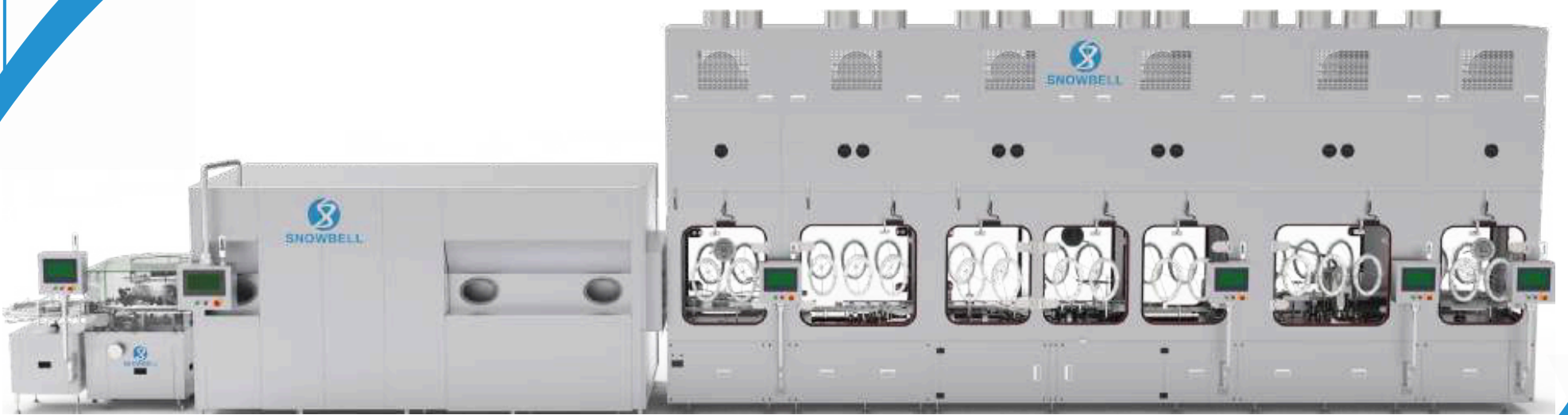




Snowbell Machines US Inc.

Complete Solution for your Injectables



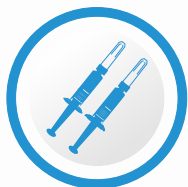
Sterile / Aseptic Filling Lines for ...



Vials



Ampoules



PFS



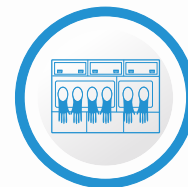
Eye/Ear
Drop



Nasal/Topical
Spray



Cartridges



Isolator



www.snowbellmachines.com

ABOUT US

Snowbell Machines has been a pioneering force in the pharmaceutical machinery industry since our inception in 2005. We have relentlessly pursued innovation, shaping the landscape of aseptic filling and sealing equipment for injectables, containment systems and advanced filling and packaging machinery for ophthalmic, nasal, and topical sprays.

Our journey is marked by unwavering dedication to excellence and a commitment to delivering superior solutions to our valued customers.

Snowbell Machines embodies the spirit of innovation with a steadfast commitment to safety. We produce containment systems, such as isolators up to OEB level 5, ensuring the highest degree of protection for operators and products.

Diversity is our strength, reflected in our extensive product range. Our portfolio includes over 100 products, such as medical device assembly machines for metered-dose injections and oncology R&D devices.

At Snowbell Machines, we are dedicated to providing high-quality solutions tailored to your unique needs and specifications. Our team of experienced professionals works diligently to understand and exceed user expectations from consultation and installation to comprehensive training and ongoing maintenance, we are committed to ensuring project success.

