

## Closed Restrictive Access Barriers System (cRABS)

The **closed RABS** is an intermediate solution between **isolators** and **open RABS**. A **cRABS** provides a higher level of contamination control because the RABs' barrier doors remain closed from the point of the last bio-decontamination, through initial set-up through processing. These systems typically use transfer systems that are similar to isolator-type transfer systems that are closed and dock with the RABs.



The system controls the full air flow (inlet and outlet), allowing the correct pressure to enter in the system thus making it suitable to be used with slightly toxic products. These systems cannot be used for highly toxic products. However this can be considered as the right technology to be applied when a slightly potent/toxic product is to be manipulated. Just like isolators, even closed RABS internally assure a "class A" environment, being the surrounding area classified as "class B".

The following are the advantages of **cRABS**

- Easy installation, also on existing machines;
- Easy to validate (air flow, air classification, doors interlocks);
- Possibility to downgrade the production area to class B;
- Humidity and temperature inside the **cRABS** can be controlled adopting a dedicated HVAC;
- Possibility to recycle the air used inside, saving HVAC energy consumption;
- Surrounding production area must be class B (with an isolator it can be downgraded to the less expensive class C);

**cRABS** have a dedicated air handling system that provides down-flow air that circulates inside physical barriers, together with the provision of fresh air make up and ducted exhaust systems. Materials transfer devices are either a fully closed system, (e.g. alpha-beta rapid transfer ports, and/or devices that connect or interface) are under aerodynamic barrier protection and remain closed to the surrounding environment during transfer procedures. Closed-design RABs may also include a gaseous decontamination system.

## Active Open Restricted Access Barriers System

An **open-operation RABS (oRABS)**, by definition, provides recognition that the barrier doors can be opened for operator intervention(s), at defined risk assessed stages during aseptic production operations, after the last bio-decontamination step. **ORABS** are further characterized:

Type 1: Process Intervention

(highest contamination risk)

Type 2: Set-up Intervention

(high contamination risk)

Type 3: Inherent Closed Barrier Interventions

(lowest contamination risk)

**ORABS** have an air handling system that is shared with the cleanrooms' ceiling down flow with air an overspill to the surrounding environment. Overspill air is directed to a low level under the physical glove-barrier screens and below the points of critical operation, typically 300 mm below and away from the point of fill. Transfer devices may include closed or aerodynamic protection at the device-barrier connection location and maintain closed separation to the surrounding environment during the transfer procedure.

**oRABS** are used to incorporate filling line equipment both for aseptic and potent products processing. This equipment is a very practical to meet most of the containment solutions such as but not limited to milling and sieving containment purposes.