

Life Science Cleanroom Doors

The new standard for clean from Rite-Hite.

RITEHITE[®]
ALWAYS LOOKING AHEAD

GMP means different things to different industries.

Good Manufacturing Practices (GMP) must be used in every facility to ensure quality products are being made in a clean, safe and controlled environment.

There are many variations to every individual facility's GMP guidelines, but the overall principle is that all critical control points and processes are compliant to certain specifications.

The contamination that should be removed may be one or more of the following types:

- » Particles and Fibers
- » Chemicals
- » Bacteria
- » Electrostatic Charges

GMP Title CFR, Part 211, S Subpart D, Section 211.63 states "Equipment used in the manufacture, processing, packaging or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance..."



What does clean look like?

Clean technology growth has been particularly strong in pharmaceutical manufacturing and related sectors such as biotechnology, medical device, hospitals and diagnostic centers.

- » In all industries, cleanrooms use high-efficiency particulate air (HEPA) filters to remove particles larger than $0.5\ \mu\text{m}$ (0.02 mils). The goal in most cases is to maintain an air pressure differential between rooms, pushing air from the opening's cleaner side to the less-clean side. Occasionally, the opposite approach is required and particulates must be kept within a certain room to avoid cross-contamination with the processes in adjoining rooms. For these reasons, most facilities incorporate multiple pressure steps within the building's structure. The steps typically range from 5 to 13 Pa (0.02 to 0.05 w.g.) between rooms, but can be as high as 50 Pa (0.2 w.g.).
- » Every cleanroom has a controlled level of contamination determined by the number of particles per cubic meter at a specified particle size. While regulatory bodies vary by country, the ISO (International Organization for Standardization) standards are universally recognized, with the most pertinent being ISO 14644 and its related sub-standards, as well as US FDA and GMP requirements.
- » Requirements differ by application and defined by ISO classes; pharma industry cleanrooms are generally in the range of ISO 5, 6, 7 or 8. To give perspective, the outside air in a typical city contains 35 million particles per cubic meter in the range of $0.5\ \mu\text{m}$ (0.02 mils) and larger in diameter, corresponding to an ISO 9 cleanroom. On the opposite end of the spectrum, an ISO 1 cleanroom allows no particles in that size range and only 12 particles per cubic meter of $0.3\ \mu\text{m}$ (0.01 mils) and smaller.



Our line of cleanroom doors are designed to meet rigorous ISO, cGMP or Annex 1 standards bringing your workflow to its highest potential. Known for **controlling contaminants and particulates, preventing cross contamination between cleanroom environments and maintaining conditioned environments**, Rite-Hite doors offer the industry's widest range of solutions to fit your every need.

Versatility for any environment.

① CLEAN.



The Rite-Hite ISO-Clean Glider door has the most robust and advanced Smart Seal™ System, with the ability to predict seal wear and reduce downtime. Having the right door for your application can do wonders for your facility to improve quality control, increase productivity while reducing energy costs while improving safety and communication at the opening.

② SAFE.



For pharmaceutical safety managers who are responsible for creating the safest facility environment but have faced challenges in communication with the flow of traffic through cleanroom doors, the Rite-Hite ISO-Clean Glider door has the only Safe Alert™ System in the industry, with visual indicator that heightens communication and raises safety awareness, minimizing the risk of accidents and injuries.

③ SIMPLE.



To ensure maximum equipment uptime but faced challenges maintaining equipment in a timely manner and with minimal personnel, the Rite-Hite ISO-Clean Glider door has the only Graphic User Interface in the industry, with color LCD touch screen that provides smart, intuitive troubleshooting capabilities, resulting in time saved performing maintenance.



ISO-Clean™ Glider Doors

Our doors sets the standard for excellence in the industry, offering superior durability, safety, and clean functionality that brings us to the forefront of the market.

The ISO-Clean Glider doors, either bi-parting or single slide, improves on the technology of traditional cleanroom doors to deliver more value and low maintenance.

Clean

With our advanced SmartSeal™ System, our door is designed with premium features as standard, aiding in environmental separation and control.

Safe

Innovative design and enhanced communication with our SafeAlert™ System.

Simple

Fewer moving parts and low maintenance.

ISO-Clean™ Glider Door

Clean, safe & simple



» Header assembly

Header track assembly is aluminum (optional fully stainless steel). Available with standard multipiece stainless steel header shroud, with bolted seams and endcaps, or optional fully single piece, stainless steel header shroud. Electronic solenoid lock is optional.

» Strong, silent type

Powerful 1 HP motor and variable frequency drive system combine for class-leading speed and super-quiet performance.

» Wireless interlock

Wireless interlock comes standard and locks up to (15) Rite-Hite Doors without the expense and hassle of hard wiring.

» Panel design

1.75" (45 mm) thick white fiberglass panel with stainless steel edge capping and insulated foam core. Flush vision panels and stainless steel 12" high kickplates come standard.

» Safety features

SafeAlert™ System provides communication of the door status (counting down time until door auto-closes, door will not open due to interlock, door in fault status, etc.). SafeAlert System display mounted integrally in header comes standard. Two (2) thru-beam photo eyes at 18" (457 mm) and 54" (1372 mm) from floor. Torque sensing reverses the door back open if contact with personnel or equipment while closing.

» Graphic User Interface (GUI)

Industry's only 7" (178 mm) LCD touch screen interface that provides increased safety by allowing an individual to simply access the control box settings without wearing the necessary PPE often required for accessing a live electrical panel. Available to be flush-mounted for more safety against environmental bacteria, particles and fibers.

