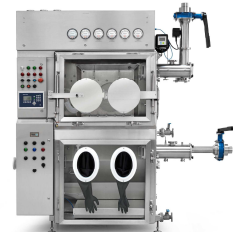


ENQUIRY QUESTIONNAIRE – GLOVEBOX ISOLATOR



The following questions are designed to gain specific basic information related to your required Glovebox Isolator application. Your information will enable us to develop & specify the correct type and configuration of the Isolator which best suits your process requirements.

First name:	
Surname:	
Email address:	
Company:	
Company address:	
City:	
Country:	
Tel:	
Cell:	

Isolator Application: Please mark the activities intended/required for the isolator.

<input type="checkbox"/> Powder Dispensing <input type="checkbox"/> Sub-division <input type="checkbox"/> Sampling <input type="checkbox"/> IBC Filling <input type="checkbox"/> Compounding <input type="checkbox"/> Process Transfer (charging) by gravity <input type="checkbox"/> Process Transfer (charging) by suction <input type="checkbox"/> Process Containment <input type="checkbox"/> Milling <input type="checkbox"/> Micronisation <input type="checkbox"/> Blending <input type="checkbox"/> Sieving <input type="checkbox"/> Vacuum Tray Dryer <input type="checkbox"/> Lyophiliser Discharge <input type="checkbox"/> Pack-off <input type="checkbox"/> With check-weighing <input type="checkbox"/> With controlled dosing <input type="checkbox"/> Filter-Dryer Discharge – Large Scale with isolator fixed to discharge port <input type="checkbox"/> Filter-Dryer Discharge – Small Scale With dryer mounted through isolator top <input type="checkbox"/> Sterility Test <input type="checkbox"/> Other: _____

Containment Requirement Classification (8 hr Time-weighted Average):

<input type="checkbox"/> OEB5 (<1.0 µg/m ³) <input type="checkbox"/> OEB4 (1-10 µg/m ³) <input type="checkbox"/> OEB3 (10-100 µg/m ³) <input type="checkbox"/> OEB2 (100-1'000 µg/m ³) <input type="checkbox"/> OEB1 (1'000-10'000 µg/m ³)



Hazardous Area Classification:

Classification	Category	ATEX	Internal	External
Non-Hazardous	-	-	<input type="checkbox"/>	<input type="checkbox"/>
European: ATEX	1 Gas	2G	<input type="checkbox"/>	<input type="checkbox"/>
	21 Dust	2D	<input type="checkbox"/>	<input type="checkbox"/>
	2 Gas	3G	<input type="checkbox"/>	<input type="checkbox"/>
	22 Dust	3D	<input type="checkbox"/>	<input type="checkbox"/>
Gas group	IIA	-	<input type="checkbox"/>	<input type="checkbox"/>
	IIB	-	<input type="checkbox"/>	<input type="checkbox"/>
	IIC	-	<input type="checkbox"/>	<input type="checkbox"/>
Temperature class	T3	-	<input type="checkbox"/>	<input type="checkbox"/>
	T4	-	<input type="checkbox"/>	<input type="checkbox"/>
	<135 Deg.C	-	<input type="checkbox"/>	<input type="checkbox"/>
USA: (specify)	Class	Groups	Division	Zone
Internal				
External				

Materials of Construction:

Contact parts	<input type="checkbox"/> 316L Stainless Steel	<input type="checkbox"/> Alloy 22 (Hastelloy)	<input type="checkbox"/> Other
External parts	<input type="checkbox"/> 304L Stainless Steel	<input type="checkbox"/> 316L Stainless Steel	<input type="checkbox"/> Other
Internal finish	<input type="checkbox"/> <0.5 µmRa Satin	<input type="checkbox"/> <0.8 µmRa Satin	<input type="checkbox"/> Mirror
External finish	<input type="checkbox"/> <0.9 µmRa Satin	<input type="checkbox"/> <1.2 µmRa Satin	<input type="checkbox"/> Other
Solvent in use	<input type="checkbox"/> Ethanol	<input type="checkbox"/> Methanol	<input type="checkbox"/> Acetone
	<input type="checkbox"/> THF	<input type="checkbox"/> Toluene	<input type="checkbox"/> Isopropanol
	<input type="checkbox"/> IMS	<input type="checkbox"/> Other (specify)	
Gloves materials	<input type="checkbox"/> CSM (Hypalon)	<input type="checkbox"/> EPDM FDA A/S	<input type="checkbox"/> Sleeves with cuffs
	<input type="checkbox"/> Butyl	<input type="checkbox"/> Other:	
Fan case preferred	<input type="checkbox"/> Painted Carb Steel	<input type="checkbox"/> Stainless Steel	<input type="checkbox"/> Plastic