CLIENTELE



PRODUCT LIST

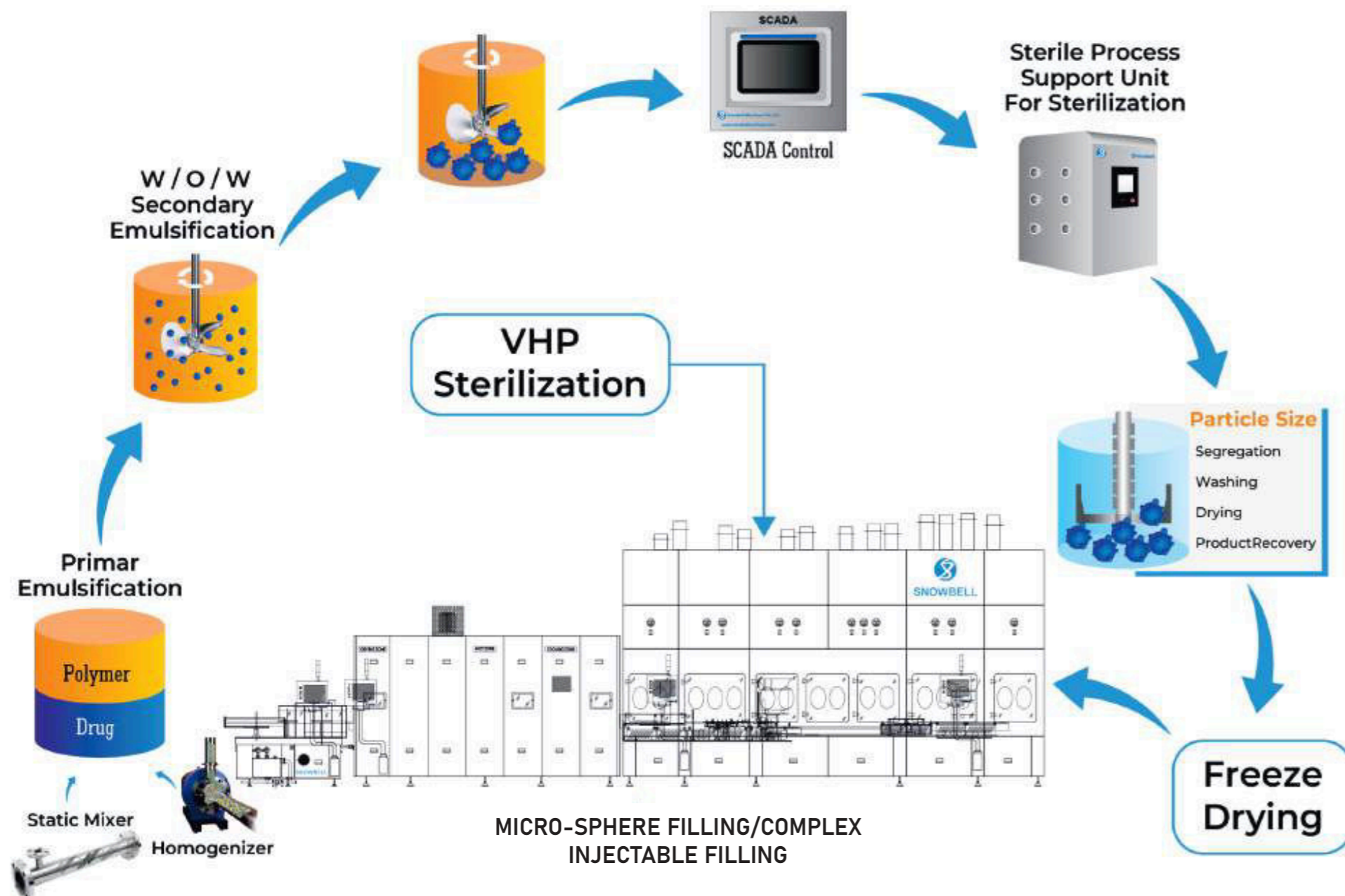
- Vial Liquid Filling Line.
- Vial Powder Filling Line.
- Ampoule Liquid Filling Line.
- Bottle Filling Line (50ml to 500ml - LVP Line).
- Eyedrop Filling Line.
- Cartridge Filling Line.
- PFS Filling & Stoppering.
- PFS Denester.
- PFS Plunger Rod Insertion and Labelling Machine.
- Combi Vial Liquid Powder Filling Line.
- Combi Ampoule / Vial Line.
- Combi PFS / Cartridge Filling Line.
- Combi Vial / Eye Drop Filling Machine.
- IV Bag Filling & Plugging Machine.
- Robofill Triple Combi Vials / PFS / Cartridge Filling Machine.
- Robofill Triple Combi Ampoule / Vial / PFS Filling Machine.
- Nasal Spray Filling Line.
- Topical Spray Line.
- Onion Skin Ampoule Filling & Sealing Machine.
- Vacutainer Filling Machine (For Pre-Stoppered Vacutainer).
- NIR Inspection Machine.
- Ointment Filling Line.
- **Isolators.**
- Compounding Isolator with Compounding Vessel.
- Filtration Isolator with Filtration Skid.
- Isolator for Sampling.
- Isolator for Dispensing.
- Isolator for Oral Solid Dosage (OSD).

