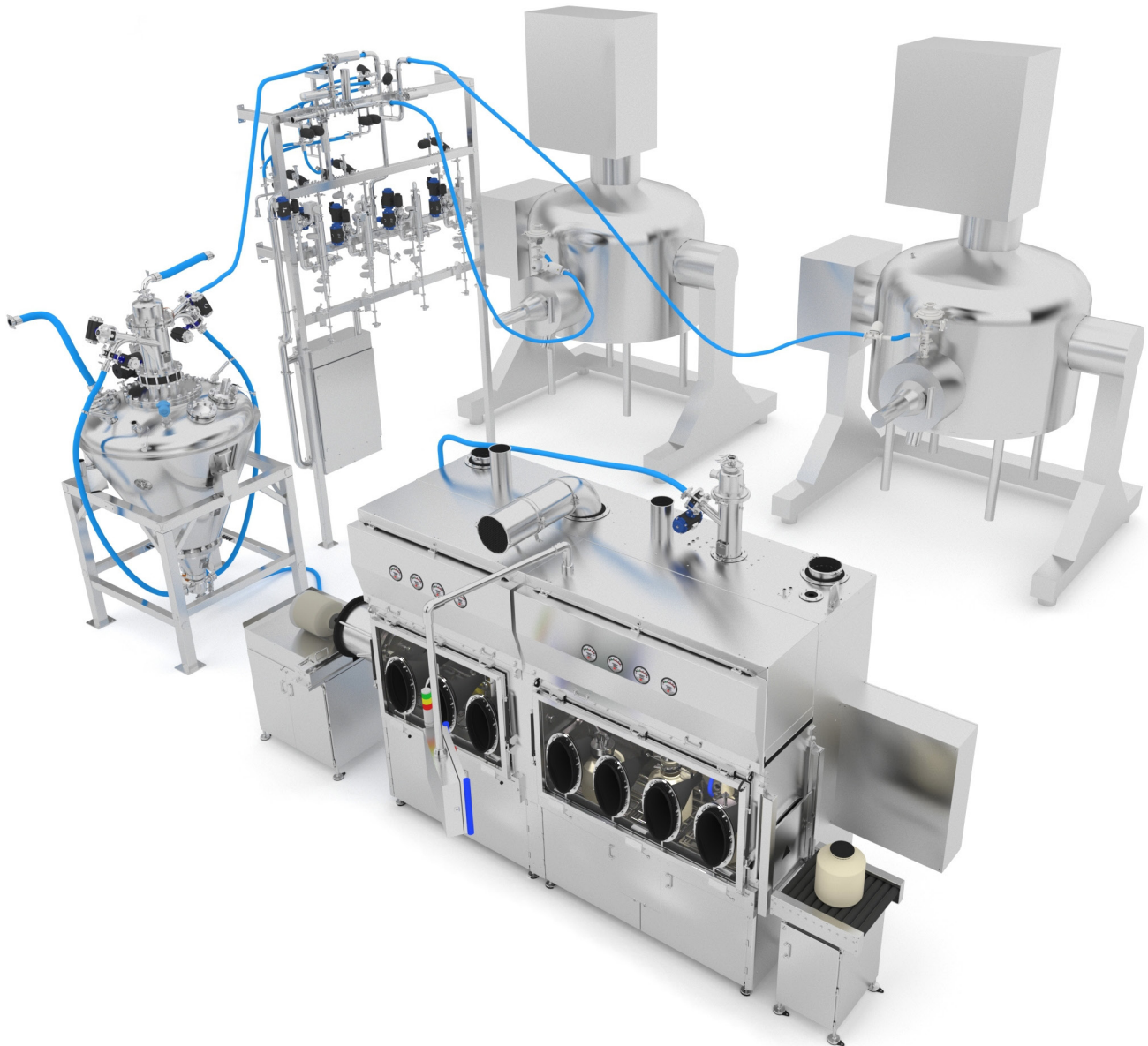


# Sterile Products



New EU/FDA legislation outlawing irradiation of products makes the issues of sterile powder handling a current topic of increasing relevance for a wide range of applications.

ATEX

OEB5



High Containment

SIP

Easy Sterilization



Sanitary Standards

FDA

# Sterile Products



Dec Group is at the forefront in the development and implementation of micronising, blending/mixing, packing and dispensing of products in processes that handle sterile powders.

Dec's products ensure a robust safe system, fully recorded and controlled to the very highest standards. They are unique because the entire system remains sterile throughout the product cycle. Even during the sterilization phase the entire system is temperature and pressure mapped to validate the complete sterilization process (SIP) with controlled steam injections and condensate drainage valves easily achieving Sterility Assurance Levels of  $10^{-6}$ . In contained systems for sterile toxic products the isolator is VHP'd to achieve the same SAL level.

The following Dec products are available in sterile format:

#### Transferring

- PTS Powder Transfer System®
- PTS Aseptic Design - SIP

#### Filling

- PTS & Dosi Valve
- Continuous Liner

#### Micronising

- MC DecJet® 30
- MC DecJet® 50
- MC DecJet® 100
- MC DecJet® 150
- MC DecJet® 200
- MC DecJet® 300
- MC DecJet® 400
- Consultancy

#### Containment

- Dispensing systems
- Flexible systems
- Isolated systems
- MPTS sampling
- Pack off systems
- Packing heads
- Micronising systems

#### Cleaning

- Retractable spray ball

#### Accessories

- Rotary valve



All of Dec's containment technologies and systems comply with pharmaceutical quality manufacturing standards and are available for aseptic operations. These can be easily integrated into existing production lines. Dec has designed various sterile isolator solutions with specific control over potential contamination sources. Operator intervention, the highest contamination cause is eliminated. To ensure the Sterility Assurance Level, the isolator is biologically decontaminated with VHP (Vaporized Hydrogen Peroxide) and the process equipment is sterilized with steam.