

# ModRABs™

THE MODULAR RAB SYSTEM



*A cost-effective solution to retrofit your aged filling line and achieve cGMP compliance*

Maintaining a state of compliance with Current Good Manufacturing Practices (cGMP) remains a challenge for manufacturing automated processes within pharmaceuticals industries. The challenge lies in assuring ISO 5 continuity space over the filling line, thus designing a retrofit solution capable of assuring the product is being filled aseptically. Depending on the application and the status of the existing line, an active/passive oRABS or cRABS will be foreseen. The retrofit is a reliable approach that dramatically reduces the risk of manufacturing faults and regulatory issues, both of which are costly to the organization.

## Which solutions are available?

1. Purchasing completely new cGMP compliant equipment, that is, new isolators integrated with new filling lines: this option would be capital-intensive
2. Finding a less expensive solution to protect and to adequately isolate your existing filling lines by means of a retrofit capable to ensure the product is being filled aseptically. In other words, a full retrofitting to make your filling line "cGMP compliant" again. This solution would be a RABS (Restrictive Access Barrier System shown on a side).

The Comecer ModRABS offering foresees a modular RAB system designed to retrofit your aging filling line. Modularity gives the flexibility to handle all sorts of filling lines.

## What does the retrofitting entail?

A retrofitting project includes a number of key milestones for its success:

1. Preliminary Feasibility Assessment
2. Ergonomic Study carried out with a mockup including the filling line and the new proposed barrier arrangement
3. 3D Design Qualification
4. On-site installation and Start-Up
5. Qualification activities (IQ/OQ).

## Why Comecer for a successful retrofitting projects?

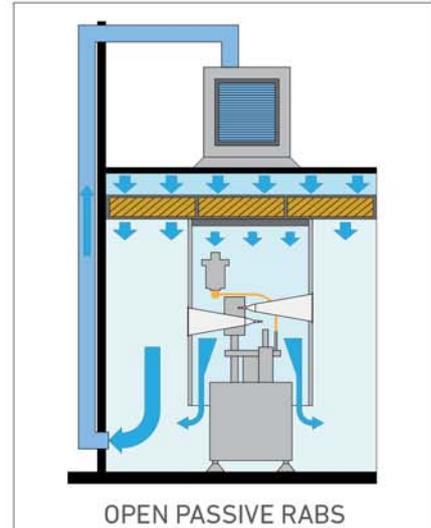
Comecer is a RABS manufacturer with the skills and the resources to provide a custom-built RABS and a complete package to support pharmaceutical companies from feasibility to finished product.

Our experienced 1MP engineering team coordinates the steps listed above, plus the handling of the new layout rearrangement, the team coordination and project management duties. Our trained field engineers will execute all the on-site activities.

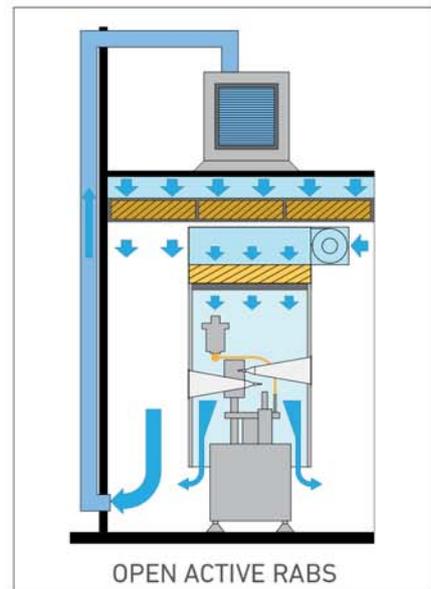
*"Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards."*

*"It is important to note that cGMPs are minimum requirements. Many pharmaceutical manufacturers are already implementing comprehensive, modern quality systems and risk management approaches that exceed these minimum standards."*

\*Source: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm>



OPEN PASSIVE RABS



OPEN ACTIVE RABS

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