

# LAFFERTY.

Drug Product

## Lifecycle Management

### The Brief:

Lafferty were engaged by one of our clients to provide project management and drug product (fill finish) SME level experience to a critical project within a commercial fill finish facility. The project entails the significant upgrading of fill line, isolator, and capping equipment. The facility is critical to the supply chain for key growth products; therefore, the planning and risk management of the project work is of utmost importance to the business.

### The Approach:

Lafferty were engaged to lead the client project engineering team in the design and deployment of this project to ensure risk to ongoing commercial operations is minimised.

- Lafferty facilitated the initial scoping of the various upgrades required across the fill line, isolator, capper, and scope associated with a conversion of a Grade B room to Grade C. We also identified all client user requirements and documented the same for review and approval by all client internal stakeholders.
- Lafferty developed a high-level project schedule for communication to key stakeholders and senior management. We facilitated multiple interactive planning sessions to fully develop the project schedule and its impact on product availability.
- We identified key business risks, established a project risk register and assigned mitigation responsibility as appropriate.
- We provided technical SME input to design reviews of vendor technical submittals associated with the process equipment upgrades.
- Lafferty inputted into the shutdown planning of each of the interventions required to implement the upgrades, including planning of installation and CQV activity associated with the upgrades.
- Lafferty engaged key internal stakeholders in quality, sterility assurance, operations, CQV, and regulatory affairs to obtain buy-in to the scope, schedule and identify all risks.
- We identified design scope and produced bid documents for the client to engage engineering design firms where necessary.



### The Outcome:

The following outcomes were realised for the client:

- Detailed identification of the user requirements converted into project scope for each of the upgrades.
- SME level input to the technical reviews required on the project.
- Detailed project schedule and robust planning of the shutdown, CQV, media fill, and regulatory strategy for return to commercial production and realisation of the project benefits.
- Implementation of a risk management plan including mitigation for key risks and a defined escalation process with project governance.
- Improved internal coordination and stakeholder management.



### Key Statistics:

Location | Ireland

Duration | 8 weeks duration

Scope | Lifecycle Management

Cost | OOM cost estimate (€6m)

Integrated project schedule