



Case Study



New Aseptic Manufacturing Process

New Multi-Step Aseptic Manufacturing Process

(£1.7 m Detailed Design, Validation Services, Project Management)

Pharmaceutical Manufacturing Facility, UK

The Problem

The existing process had been operated at bench and semi-commercial scale. Sales opportunities demanded that the operation be fully scaled up. The operations included protein extraction, modification and formulation into final drug substance.

The new plant had to be integrated into existing Class A and C clean rooms with a minimum of disruption to the ongoing operations.

The Solution

BPE provided the Project Management, Engineering and Validation expertise supported by Client representatives in an integrated team environment.

A new small scale manufacturing concept was proposed. Key technical areas were identified as process critical requiring scale up data to ensure that product conformity was maintained. BPE staff assisted the client in a range of developmental process tests from which data was obtained and used to define the full scale equipment requirements.

