

LAFFERTY.

Drug Substance

Design Management

The Brief:

Lafferty were engaged by one of our clients to provide design management services on a greenfield bulk drug substance facility to be constructed in central Europe.

The design phase of the project faced a number of challenges which Lafferty were onboarded to assist resolving, these included:

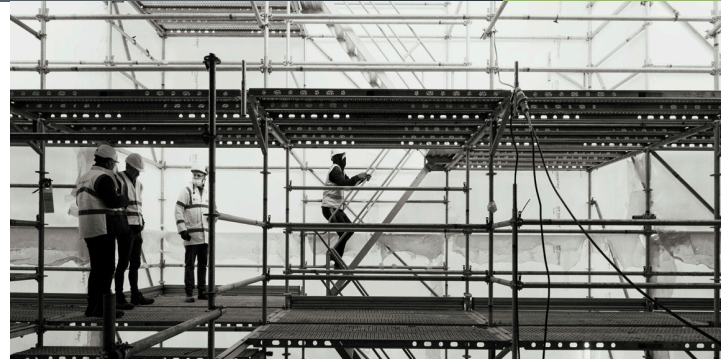
- Inadequate project management and coordination within design offices and between the design firm and client team.
- Inadequate management and control of the design process in the sequence required to deliver the project efficiently and minimise risk of future design and construction changes. Progression through the design phases with inadequate information.
- Inadequate management and control of the design and overall project schedule.
- A lack of accountability and end user engagement within the project team to make design decisions and finalise the design basis.
- A lack of visibility in terms of design progress reporting.
- An incomplete complete basis of design and a transition to new design firms.

The client required this benchmarking activity to ensure they were consistent in their headcount planning for this new facility and to support their own assessment of operational costs that would be required to support the capital project. The benchmarking also provided phase and overall durations for a major (>€500M) drug substance capital request going forward at board level for approval.

The Approach:

Lafferty were engaged on completion of the basis of design phase and commencement of detailed design.

- An initial assessment of the BOD status, quality of design deliverables, long lead equipment status, cost estimate, and overall project schedule was undertaken. Risks were identified and mitigating recommendations were made to the project director for any areas of concern or underdeveloped design / scope.
- We assumed the role of design leadership and coordination.
- We identified key areas such as the client project organisation, associated roles & responsibilities, system ownership, and design deliverable RACI matrix as items requiring prompt attention. We led the resolution of these areas.
- Design schedules were developed and agreed with each of the engineering firms. Key inputs/outputs and the timing required from one engineering firm to the other were identified. These were built working back from project CQV start dates and field need dates for construction.



- A risk management plan was developed identifying key risks and assumptions being made to progress design due to an incomplete BOD. Ownership and mitigation of the risks were identified.
- Weekly coordination meetings were established with each of the engineering firms, inter firm coordination meetings, internal coordination, and 3D model coordination.
- Design progress reporting was established with the design firms inclusive of project status, 2 and 4 week lookahead, RFI status, action log, risk matrix, milestone (IFT/IFC) summary, progress measure (EV), client review status, hot topics/roadblocks, and cost alerts/design variations.

The Outcome:

The following outcomes were realised for the client:

- Identification of open BOD issues and design risks to be resolved on commencing detailed design.
- The project director and client team were fully briefed on the gaps, risks, and assumptions being made by the team in order to progress design. Established a risk management process with clear ownership and mitigation of risks.
- Clear identification of roles, responsibilities, and system owners. Increased end user engagement and accountability. Improved decision making and freezing of design decisions.
- Improved coordination between design firms and clear identification and timing of client inputs required by design firms. Improved coordination between design firms within the 3D model environment.
- Improved schedule adherence, and a clear and measurable reporting system for design progress.
- Design sequence aligned with the needs of the process start up and product manufacturing priorities.

Key Statistics:

Location | Ireland/ EU

Duration | 4 Months

Scope | Design Management

Cost | €150m