

SHIELDED DISPENSING BOX

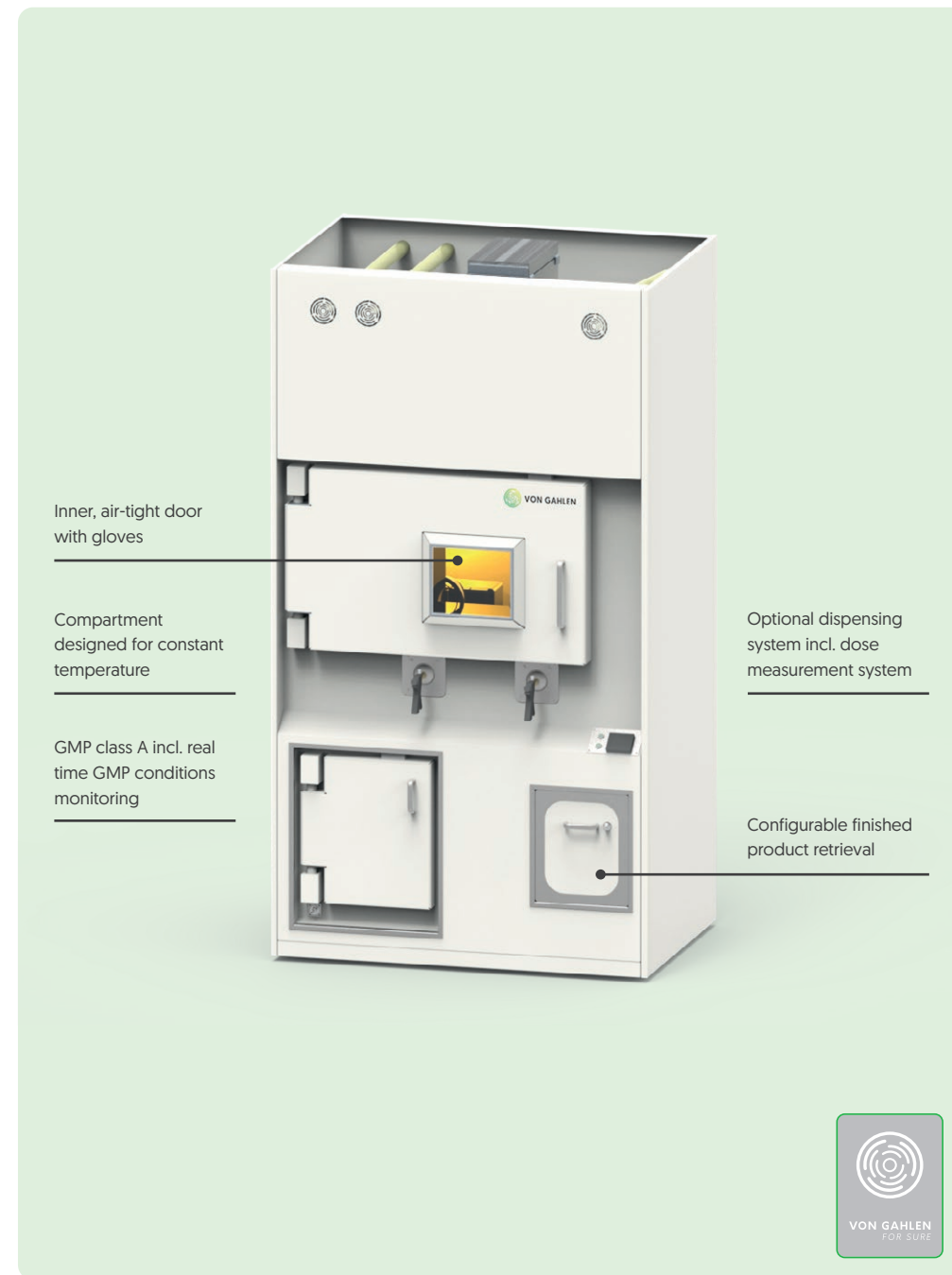
Our dispensing hot cell provides a complete solution for aseptic manipulation and dispensing of radiopharmaceuticals. The integrated laminar downflow system ensures a sterile environment, in compliance with the current Good Manufacturing Practices [GMP] class A standards.