Application Specific Items:

Category	Options		
CIP	<input type="checkbox"/> Spray hand gun	<input type="checkbox"/> Rotary Spray Head	<input type="checkbox"/> Manifold
CIP fluid	<input type="checkbox"/> Water	<input type="checkbox"/> Demineralized Water	<input type="checkbox"/> Solvent
WIP	<input type="checkbox"/> Retractable Spray Head		
Purge	Process Equipment:	<input type="checkbox"/> Air	<input type="checkbox"/> Nitrogen
	Isolator:	<input type="checkbox"/> Air	<input type="checkbox"/> Nitrogen
Purge complete (N2)	<input type="checkbox"/> Preset Time Period	<input type="checkbox"/> Continuous Sensor Monitoring	
Supply voltage	V:	Hz:	Phase:
Static / Mobile	<input type="checkbox"/> Static	<input type="checkbox"/> Mobile by truck	<input type="checkbox"/> On wheels
Glove tester	<input type="checkbox"/> No	<input type="checkbox"/> Simple	<input type="checkbox"/> WIFI
Control System:			
Operator controls	<input type="checkbox"/> HMI	<input type="checkbox"/> Pushbutton / Lamp	
Logic-Software	<input type="checkbox"/> Dec	<input type="checkbox"/> Client	
HMI	<input type="checkbox"/> Dec	<input type="checkbox"/> Client	
MCC	<input type="checkbox"/> Dec	<input type="checkbox"/> Client	
Connecting cables*	<input type="checkbox"/> Dec	<input type="checkbox"/> Client	*MCC to Isolator
Other			



Sterile Production:

Sterile application ISO-14644-1	<input type="checkbox"/> ISO-05	<input type="checkbox"/> No	
Isolator background environment	<input type="checkbox"/> ISO-7	<input type="checkbox"/> ISO-08	
Process equipment SIP	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Hot
Isolator biological decontamination*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	*VHP
Air sampling	<input type="checkbox"/> No	<input type="checkbox"/> Microbiological	<input type="checkbox"/> Particle
Temperature & relative humidity	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Other			

Powder Packaging:

Category	Type	Size	Weight
Inlet	<input type="checkbox"/> Drum		
	<input type="checkbox"/> Carton		
	<input type="checkbox"/> Poly Bag		
	<input type="checkbox"/> Bottle		
	<input type="checkbox"/> Lyo Tray		
Outlet	<input type="checkbox"/> Liner		
	<input type="checkbox"/> Drum		
	<input type="checkbox"/> Bottle		
	<input type="checkbox"/> VHP		
	<input type="checkbox"/> IBC		
	<input type="checkbox"/> Other		

Site Specific Requirements:

Category	Size			
Room height				
Length limit				
Depth limit				
Room door size				
Lift size/Weight limit				
Corridor routing				
Site Eng standard	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
Applicable to:	<input type="checkbox"/> Piping	<input type="checkbox"/> Electrical	<input type="checkbox"/> Instruments	<input type="checkbox"/> Valves
Other				

Documentation & Services:

Category	Options		
Documents *	<input type="checkbox"/> Dec Standard	<input type="checkbox"/> Validation Life Cycle	<input type="checkbox"/> GAMP5
Services	<input type="checkbox"/> Install Supervise	<input type="checkbox"/> Start-up/Commission	<input type="checkbox"/> SAT
	<input type="checkbox"/> IQ Testing	<input type="checkbox"/> OQ Testing	<input type="checkbox"/> SMEPAC
*Included:			
Dec Standard	Project Plan, GA, PID, FS, Elec & Pneu Diagrams, Instrument List, FAT Protocol, ATEX and Material Certs, OEM Manual		
Validation Life Cycle	Quality Plan, SDI, FDS, SDS, HDS, SAT Protocol, IQOQ Protocol		



Additional Notes - please add any additional explanatory notes applicable:

Please draw a sketch of the concept expected arrangement or processing steps applicable to the isolator on the following page.



A large, empty rectangular box with a thin black border, intended for a signature or stamp.

Date: _____ Signature: _____