PRODUCT LIST

- Automatic Loading Unloading System (ALUS).
- External Washing Machine.
- Leak Testing Machine for Vials.
- Labelling Machine.
- Cosmetic Inspection Machine.
- Isolator for Capsule Filling Machine.
- Sterility Test Isolator.
- Isolator for Tablet Compression Machine.
- Isolator for Ball Mill.
- Isolator for Sterile Milling Process With Half Suit.
- Glove Box for API Charging In Reactors (Acrylic).
- Glove Box for Weighing (For Laboratory Use).
- Glove Leak Tester Wifi Type.
- Glove Leak Tester Wired Type.
- Dry Syrup Filling Line.
- Lyophilizer Tray Loading System.
- Gel Filling Line.
- Pass Boxes (Static & Dynamic).
- De-dusting booth.
- Laminar Flow (Horizontal, Vertical, Ceiling Suspended & Stand Mounted).
- Air Shower.
- Mist Shower.
- Bio Safety Cabinet.
- Sampling & Dispensing Booth.
- Mobile Trolley.
- Garment Storage Cabinet.

COMPLEX INJECTABLE

ASEPTIC PROCESS



Snowbell Machines specializes in the supply and support of complex injectable formulations and their aseptic process, covered R&D trials from commercial manufacturing to final product filling in Vial, PFS, and Dual Chamber PFS.

We offer technological advancements for Biopharma R&D, focusing on Novel Drug Delivery System (NDDS) products from research to commercial production.

Snowbell Machines provides comprehensive support throughout the aseptic process, including process support skids and suitable analytical Process Analytical Technology (PAT) tools.

Connect with Snowbell Machines for all your complex injectable needs in human healthcare and veterinary medicine.

WASHING MACHINE / STERILIZATION AND DEPYROGENATION TUNNEL

Features

- Equipped with standard 6 stages of washing consisting of Recycled water, Purified water, Water for Injection & Compressed air.
- Pre & Post purging for Nitrogen.
- WFI flushing at the start of batch.
- Compressed Air purging at the end of batch.
- Ultrasonic washing station (optional).
- Auto drain facility.
- Recirculation tank with pump.
- Integration with depyrogenation tunnel.
- Online/offline data recording.
- SCADA 21 CFR part 11 compliant.



