Case Study

Integrated Timeline Development for new Greenfield Facility

Background:

When we started work on this large project it was being viewed as the construction of a manufacturing facility and as such the engineering group had been appointed, they had developed construction timelines and were progressing significantly with the design and construction. To summarise the engineering aspects of the project were well advanced. What was less advanced was the operational start up aspects of the project. These operational aspects included resourcing, compliance standards to be met, process qualification and technology transfer. Since these items had not been developed, the crucial issue of product launch to market from the new facility was still unclear and as a result the project costs were increasing due to the fact that engineering design was progressing and the operational start up plan was not keeping pace.

Scope of work:

We identified that this mismatch between the engineering design and construction plans and the operational start up activities had the potential to cause major delays and cost overruns within the project. We were contracted to develop an integrated timeline that would encompass all aspects of both areas and would identify and manage all issues and risks to the project resulting from mismatches between design, construction and start up needs, gaps in the technology transfer and project issues that were remaining unresolved.

Process:

The process we followed during this assignment was to

1 Identify the major phases of the integrated timeline from both the construction and the operational start-up.
2 We then identified the initial dependencies between the major phases
3 Having identified these we undertook a data gathering and assessment process. We did this by interviewing the key senior managers and project managers. We then facilitated a series of workshops with the senior managers, our experts and the project management groups to tease out the project issues, activities, timelines, risks, and mitigating factors in each category. We focused our work on the integration of the engineering program including commissioning and validation (IQ/OQ), into the overall timeline, and provided specific focus on those activities that were not being tackled at that time and that would have significant impact on the overall program related to:
   - Independent facility design reviews
   - Recruitment,
   - Technology transfer,
   - Scale-up,

- Process validation,
- Exhibit batch manufacture,
- Stability studies,
- Regulatory strategy,
- Overall project Risks and Issues and Mitigating factors

4 Coming out of these discussions we developed a series of integrated timelines that could be rolled up to various high level views that met the requirements of the various tiers of management within the organisation.

5 Having developed the initial integrated timelines we documented a robust project management process that ensured that the risks and issues to the integrated timeline were addressed and actioned before they appeared on the critical path of the project. This process provided the construction teams with the flexibility to manage their timelines while ensuring that the operational start up teams developed the processes, work flows, IT systems, compliance standards and organisation structure in advance of these areas causing design issues or cost overruns due to the need to effect changes in the initial design.

6 Utilising our expertise in pharmaceutical operations and project management we provided support to the operational start-up team on the issues that would impact on the project. We proposed strategies and solutions, and mitigating factors for all identified risks, for example, the availability of a testing facility for water was required much earlier than was initially planned and this was solved with installation of a temporary testing facility.

Result:

We produced

1 An integrated timeline that identified all critical path activities and that could be maintained easily and allowed all participants to envisage their role through to product launch.

2 We developed a project management process that ensured that all project activities, risks and issues were classified and actioned prior to impacting on the critical path.

3 Having developed the timelines we then challenged them for validity and the result was a new integrated timeline with an earlier product launch date (12 month's earlier) than was originally anticipated.

Lessons learnt:

The operational start up phases of any project are more important than the design and construction as it is these areas that that define the constraints and compliance needs for the design teams.

Failure to develop an integrated timeline causes budget overruns because issues are not addressed before they cause slippage in the design and construction.

Most engineering design personnel have never managed or operated the type of facilities that are constructed. As such they need an immense amount of input from the operational start up teams to ensure that operational solutions are arrived at when resolving issues rather than purely engineering answers.