Project Management for the Pharmaceutical Industry

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Preface

Project management has been a well embedded technique outside the pharmaceutical sector for many decades now. But in the last decade it has become increasingly important within the pharma industry.

This industry is one which traditionally had been previously relatively insulated from intense competitive pressure, and is thus a latecomer to full-blown project management. But now due to over the increasing threat of generic drugs, increasing regulatory requirements, health innovations and the wave of mergers in the mid/late 1990s and early 2000s it is no longer possible to manage the business without it – and it must also be taken beyond its simplest and most mechanistic form.

Since the first edition of this book was published these pressures have significantly intensified with the disruptive effects of the credit crunch, recession and soaring public sector deficits and government borrowing worldwide. This is leading governments to seek better value for money out of big pharma. In parallel, as global demand for drugs increases, as result of an increasingly ageing population and through medical advances, the viability of finances of health services across the world will be threatened.

In addition, in the US, President Obama has wasted no time in addressing the regulatory and economic provisions for drug development, purchasing and pricing – these changes will put more pressure indirectly on the management of pharma projects. Concerns too about the dangers attendant to side effects from drugs will make it much more risky to roll out any blockbuster drugs – so the more likely scenario in future will be that such drugs will be gradually exploited over a range of therapeutic applications. This will greatly dilute the economic benefit of the blockbuster effect through slowing down value creation, and through increasing the costs and complexity of drug development. The whole area of risk management will become far more important even than before.
Also there are a significant number of drugs coming off-patent resulting in many companies having limited pipelines. Pharma projects therefore need to be managed more strategically as companies will have a squeeze on the resource they can plough back into R&D due to pressures on average margins – and even more pressure will be placed on completing projects within timelines as well as to control, if not to reduce, cost.

President Obama also wants into encourage the expansion of the generics market – making further inroads into the traditional terrain of big pharma. In sum, pharma companies will have to do a lot more – and with less – and even then returns are unlikely to be as great. This suggests that project management processes will have to be ever sharper for companies to succeed.

Increases in competitive change led to intensified internal pressure to deliver much faster – and to reduce time to market. The pharma industry increasingly has looked to project management to accelerate drug development and particularly the clinical research part of the process. Unfortunately the industry has tended to see projects as standardised, and as relatively uniform, which in reality they were not. As one of the authors, Laura Brown, reflects:

> Each clinical trial project is different from the rest. You may have a different population to trial the drug out on, a drug with different beneficial effects and method of administration, and a different project team. There may also be a different set of regulatory stakeholders to manage. Above all, the organisational timing and context will be unique. As a result, a project team, relying primarily on activity analysis and computer software, critical path and resource planning, will still tend to get bogged down in internal politics, will struggle with often inadequate resources, inadequate project training and project team development. And this is before having to deal with endemic difficulties of recruiting patients on a just-in-time basis – and likewise clearing regulatory hurdles.

This example demonstrates that even within a more technical project environment we see projects as beset with environmental uncertainty, with interdependencies, and with struggles to allocate strategically, and all within a complex organisational environment.
The Pharmaceutical Project Management Process

Traditional project management is therefore not up to the challenge posed by the pharma industry and needs to be augmented by other perspectives. These perspectives include the strategic, operational, organisational and also the financial, as we see in Figure P.1.

Figure P.1  Perspectives on pharmaceutical project management

The authors’ own process developed over many years as a response to the increasing number and diversity of business projects which we and managers were facing in the pharma industry. Initially we began by looking at how managers could link business projects back to the strategic goals of their business. Drawing on the PhD research of one of the authors (into strategic and financial project appraisal) we were then able to bring in techniques of assessing how pharma projects add to, dilute or even destroy shareholder value. This helped to integrate project management with both strategic and financial analysis, which are often not well linked in the pharma industry.

Next, we brought in approaches to assessing implementation difficulty drawn originally from organisational theory – particularly in applying force-field analysis. (Around ten years ago the project management literature generally
was almost totally devoid of any mention of force-field analysis.) This approach was then further enriched by bringing in stakeholder analysis techniques (which are particularly important for pharma projects, given their technical and political complexity), and was found in the strategy literature, and now developed further in this book.

Operational analysis was also helpful in extending and enriching traditional project management – as practised in the pharma industry. For instance, as managers appeared to lack adequate problem-solving in the definition of many projects, we were drawn to the diagnosis technique of fishbone analysis which is normally associated with Total Quality Management (TQM). Moving on, then, to the imperative to prioritise projects more effectively, we brought in Attractiveness–Implementation Difficulty (AID) analysis, which had been discovered in managing cost breakthroughs when working with the pharma company, then called Amersham-Nycomed, some years ago.