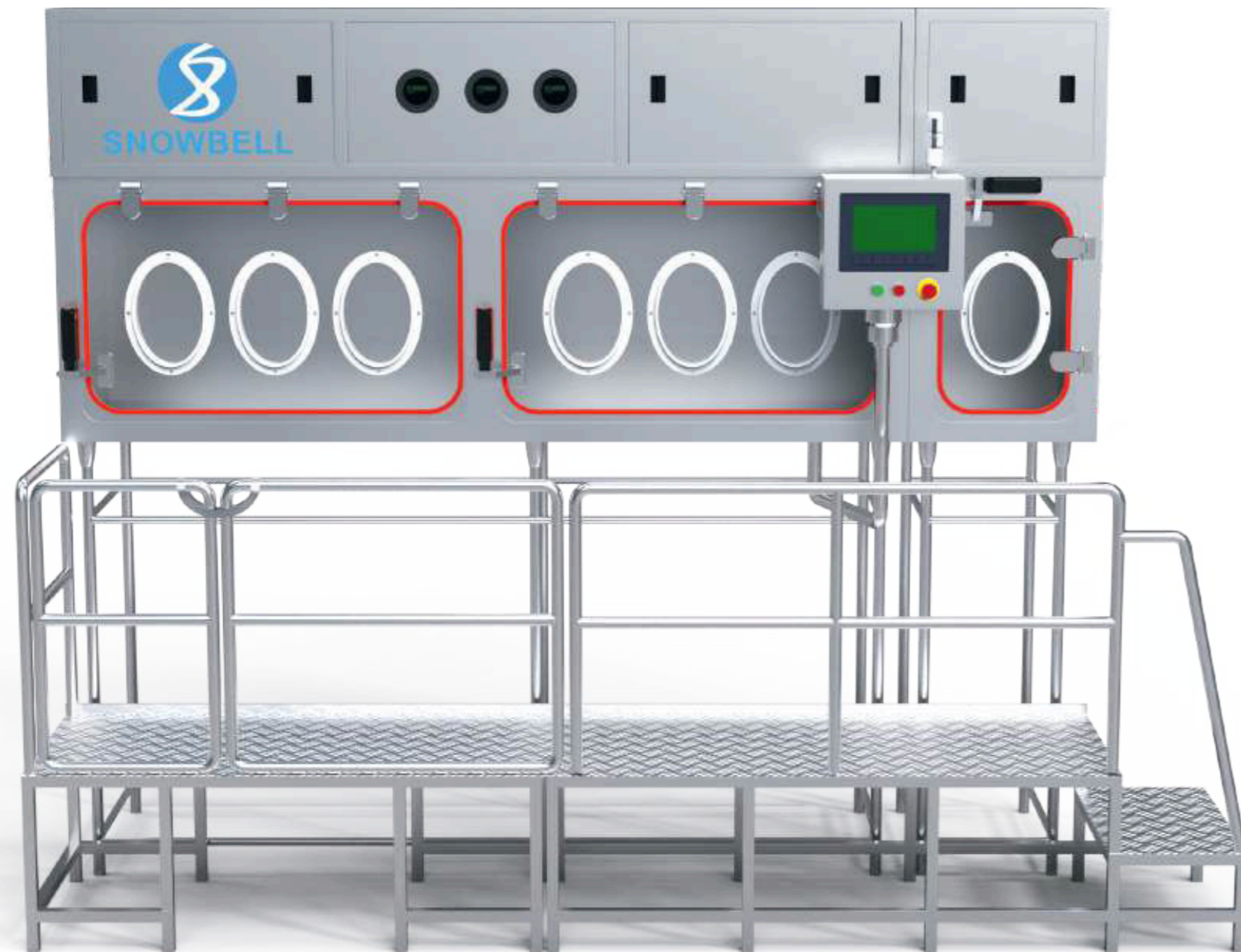
Features

- Snowbell Machines Depyrogenation tunnels are dimensioned to perform an endotoxin reduction of greater than 3 log.
- The tunnel is divided into three zones which are drying zone, hot zone, & cooling zone.
- The hot zone is equipped with the HEPA (H-13 grade) filter for resisting high temperature up to 350°C.
- It is equipped with automatic excess air control in the cooling zone to balance the air pressure between the aseptic & non-aseptic space.
- Chilled water coil in the cooling zone.
- Sterilization of cooling zone by heating.
- Gates between zones & exits of the cooling zone.
- Cooling zone.
- Online/offline data recording.



CONTAINMENT SOLUTION

Compounding Isolator



Features

- > Rigid wall enclosure (SS 316/316L).
- > Suitable for handling cytotoxic and hazardous products.
- > Rapid transfer port for material transfer and waste disposal.
- > Customised integration with process equipments.
- > SCADA 21 CFR part 11 compliant.

08

CONTAINMENT SOLUTION

Snowbell provides and supports pharmaceutical containment processes used for the protection of products, personnel & environment for customized requirements up to OEB Level 5.

Application

- > High potent API process.
- > Solid oral dosage formulation.
- > Injectables.
- > Sterility testing.
- > Customized applications.

API

- > Rigid wall enclosure.
- > Negative pressure regime.
- > Static/Inflatable gasket for doors.
- > Material transfer and solid waste disposal.
- > Safe change filters-integrated weighing scale.
- > Provision for monitoring pressure, temperature, RH & temperature control.
- > SCADA 21 CFR part 11 compliant.

Solid Oral Dosage (Formulation Customized Process)

- > Rigid wall enclosure.
- > Negative pressure regime.
- > Static/Inflatable gasket for doors.
- > Material transfer and solid waste disposal.
- > Liquid waste disposal.
- > Integrated equipments.
- > Safe change filters.
- > SCADA 21 CFR part 11 compliant.



