

Smart Access Control System (SACS)

by Mactus Automation

Mactus SACS is a fully configurable solution which defines, tracks, manages and reports all compliance related activities related to personnel working in a clean room environment

The Regulation

Bio burden control during operations is a critical part of Good Manufacturing Practice(GMP)s for the manufacture of products marketed as Sterile

Unless appropriately controlled, bioburden may contaminate or proliferate to an extent which will compromise the product Quality.

Hence Regulations mandate firms to have written procedures to control bioburden at all applicable stages in the manufacture of sterile products.

Challenges

With bioburden control, as a singular goal in aseptic processing to ensure safety of any Sterile Product, the main control is to minimise Human contamination potential, as Personnel are source of primary risk in clean rooms

It is a huge challenge if microbiological related failures, caused by operating personnel in clean rooms require investigation.

The solution- Mactus SACS

SACS has unique features designed for consistent compliance to a firms written procedures in Clean Room Environments.

- Biometric access system uses unique logic and entry granted to trained and qualified personnel.
- Controls and Monitors the number of personnel entering/exiting Clean Rooms as per firm's SOP (access limited to permitted number, identify purpose of each entry- operation/cleaning, maintenance, monitoring, visitor/auditor etc)
- Optional Health Checks can be implemented.
- Tracks Various alarms eg: "Door Open Too Long" or "Emergency Door Open" etc.
- Activities such as "Fogging" (fogging mode), Material transfer (sterilized garments from clean room to gowning area) can also be tracked.
- Provides Audio Alerts/early warnings to ensure personnel adhere to qualified/validated times in clean room
- Provision for periodic Announcement system for clean room personnel is designed, to enable supervisors to provide one way communication to the area.
- User Events in Multiple Filling Lines with common change room and sterile corridor can be tracked.
- Data generated can be processed into an intelligent report through a PC, which in turn helps in data trending and informed decision making
- Meets 21 CFR part 11/Annex 11 requirements
- This installation has successfully met the most stringent Health Authority expectations at inspected sites

Usage Scenarios

Entry/exit control
Early Voice Alerts for Operator Exit
Ensure Compliance to Required Trainings and Personnel Monitoring
Tracks Alarms, Device Errors (e.g. OnLine / Offline), Personnel Errors (e.g. No IN Punch) and Personnel Monitoring

Functionality

User Administration
Analytics and Reporting
Automatic Data Backup
Ease of Configuration
Data Archived for future use
Audit trail enabled
Can integrate with firms other system (eg: Attendance management)

Benefits

Delivers Right First time results in operational compliance
Data generated in compliance to ALCOA+ expectations
Reduced paper work
Ease of installation and operation
Ease of data tracking and trending
Meets global health authority expectations

In summary - The Mactus SACS Solution

- Most trusted and Patent pending Clean Room control solution
- Proven to be the product of choice over conventional access control
- Risk is minimized due to design features
- Substantial reduction in deviations and saving significant time/resources in investigation
- Minimises batch rejections and consequently internal failure costs
- Ease of compliance and minimize paper work
- Provides industry with implementation of best practice with several successful installations
- Seamlessly integrates with Existing Door Interlocking System

Example screen views



Admin Client as well as view current status



Entry HMI of Sterile Area Entry Door with multiple filling lines