Project uncertainty was clearly one of the main reasons why traditional project management techniques ended up producing spuriously accurate but unrealistic project plans in the pharma industry. This led us to look at what help strategic management could provide, and to scenario analysis in particular. We incorporated the uncertainty grid to help surface and evaluate key project assumptions for pharma projects along with traditional risk assessment techniques already well known in the pharma industry. Later on this was expanded to incorporate scenario-generating and story-telling techniques to help flesh-out and explore the possible trajectories which each pharma project might take.

Finally, in the late 1990s, one of us undertook some fascinating research into senior managers’ behaviour when engaged in managing major projects (Grundy, 1998b). This study focused on a small but influential team of technical strategists who were engaged in project managing some major breakthroughs in the organisation. Besides discovering much about how and why teams tend to get so entangled in seeking to manage complex projects, some very practical techniques for monitoring and managing both the dynamics of projects were drawn out, and of the somewhat turbulent behaviours associated with them. (We will see these later in Chapter 7, ‘Influencing People and Behaviour’, how to cope with these more effectively.)

So, our approach to Project Management for the Pharmaceutical Industry is very much an eclectic one, which manages projects as part of overall programmes.
These ‘programmes’ help to implement business strategy and organisational breakthroughs of pharma companies.

Many pharma companies have now benefited from some or all of the techniques contained in this book. These include Altana, Amgen, Arrow Therapeutics, Tripos Receptor Research, Lilly, Novi Nordisk, Napp, Galderma and UCB. Hopefully, over time, these techniques will be taken up by your own company.

Our book will help a number of groups of manager, particularly:

• senior pharma managers engaged in turning business strategies into implementation through project management;

• practising middle and senior managers in pharma companies working on internal, cross-functional or within functional projects at a strategic level;

• pharmaceutical professionals managing projects within their own roles.

Since this book was first published many pharma organisations and individual professionals have been using not merely the more traditional elements like critical path analysis and Gantt charts but also tools such as:

• strategic gap analysis;

• the project option grid;

• stakeholder analysis;

• force-field analysis;

• interdependency analysis;

for diagnosis, project strategy development, detailed planning, influencing and monitoring implementation. These highly visual tools have had a big impact on the clarity and transparency of complex project management processes.
Taking two quick examples of this:

- At one pharma company, the Clinical Research function used stakeholder analysis to influence and manage US stakeholders proactively to return project leadership to Europe, rather than managing this, with difficulty, from the US.

- At another very large European pharma company, the head of global training used the project option grid to evaluate options and to then prioritise plans for a Global Training Strategy.

**Structure and Content of this Book**

*Project Management for the Pharmaceutical Industry* is structured as follows:

- Chapter 1 looks at how pharma projects need to be managed strategically.

- Chapter 2 turns to the key links of pharma projects with pharma business strategy.

- Chapter 3 looks at the pharma project process itself, considering the first two phases of pharma project definition (and diagnosis).

- Chapter 4 examines phases II and III of the project management process by considering Project Strategy and Plans together and contains the core of the project management tools – both traditional and new.

- Chapter 5 explores the intricacies of project evaluation and, in particular, how we can grapple with the difficulties of putting a realistic financial value on a pharma project. (Many project management books either refer to texts on Financial Project Appraisal or tend to regard this area as a question purely of Discounted Cash Flow (DCF). We take the view that prior to the deployment of DCF techniques we also need to perform analysis of key value and cost drivers impacting on pharma projects, and (potentially) to describe some key project scenarios.)

- Chapter 6 focuses on the practicalities of making projects happen, including project mobilisation. This chapter contains a number of
formats for detailed project management systems and controls. We also take a brief look at how information technology (IT) systems have changed project management processes.

- Chapter 7 examines the more purely people and behavioural dimensions of project management – not only through project management systems, but also through documentation processes and the Internet.

- Chapter 8 looks at a number of generic types of projects and explores some tailored checklists for applying project management to them. These include:
  
  - R&D projects;
  - acquisition projects;
  - alliance and joint venture projects;
  - operational improvement projects; and
  - organisational change projects.

- Chapter 9 shows how these techniques can be deployed both to micro-issues within your own role. This chapter also finally draws together the key lessons on project management and focuses especially on how to implement the techniques.

Throughout the book you are invited to invest some time in working through exercises on your own projects so that you can extract maximum learning. Whilst some readers may be tempted to skim these they really will enhance your retention and incorporation of the tools and techniques by the order of at least 100 per cent. Please do not be tempted just to browse the book.

In conclusion, Project Management for the Pharmaceutical Industry has developed from many sources. All of these sources are essential in order to get real value out of these projects, not to mention making your life in pharma companies generally less stressful! We now urge you therefore to read, digest and to apply this book which we have been most fortunate to have project managed.