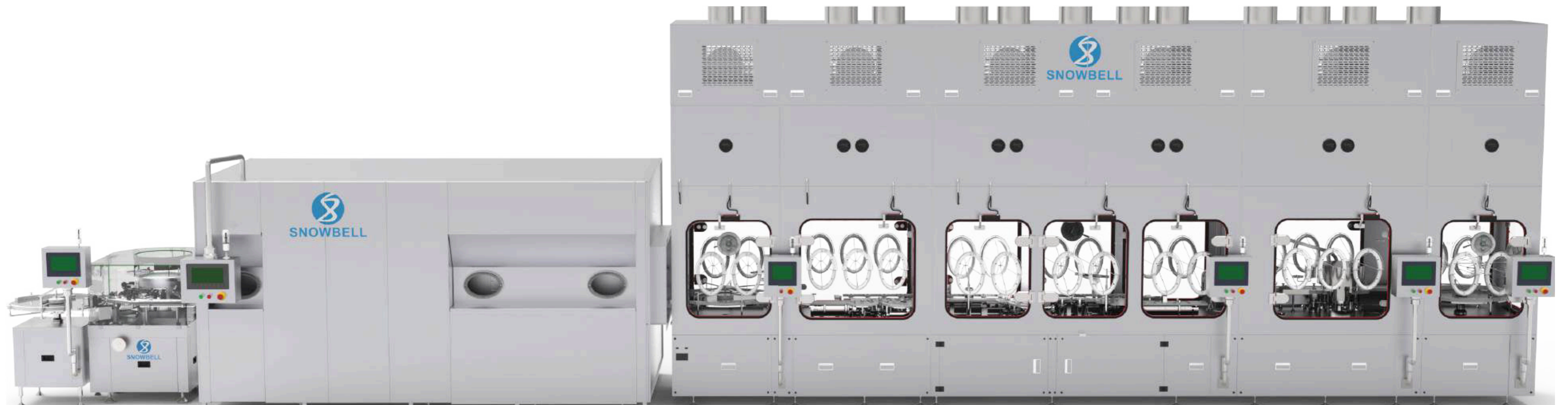
Sampling and Dispensing Isolator



Sifting & Blending Isolator

09

VIAL FILLING LINE UNDER ISOLATOR WITH LYO INTEGRATION



Complete Integrated Line Consisting of Following Machine

- Vertical rotary vial washing machine.
- Sterilizing & depyrogenating tunnel.
- Integrated with RTP & LTP.
- Liquid vial filling & stoppering machine with statistical/100% check weighing under isolator.
- Transfer conveyors integrated in isolators.
- Automatic Lyophilizer loading & unloading system with isolator.
- Vial cap sealing machine inside isolator.
- External vial washing machine with isolator.

10

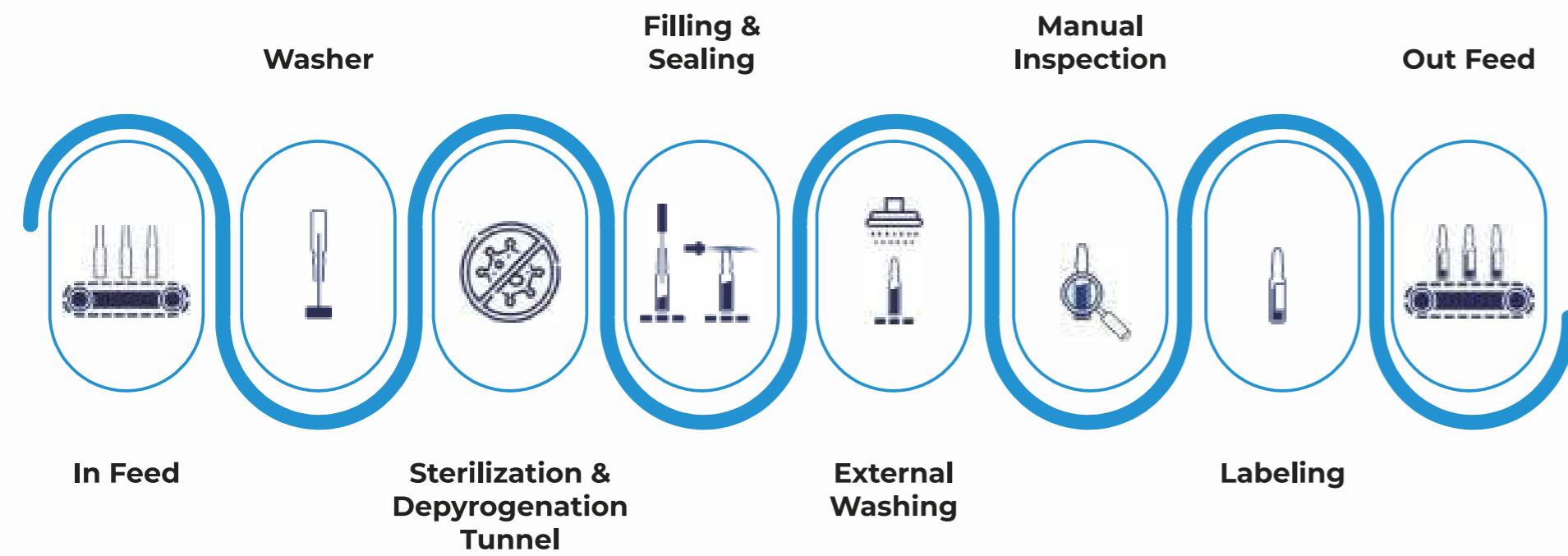
Salient Features of Isolator

- Vertical positive pressure isolator for aseptic processing of OEB level 5 product.
- Rigid wall construction in SS316L.
- Integrated with RTP & LTP.
- Monitoring & Controlling of pressure, temperature & RH.
- AHU for supply & exhaust air with recirculation system.
- Air exhaust through bag in bag out (BIBO) unit safe change double HEPA filters.
- WIP Gun & spray balls for CIP.
- Automatic Leak Testing.
- Integrated VHP decontamination system.
- SCADA 21 CFR part 11 compliant.