Smart, Connected Capabilities

Rite-Hite provides smart, connected capabilities as part of the Rite-Hite Extended Warranty. Facilities gain visibility into their doors productivity and maintenance, helping to increase safety through the Rite-Hite Digital Platform.



ISO-Clean™ Roll Door

The new standard for reliable, productive performance in the industrial and life science cleanroom door category.

From the soft bottom edge to the simple, cleanable design platform, ISO-Clean Roll Door helps maintain the integrity of clean environments with ease.

Its tapered surfaces minimize dust collection points better than flat surfaces and it is designed with no exposed fasteners to allow quick and easy cleaning. The tight seal maintains pressure differentials from room-to-room and can withstand pressures up to 0.2 in H₂O (50 Pa).

ISO-Clean™ Roll Door

Fast, efficient & safe



» **An edge on safety**

No hidden metal or plastic support. No buried electrical wiring. 100% fabric for a softer, safer cushion. And a higher degree of protection for product, personnel and equipment.

» **Strong, silent type**

Powerful 1 HP motor and variable frequency drive system combine for class-leading speed and super-quiet performance.

» **The speed advantage starts with installation**

Comes fully pre-wired and tested from the factory. Reduces electrical installation by up to two hours. We offer wireless interlocking for multiple doors.

» **TRUE Auto Re-feed™**

For automatic re-feeds, on the fly, with no human interaction. Impacts won't impact production.

» **Smaller footprint**

Compact stainless steel side frames for a cleaner look. Ideal for installation in tighter spaces.

» **Safety Features**

Soft Breakaway Technology thru-beam photo eye at 18" (457 mm) off the floor, reversing sensor. **Optional** – Virtual Vision™, non-power opening, motion and presence sensors. Our SafeAlert™ System is the visual indicator that heightens communication and raises safety awareness, minimizing the risk of accidents and injuries.

» **Graphic User Interface (GUI)**

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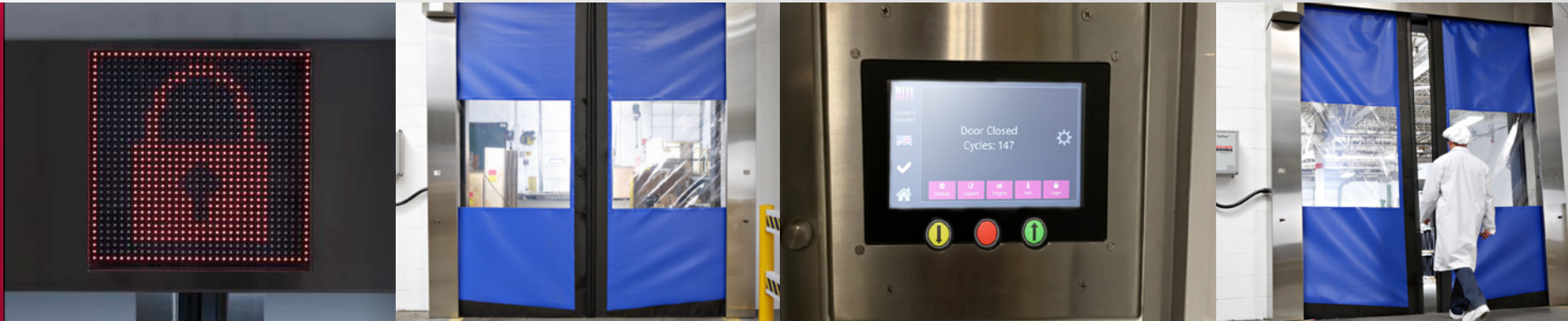
ISO-Clean™ Split Door

Rite-Hite® ISO-Clean Split high performance industrial door boosts efficiency, productivity and safety in a simple, reliable, compact design.

This high performance bi-parting design and class leading speed minimizes air transfer to help prevent contamination between rooms. More speed equals more production efficiency and more control of your facility's environment. Additionally, the bi-parting door takes up less wall space and incorporates a host of innovative features designed specifically to increase productivity, improve safety, and ensure a tight door seal.

ISO-Clean™ Split Door

Efficient, productive & safe.



» Split-center design

Bi-parting door features spring tube design to collect the curtain in the side frames and reduce overhead contaminants.

» Accelerated thinking

Variable frequency drive for an unmatched peak speed of up to 120"/sec (3 m/sec) allows for maximized productivity, less air movement and better separation between zones.

» FDA and GMP compliant

Smooth curtain fabric and stainless steel components for easy wipe down and corrosion resistance. Recommended for ISO 8 Cleanrooms.

» Safer work environments

Two large vision windows and immediate top-to-bottom visibility decreases blind spots. Superior auto reverse sensing system using 3 photo eyes and torque sensor. Our SafeAlert™ System is the visual indicator that heightens communication and raises safety awareness, minimizing the risk of accidents and injuries.

» Communication

Rite-Hite Doors has a series of light communication products to help reduce common collision accidents between forklifts and pedestrians. SafeAlert™ System, LED Pre-Announce and LED Virtual Vision available.

» Graphic User Interface (GUI)

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Improving industrial **safety**, **security**, and **productivity** worldwide through quality and innovation.

- ▶ VEHICLE RESTRAINTS
- ▶ LOADING DOCK LEVELERS
- ▶ DOCK SEALS AND SHELTERS
- ▶ INDUSTRIAL DOORS
- ▶ SOFTWARE SOLUTIONS
- ▶ INDUSTRIAL CURTAIN WALLS
- ▶ MACHINE GUARDING
- ▶ INDUSTRIAL FANS
- ▶ BARRIER SAFETY SYSTEMS
- ▶ SNOW REMOVAL MACHINES

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