STERILE*LIZER*™
ENGINEERING

The DSE STERIE*LIZER*™ Engineering Services provides advanced, state-of-the-art barrier isolation, aseptic processing and sterilization system technologies for the pharmaceutical, biotechnology, manufacturing and medical device industries.

Our team has been pioneers and leaders in the application of isolation technology to advanced aseptic processing since 1994, the earliest stages of industry development. We offer a complete spectrum of support services.

SERVICES

User Requirements Specifications

Accurately define your requirements to improve system performance, set clear client/vendor expectations, minimize change orders, control cost, and maintain schedule.

Systems Integration

Work closely with our manufacturing team to select, integrate, and validate the equipment required to support aseptic processing and sterility testing isolation applications.

Validation Planning

A validation master plan, developed properly during the early phases of project planning, can save time and resources and lead to faster facility licensing. Our experienced team integrates key design decisions and important validation strategic decisions into a comprehensive, realistic validation strategy.

Factory Acceptance Testing

The more thoroughly the system is tested in the factory, the greater the assurance that the system will operate as intended in the field, thereby facilitating installation, validation, and start-up. Our team will test total systems (both mechanical and microbiological parameters) before they leave the factory floor to eliminate unpleasant surprises during start-up and validation.

Site Acceptance Training

The system is challenged under field conditions, plus factory test punch list items are finally reviewed and closed in preparation for validation.

Installation & Operational Qualification

Testing a system per your quality system and the most current industry standards will provide you with the most consistent comprehensive equipment validation program throughout your plant. Our team can address individual equipment validation issues as well as system-wide interface challenges.

Process Development/Cycle Development

Optimize the decontamination cycle of the qualified equipment to provide the most efficient turn-around times or the decontamination cycle can be tuned to achieve certain process specific goals.

Performance Qualification

Our team can properly and efficiently challenge your isolator decontamination process to account for your unique process characteristics plus comply with the best practices on current US and European systems.

SOP Development

In-house existing procedures may need to be adapted to isolated equipment or you may need guidance on writing new documents. Our team has a broad range of experience in the best industry practices

Operator Training

Our team provides proper documentation and hands-on teaching to ensure that your operators are thoroughly trained to understand and embrace the new technologies that they will be working with on a daily basis.

Annual Requalification

DSE knows how to set-up and execute an annual re-qualification program that keeps your system in compliance but still maximizes efficiency to keep you up and running in production.

DECONTAMINATION
SPECIALTY EQUIPMENT

Our team of subject matter experts brings more than 160+ years of proven experience in the design, equipment manufacturing and maintenance of sterile environments to meet the needs of our customers.

2101 West 12TH Street · Erie, PA 16505 | phone 1.412.916.8609 | inquiries@dse-global.com