11

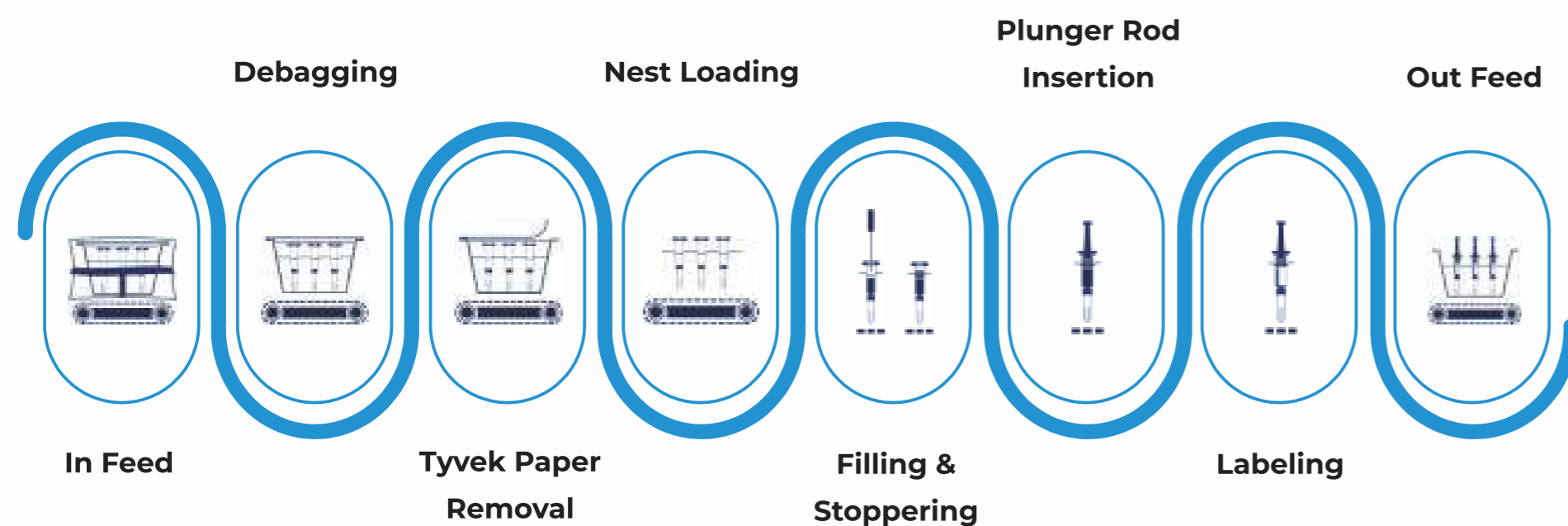
AMPOULE FILLING LINE

Process Flow



PRE-FILLED SYRINGES FILLING LINE

Process Flow



12

VIAL CAP SEALING MACHINE



Features

- > Consists of a vial transfer system, rotating vial base rest, and cap sealing roller.
- > Camera/Sensor based rejection system for raised stoppers.
- > Camera/Sensor based rejection system for uncapped and different color seals.
- > Sealing torque monitoring system.
- > Vibratory orientors for seals.
- > Aseptic loading of seals into the vibratory orientors.
- > Burr extractor system.
- > Available in oRABS/cRABS/Isolator.

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POWDER FILLING LINE



Features

- Full complete integrated production line consisting of washing machine, sterilizing & depyrogenating tunnel, liquid/micro powder dosing, filling, stoppering & cap sealing machine.
- Containment system in the form of oRABS/cRABS/Isolator.
- Powder filling by measures of cams/servo motor.
- Powder filling line using vacuum & compressed air measure system servo based on indexing movement of the dosing disc.
- Dosing range: 40mg to 1250mg in a single dose.
- Multiple dosing systems are available.

