

Job Title:

Clean Utilities

Company:

Major Pharma Biologics

Location:

Western Ireland

Duration:

18 months

Objectives:

**Provide Clean Utilities
for Lyophilisation
Facility**

Get In Touch

Tel: [+353 56 77 90100](tel:+353567790100)

Fax: [+353 56 77 90101](tel:+353567790101)

Email: info@prochem.ie

Mobile: [087 2648000](tel:0872648000)

Web: www.prochem.ie

WFI, Clean Steam and PuW Generation and Distribution Systems.

Prochem's client, a major Pharmaceutical manufacturer located in the west of Ireland had a requirement for a new biologics facility on its existing site. Together with our project partner, **Prochem** were awarded the contract for detailed design and construction management of the clean utility systems for the project.

At project commencement **Prochem** assessed the complete user demand profile schedules of the client for the utilities. This helped to establish the basis of design (BOD) and allowed **Prochem** to generate and issue draft URS documents for the Clean Steam, WFI and Purified Water Systems. The WFI tank had a capacity in excess of 20m³, the Purified Water generation was greater than 5m³/hr and the Clean Steam capacity was in excess of 2000 kg/hr. **Prochem** also had to evaluate the procurement strategy for the equipment.

The system needed to be in compliance with the relevant FDA, ISPE, JP and EU Pharmacopoeia requirements. Automation needed to be in adherence with 21 CFR Part 11.

Prochem then developed schematic P&ID's of the systems and worked with project partners on equipment layouts for the facility. **Prochem** managed the tender process for generation skids, pumps, heat exchangers and tanks used in the process and executed a design review of the proposed equipment. Qualified vendors were interviewed on site by **Prochem** prior to being awarded work on the project. Once equipment was chosen, **Prochem** evaluated the utilities and electrical demands and developed the control philosophy in conjunction with our project partner.

The supply and installation of the entire clean utility package was awarded to a single company. **Prochem** were involved throughout the entire process from order placement and design review, through to equipment acceptance, FAT's, IQ, and OQ of the completed systems.

The client received a fully OQ'd Clean Utility system on schedule and within budget to support the other elements of the project, which included lyophilisers, stopper washers, vial washing, vial fillers, autoclaves and humidification.

Prochem's specialist expertise in Clean Utilities ensured the largest project of its kind within the sector in that year was successfully delivered.