

cGMP DOCUMENTATION

Materials verification package
(HEPA filter, motor blower, SS lot,
calibration of the pressure gauge)

IQ/OQ documents (Protocol Only
or Protocol, Execution & Report)

ISO Class 5 environment for aseptic processing and cGMP support laboratories

Engineering controls to support cGMP cleanroom conditions

Grade A	Grade B	Grade C	Grade D
Sinks and drains are prohibited in Grade A	Sinks and drains are prohibited in Grade B	Less critical operations	Less critical operations
High-risk operations (filling zone, stopper bowls, open ampules, and vials, making aseptic connections)	ISO 5 at rest, ISO 7 in operation	ISO 7 at rest, ISO 8 in operation	ISO 8 at rest, not defined for in operation
Laminar airflow cabinet can obtain Grade A cleanliness in Grade B background	Particle monitoring system with alarm if limits are exceeded is required	Monitoring depends on the quality risk management	Dirtiest area of cGMP guidelines
Equivalent to an ISO 5 cleanroom environment (at rest and in operation)	Background zone for Grade A	Used for filling of products for terminal sterilization (at least in a Grade C)	
	Used for aseptic preparation and filling	Preparation of solutions to be filtered, including weighing	

Mecart Cleanrooms, 2002

SterilGARD® e3

Biological safety cabinets for
use in cGMP environment



BioPharma Package

 Baker

SterilGARD® e3

Class II Type A2 Biosafety Cabinets

Providing cGMP / cGLP engineering solutions with the SterilGARD® e3 by selecting standard and optional features.

STANDARD FEATURES

- (-)Pressure double wall plenum
- Internal GFCI duplex outlet
- Audible and visual alarms
- Momentum air curtain
- High-velocity return air slots
- Removable work surface
- ReadySafe™ low-flow operating mode
- StediFlow™ - VFD motor controller
- UniPressure™ - preflow plenum SS air bypass

cGMP OPTIONAL FEATURES

- All stainless steel (SS) construction 304 or 316, interior or exterior
- SS cable port(s) & sleeves
- Isokinetic sampling probe / shelf for counter is possible under drain pan
- Microbial sampling of viable particles
- Cabinet set point monitor with BAS / BMS connectivity
- SS channel stand
- Minimal penetrations in work area
- Green status light - visual indicator for operator of fully operational mode
- Patch Free HEPA filters
- SS Casters
- SS Needle Valve and Piping
- H2O2 Decon Injection Ports

Baker is a component provider and is not responsible for cGMP compliance.

Create an ISO Class 5 / Aseptic Processing Environment*

Ideal for cell and gene therapy and personalized medicine.

CABINET SET POINT MONITOR

Digital display of Differential Pressure Gauge with optional upgrade for signal to BAS/BMS connectivity

MINIMAL PENETRATIONS IN WORK AREA

Reducing the amount of penetrations or punctures through the steel to give multiple options for optimal cleanability

STAINLESS STEEL OUTLET COVER

STAINLESS STEEL CABLE PORT(S) & SLEEVES

To facilitate tubing and cabling needs under negative pressure

STAINLESS STEEL CHANNEL STAND

Increased chemical resistance & cleanability

STAINLESS STEEL AIR BYPASS

Sight-tight air bypass for closed sash operation



BMS CABLE INTERFACE ASSEMBLY

Cable Package providing dry contacts to send signal to turn on exhaust blower on roof, alert a power failure, alert blower is operational or signify cabinet is in Ready Safe Mode

ALL STAINLESS STEEL CONSTRUCTION

Increased cleanability and resistance to corrosion

PARTICLE MONITORING

Provides continuous non-viable particle monitoring via isokinetic probe and viable particle monitoring via air sampling

*per ISO 14644

Talk to us about the features presented and how they can help you work towards cGMP / cGLP

bakerco.com    