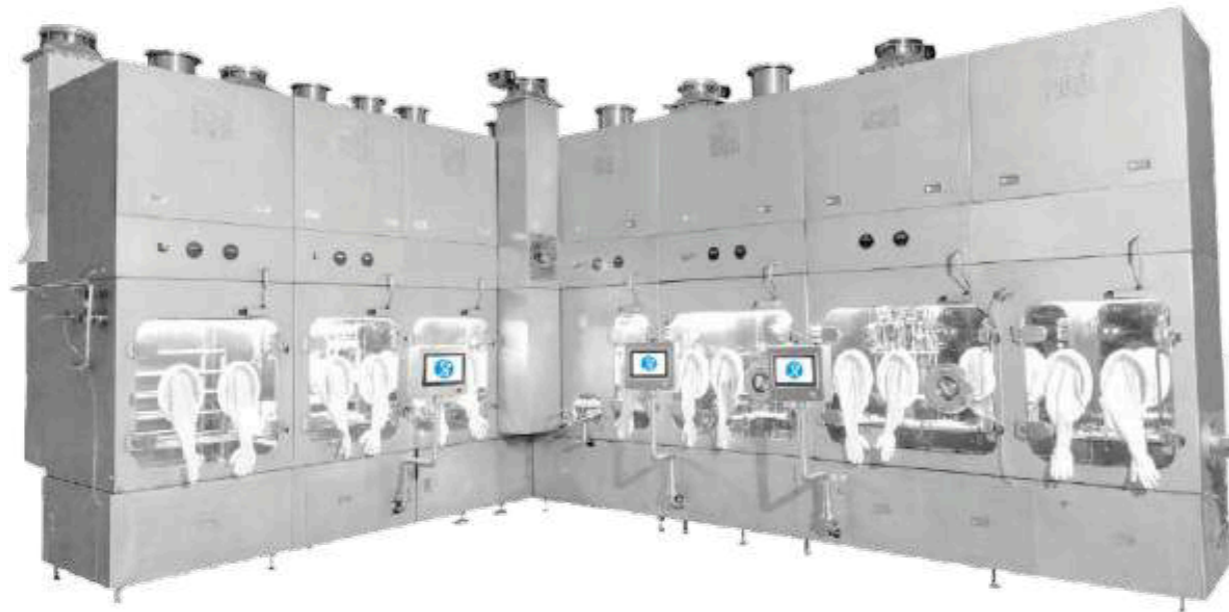
14

Features

- Statistical check weighing system with provision for 100% check weighing.
- Servo-driven dosing disc.
- External dosing system for powder canister.
- Media filling system.
- Aseptic loading of rubber stoppers in vibratory feeders.
- SCADA 21 CFR part 11 compliant.
- Available with oRABS/cRABS/Isolator.

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ROBOFILL DUAL COMBI LIQUID LINE WITH ISOLATOR



Features

- > Full vial line integrated with isolator pre-sterilized Vials and PFS.
- > Inline check weighing.
- > Integrated with VHP decontamination system.
- > Inline vial leak testing to check the seal integrity of sealed vials.
- > SCADA 21 CFR part 11 compliant.

AUTOMATIC IV BAG FILLING MACHINE



Features

- > Printing and OCR/OCV inspection of data.
- > Bag pick and place using a Robotic Arm.
- > Bag filling using a peristaltic pump.
- > Nitrogen purging during filling operation.
- > Ultrasonic plug sealing.
- > SCADA 21 CFR part 11 compliant.

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ROBOFILL TRIPLE COMBI WITH oRABS



Features

- > Rated output - 20 to 200 containers/min.
- > Fill volume range: 0.08 ml to 5 ml.
- > Fully automated servo-controlled operations.
- > Buffer tank with load cell for automatic product-level controlling.
- > High-precision load cell for PFS and Cartridge.
- > Provision of placement for isokinetic probe.
- > Conveyor integration for tub transfer from oRABS.
- > Light curtain for glove ports.
- > SCADA 21 CFR part 11 compliant.

Suitable For



Vials



PFS



Cartridges

Operations by Robotic Arm

- > Autobag cutting.
- > Robotic de-lidding.
- > Tyvek paper removal from the tub.
- > Lifting and placing of the tub.
- > Statistical/100% Check weighing.
- > Lifting of the nest from the nest holder and placing it on conveyor/denesting station.
- > Automatic vial denesting operation.
- > Handling vial PFS and cartridges.



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NASAL SPRAY FILLING LINE

Features

- > Filling line with single/double/triple pieces assemblies.
- > Screw ON/Snap fit type pumps.
- > Servo-driven reciprocating filling syringes.
- > Statistical check weighing system with provision for 100% weighing.
- > oRABS/cRABS/Isolator.
- > SCADA 21 CFR part 11 compliant.



OPHTHALMIC LIQUID LINE WITH ISOLATOR

Features

- > A monoblock filling, nozzle placing & capping machine.
- > Unscrambler for feeding bottles.
- > Interlock for low nitrogen pressure.
- > Filling by reciprocating pumps.
- > Vibrator hopper for nozzle & cap feeding.
- > Nozzle assembly & cap assembly by pick and place mechanism torque-controlled capping unit.
- > Rejection system for bottles.
- > oRABS/cRABS/Isolators.
- > SCADA 21 CFR part 11 compliant.



CLEAN ROOM EQUIPMENTS & CONTAINMENT SOLUTIONS

Pass Box

- > Static Pass Box.
- > Dynamic Pass Box.



Shower

- > Air shower.
- > Mist shower.



Garment Storage Cabinet

- > Horizontal air flow.
- > Vertical air flow.



