LAFFERTY.

Delivering a complex
Tech Transfer
program in an integrated manner.

The Brief:

The client required the transfer of both drug substance and drug product manufacturing from China to Europe. This was a highly schedule driven program and required all parties to work collaboratively to a shared plan. To ensure this there was the need to develop and integrated plan that MS&T, Quality, Supply Chain, Regulatory and CMC all bought into. The manufacturing was to be carried out by two different CMO sites in Europe. Highly effective risk management was required to ensure the schedule to regulatory approval and transition to commercial operations was not delayed.

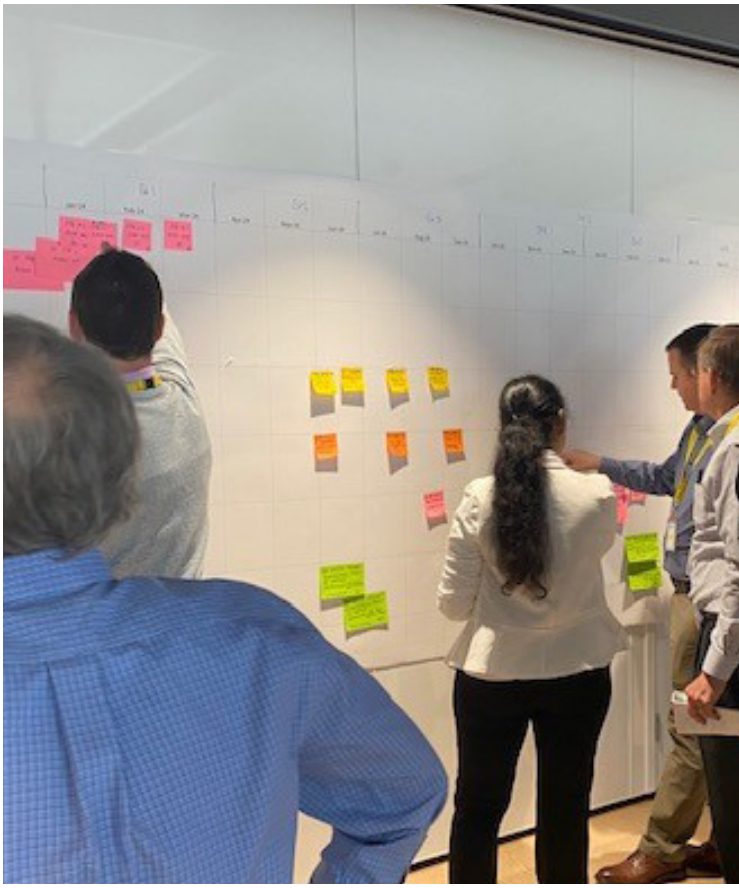
The Approach:

Lafferty Life Sciences ensured a strong alignment of all team members was achieved with the following key enablers:

- Agreement of an overall program charter that captured the key business objectives and measures of success. Clear communication and buy into the charter was achieved by the sponsor and executives.
- Development of a comprehensive integrated schedule via interactive planning & breakout sessions. Clear communication to all team members and full buy in was achieved by all workstream leaders.
- A weekly cross program coordination meeting was held to ensure adherence to the integrated schedule and the objectives of the program charter. Each of the workstream leads reported on progress, issues, risk and mitigations. Strong communication of key developments was provided by the program sponsor.
- Lafferty project managed some of the key workstreams that required additional attention due to their criticality.
- Close collaboration with the drug substance and drug product CMO's was essential to drive those areas of the schedule related to engineering runs, PPQ and release testing.
- Governance meetings were established to make key business decisions that the team required or addressing external factors that impacted the program.
- The list of program meetings were shortened and consolidated to make sure more time was made available to busy team members to focus on getting the job done.

The Outcome:

The program had a robust integrated schedule driven by a high performing client team and CMO team sharing an aligned plan. Risk management was driven across the program to ensure achievement of business objectives including regulatory approval at 2 sites and effective transition to commercial operations and patient supply.



Key Statistics:

Location I Ireland / EU/USA/China

Duration I 3 Years

Scope I Multiple Tech Transfer Program Management and Regulatory Approval

Cost I €35 Million

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