

Job Title:
<b>New Process Introductions</b>
Company:
<b>API Manufacturer</b>
Location:
<b>Leinster, Ireland</b>
Duration:
<b>3 Months</b>
Objectives:
<b>- Develop layouts and PFD's</b>
<b>- Recommend location options within site</b>
<b>- Generate a preliminary project costing +/- 50%</b>
<b>- Prepare a report as a basis for developing the project rationale and justification</b>

<b>Get In Touch</b>
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Our client, a major Pharma manufacturer in Leinster, wished to identify how 3 potential new biotech products would fit with the existing API operations on their site. They engaged **Prochem** in a 3 month concept study with the objective of establishing the following:

- Compatibility with the sites facilities and skillsets
- The production supports required e.g. Utilities, QC, Logistics
- Potential locations and layouts for the new products
- Process or technical opportunities or constraints
- +/- 50% Cost Estimates for introduction of the new products.

The new products involved a range of technologies, primarily:

- Antibody Drug Conjugation
- Peptide/Oligonucleotide manufacture
- Small Scale API Manufacture (5 – 25 L)
- Bio- Processing at 3 different scales – 200 L, 1000 L & 2500 L
- Minimum Shear Mixing
- High Containment to 10 ng level
- Blast Freezing
- Rapid Thawing

From the initial outline process information received, **Prochem** generated PFD's. These formed the basis for assessing location and layout options with the client, from which detailed layouts and equipment lists were subsequently generated. Completion of this element enabled the costing exercise to be completed. A final report was then generated collating all the aspects of the study.

**Prochem** deployed a vastly experienced team, ensuring a successful and enhanced outcome to the study. Specific areas where **Prochem's** expertise ensured that delivery exceeded the clients initial brief were:

- **Prochem's** ability to interpret the preliminary process information in narrative form in the generation of PFD's, while seeking and receiving clarifications, will ensure that the inputs to detailed design are robust.
- Whilst the plant footprint and layout were significantly larger than the client had initially anticipated, **Prochem** ensured optimum layouts were developed.
- Single use equipment was considered for each product.
- **Prochem's** Containment specialist produced a comprehensive design and rationale for the project containment requirements.
- Numerous location options were developed, outlining the pros and cons of each, as well as a recommendation on a favoured location.
- The training needs associated with the new technologies, and their alignment with similar site operations were evaluated.
- A gap analysis of existing and likely production supports was performed and recommendations developed.

**Prochem's** client has used the concept study output to develop a project justification for bringing these products to the site.