Case Study

Process Transfer for Phase III Trials

Job Title: **Process Transfer for Phase III Trials**
Company: **Bio Pharma Manufacturer**
Location: **Leinster, Ireland**
Duration: **12 Months**
Objectives: **- Process Design Development** **- Design / tender / procurement** **- Transfer from R&D (France) to clinical Phase III batch production**

Our client, a major Pharma manufacturer in Leinster, wished to transfer a new process from its French R&D facility to its Irish site to facilitate Phase III clinical trials and full scale manufacture. A key consideration was a significant change required to the pre-existing formulation, necessitating the completion of thawing and Lyophiliser loading within a shorter Time Out of Refrigeration (TOR) so as to minimise the generation of High Molecular Weight (HMW) components.

Prochem was appointed to prepare a Basis for Design so as to:

- Provide a scope description (including layout, PFD's & P&ID's)
- Consider constructability and production impact
- Provide outline project timelines
- Prepare budget costs

Subsequently **Prochem** was awarded the Detailed Design and Construction management for the project. The scope included CSA, Process, Mechanical, Ventilation Automation and Electrical elements.

The process description was developed between the client and **Prochem,** and included the following main elements:

- Water Bath (Thawing of product in Nalgene Bottles) c/w heating / cooling skid
- Lev mixer (on load cells) with cubical disposable bags and levitating agitator for volumes between 40L and 100L
- LAF Unit to protect product during processing
- Huber Chiller
- Transfer Panel Modifications in formulation / lyophilisation areas
- Freezers (-20^{o}C) linked to site UMS and UPS
- WFI (mobile tank), Clean Air, N_2

The modified process involved rapid thawing, heating and cooling, pooling, mixing and filtration using single use technology, all of which needed to be accommodated within existing processing space. 6 options/locations were narrowed to 3 for further development and generation of the benefits case, from which the optimum location and flow was agreed with stakeholders.

The final solution involved the rapid thawing and temperature control within a formulation room of product taken from the warehouse, prior to filling and lyophilisation. In addition it involved the removal and reuse of existing equipment within a pre-existing hard piped GMP Grade A/B/C environment. A significant challenge presented was the identification of a vendor for the Water Bath who could satisfy the process and GMP requirements. Owing to the bespoke nature of the final solution, a Hazop on the system was completed.

From the initial project meeting to the final handover, **Prochem** used a consistent and experienced team, ensuring efficient knowledge management throughout the project lifecycle, and improving the quality of the ultimate outcome.

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