

## 1.1 Aseptic-Toxic Lyophilization and Fill/Finish System

**Project Overview** – This system is one of the largest automated sterile fill/finish systems in existence to date and the most flexible system in terms of batch scale and vial sizes ever undertaken. The system is two identical mirror-image fill finish lines capable of operating in 14 different configurable modes of operation. The extreme flexibility designed in the system is intended to accommodate the unique business model of the University that caters to performing clinical trial batches yet will be expandable to take on higher volume production runs in the future.

Less than 30% of the system is manufactured by CPS (Isolators, Controls and integration elements) with the rest purchased from a network of major specialist subcontractors under control of the CPS Project Management and Technical Services team.

The system operates through a SCADA system compliant with FDA 21CFR Part 11 for electronic signatures and records. Both lines are fully automated with operator intervention limited to only to load and unload vials from the system, set-up preparation and cleaning post batch.

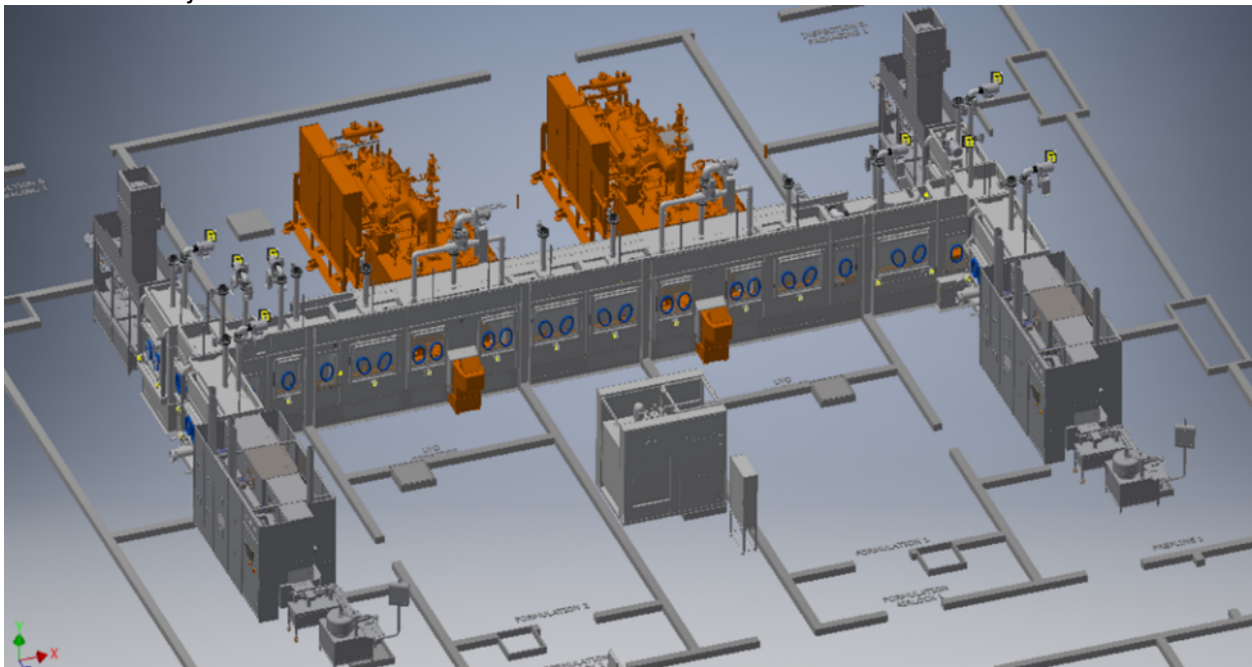
### Statistics

Date: 2018 through 2020

Location: Iowa, USA

Total Order Value: \$18,000,000

Duration of Project: 28 months



Equipment Component	Quantity
Vial Washers - Internal	2
Depyrogenation Tunnels	2
Fill and stopper	2
Cappers	2
Vial Washers External	2
Tee Switch	2
Conveyor	2
Lyophilizer loader	2
Lyophilizer Skids	2
Isolator System	1
VHP Bio-decontamination System - Equipment	1
Autoclave	1
Clean steam Skid	1
WFI Skid and WFI Tank	1
Parts Washer	1
SCADA Control System	1
VHP Bio-decontamination System - Rooms	2

