Global Pharma Networks

Case Study

Integrated Timeline Development for new Greenfield Biopharmaceutical Plant

Background:
When we started work on this large project the engineering group had been appointed and had progressed significantly with the design. Project costs were increasing, and the crucial issue of product launch to market from the new facility was still unclear.

Scope:
We identified that it would be crucial to have an integrated timeline that encompassed the facility design and construction, hiring of personnel, and the operational start-up activities. It was also crucial in our view to have all the key project risks identified.
We felt that there was significant scope to improve the engineering design and build program, and this particular work was handled by the client's engineering group primarily.

Process:
We had discussions with all the key senior managers and project managers. We defined the project into its main activities and we facilitated a series of meetings with the client, 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

Utilising our expertise in pharmaceutical operations and project management we identified those issues that would impact on the program and that therefore needed resolution. For example the availability of a testing facility for water was required much earlier than was planned previously and this was solved with installation of a temporary testing facility. We proposed strategies and solutions, and mitigating factors for all identified risks.

Outcome:
We produced an overall timeline that identified all critical path activities and that could be updated, and allowed all participants to see the end game of product launch and what needed to be done to get there. Particular activities that were not started yet and did not have owners, but were on the critical path e.g. regulatory involvement were initiated.
After construction of the timelines we then challenged the timelines and the result was an integrated timeline that had an earlier completion date, by 12 months, than what would have been achieved previously.