This complete solution can be continuously integrated into a clean room. This hot cell contains a shielded compartment with 75 mm or 100 mm lead shielding in all directions and an airtight stainless-steel box with rounded corners. The hot cell offers flexibility by allowing the addition of an airlock or a preparation glovebox. These compartments help to establish the required cascade design according to GMP requirements.

Trust in our dispensing hot cell to ensure the highest standards of pharmaceutical production while safeguarding both operator and manipulated product.

Hot Cell is available in several widths and two different shielding thickness.

Variants	DPB	DPB-XL
Outside dimensions [mm] [W*D*H]	1.115*1.421*2.650	1.470*1.421*2.650
Inside dimensions [mm] [W*D*H]	709*719*790	1.024*719*790
Weight @75 mm shielding [Kg]	8.750	10.075
Weight @100 mm shielding [Kg]	12.955	13.350
Lead glass[mm] [W*H]	250*250	300*250
Effective door opening mm [W*H]	620*460	620*460
Exhaust [m3 / hr]	62	90





STANDARD FEATURES

Radiation protection

- 75- or 100 mm lead shielding in all walls, roof and floor.
- Lead glass window in front door (lead wall equivalent).
- Shielded ion chamber (lead wall equivalent) suitable for our commonly used Dose calibrators.
- Solid waste vault shielding (50 mm lead shielding).

Sample & product handling

- Internal stainless steel 316L box with special micro-surface treatment.
- (Shielded) pass through to adjacent compartment 200*250 mm (W*H).
- Ionization chamber lift system.
- Two easy-to-use ball tong manipulation units.
- Glove ports in front door for aseptic, cold preparation.
- Acrylic inner door (hinged left) with inflatable seals to maintain airtight integrity.
- Product Retrieval Drawer, including Von Gahlen Type-A transport container (on the front side). *

Air handling / distribution

- Integrated laminar down flow over entire working surface (99,995% efficient HEPA H14 filter).
- Homogeneous air velocity of 0.36-0.54 m/s.
- Leak tightness according to ISO10648-2 Class 3 (<1% hourly leak rate).
- Air inlet: with HEPA filter (H13), including valve.
- Air exhaust: including valve. **



Cleaning

- ISO14644-1/ GMP annex 1 compliant interior surface finish for cleaning, validation and decontamination.
- Exterior finish traffic white (RAL 9016), easy to clean.
- Prepared for validated and compliant surface bio-decontamination with 35% Hydrogen Peroxide Vapor technology utilizing Registered Hydrogen Peroxide Sterilant.

System operation / control

- Control via human-machine interface (HMI) with touch screen.
- Stable temperature (max. variation to clean room temperature: + 5°C).
- Light intensity min 500 Lux.
- Visible and audible alarms.

Sensors

- Digital pressure measurement on all compartments.
- Standard particle counter, incl. isokinetic probe.
- Pressure drop over the downflow filter.
- Temperature and humidity sensors.

Utilities

- Electrical outlets inside hot cell, switchable from HMI (in accordance with local requirements).
- Airtight pass-through for custom entry of tubes and cables.
- Dose calibrator.

OPTIONAL FEATURES

- Several GMP Class A and/or B pre-chambers (required to transfer materials to the Class A compartment).
- Customizable product retrieval drawer to the rear or side.
- Radiation detection system including safety interlock.
- Acid-resistant box material (Hastelloy / Kydex) upon request.
- End-to-end contamination control and cycle development, including Hydrogen peroxide vapor decontamination generator.
- Autoclave integration (autoclave including validation).
- Glove tester.
- Monitor and / or laptop mount.

Dispensers / filling systems.

- Open vial dose divider semi-automatic (OVDD-CAN).
- Closed vial dose divider semi-automatic (CVDD-CAN).
- Closed vials and syringe dose dispenser (ADD).