Laminar Flow

- > Horizontal Laminar Flow.
- > Vertical Laminar Flow.
- > Ceiling suspended.
- > Stand Mounted.



Sterility Test Isolator



Mobile Trolley

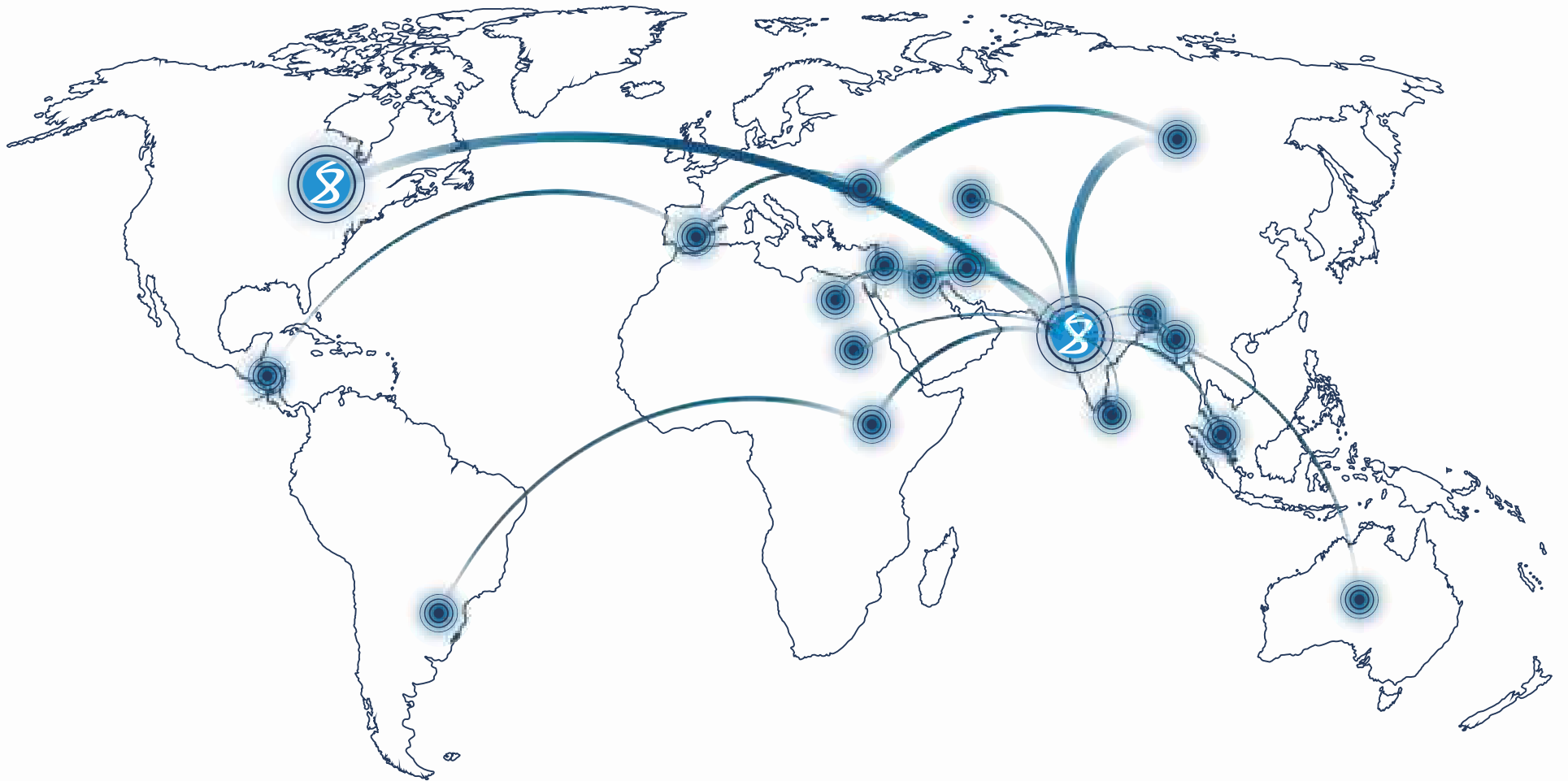
- > Horizontal air flow.
- > Vertical air flow.

Sampling & Dispensing Booth

- > De-Dusting Booth.

Snowbell Machines US Inc.

Global Reach



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www.snowbellmachines.com



info@snowbellmachines.com



Snowbell Machines



Snowbell Machines Pvt. Ltd.

Address

USA
15 Corporate South Place Suite 109 Piscataway 08854,
New Jersey

ISO 9001:2008, ISO 14001:2004, OHSAS 18001:2007 CE Certified Company