LAFFERTY.

Drug Product

Feasibility Study

The Brief:

Lafferty were engaged to lead a feasibility study assessing a potential capital project to increase drug product (fill finish) manufacturing capacity on an existing site, for a rapidly increasing patient demand. The client required a rapid feasibility level assessment of multiple locations to install a new vial filling line and two new lyophilisers along with supporting cleanrooms and utilities.

The Approach:

Lafferty deployed their best practice project management leveraging front end loading. The focus was on the robust design phases to understand and fully develop comprehensive user requirements, develop the overall project scope, end to end schedule, and cost estimate to correctly setup the capital investment and inform appropriate decision making.

- Lafferty assumed the lead as client-side project managers and process lead to deliver the study.
- Lafferty conducted a detailed review of the client brief, to verify the end user requirements, fully develop the scope of the study, its key objectives, and to ensure project milestones were understood.
- Lafferty assembled a highly relevant professional team to deliver the scope of the study. This included process engineering, M&E, CSA, automation, cost management, and some key vendors.
- The key deliverables for the feasibility study included equipment arrangements / layouts for each of the potential locations, process and utility equipment lists, and an assessment of capacity and tie-ins required to existing utility systems. Process equipment was selected to meet the client requirements in terms of format sizes, incoming component status, and output.
- Single use technology vr. traditional design and an assessment of ready to use (RTU) components was a key deliverable.
- Each of the potential locations were assessed on capital cost, constructibility, impact to ongoing operations, schedule, and operational benefits. A KT analysis was performed to apply weightings to the key criteria and score each of the potential options. Lafferty produced the overall study report, schedule, constructibility assessment, and risk register within a period of 10 weeks.

The Outcome:

The following outcomes were realised for the client:

- Definition of the business driver(s) and project justification.
- Feasibility level layouts and 3D modelling of the options under assessment.
- Rough order of magnitude cost estimate for each of the three locations under assessment.
- Project schedule developed illustrating key milestones and time periods from concept engineering through to EU/US regulatory approval for the new facility.
- Project risks, assumptions, and opportunities identified.
- Recommendation for the option to be progressed for a concept level study based on the outcome of the KT analysis.

Lafferty recommended a comprehensive concept and basis of design phase to setup the project for future success, reducing risk, including design or construction re-work often associated with squeezing early planning phases, and therefore delivering the project in the most efficient manner to achieve the earliest end date.

Key Statistics:

Location	Ireland
Duration	10 weeks duration
Scope	DP Feasibility Study
Options	3 options/1 recommendation
Cost	OOM cost estimate (€50m - €80m option dependent)
Initial level 1 integrated project schedule (incl regulatory approval)	

For more information please contact: Barry Freyne I bfreyne@lafferty.ie