-off or a large blue-chip company. Ensuring that the most appropriate systems are in place is as important whether the company is managing a portfolio of one or 200 projects.

Providing appropriate structure, systems and process without an excess of bureaucracy and cost can make the difference between early project failure and long term success. In this meeting, these issues will be discussed and debated in addition to the importance of the relationships and performance of the team itself.

Sophisticated systems for managing scheduling, costs and resources are available for large and small portfolios, providing reliable, regular feedback to project management, portfolio directors and senior management. These are often expensive to implement and time-consuming to maintain.

Using a mix of expert input and facilitated workshops, the meeting will bring together thought-leaders in the field to discuss these issues and provide guidance on how to optimise project management for your organisation.

Phil Dolamore