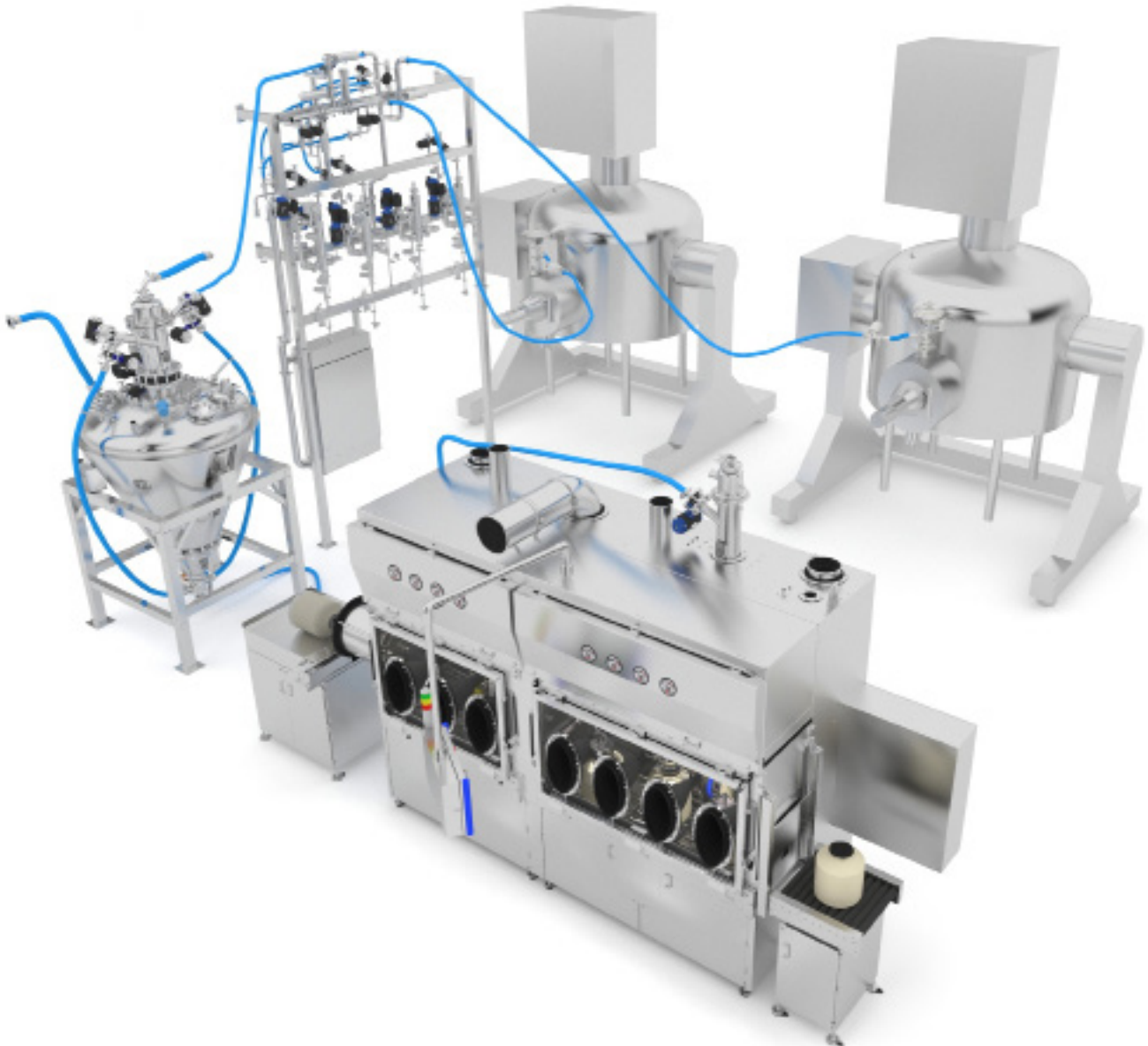


Sterile/Aseptic Process



EU & FDA legislations make the issues of sterile powder handling and aseptic processing a current topic of increasing relevance for a wide range of applications.

ATEX

OEB 7



High Containment

SIP

Easy Sterilization



Sanitary Standards

FDA

Sterile/Aseptic Process



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

Dec's solutions ensure robust and safe systems, fully monitored and controlled to the very highest standards. They are unique because the entire process remains sterile throughout the production cycle. During the sterilization phase the entire system is temperature and pressure mapped for validation purposes. SIP with controlled steam injections and condensate drainage valves easily achieve Sterility Assurance Levels (SAL) of 10^{-6} . In contained systems for sterile-toxic products Vaporized Hydrogen Peroxide (VHP) is used to achieve the same SAL level.

The following Dec systems are available

for aseptic/sterile operation:

Transferring/Dosing

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

Blending/Mixing

- PTS Batchmixer®

Filling / Emptying

- CLS System (Continuous Liner)
- SafeDock®
- DecFill® Filling Lines

Micronizing/Milling

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

- MC DecJet® 500
- UMS DecMill®

Microdosing

- Powder: μ PTS/flexPTS/sPTS
- Liquids: BoMa

Containment

- Dispensing systems
- Flexible (soft wall) systems
- DecFill® Filling lines (powder & liquids)
- MPTS sampling
- Pack off systems
- Packing heads
- Micronizing isolators
- Cell therapy isolators
- Steripharm® standard range

Cleaning

- Retractable spray ball



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 SAL, the isolator is biologically decontaminated with VHP and the process equipment is sterilized with steam.