

# Intervention Recording System (IRS)

by Mactus Automation

**Mactus IRS is a fully configurable solution which defines, tracks, manages and reports all compliance related activities related to interventions performed by operators in a fill finish Operation.**

## 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.

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

Interventions present a considerable risk of transfer of contamination from the surrounding Grade B area into the grade A zone of the fill finish machine.

Consequently, all routine and non routine Interventions represent an increased level of risk and hence appropriate control and monitoring is required in the core area (Grade A).

## 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.

Similarly Ease of Controls, Operations and Associated documentation are critical in fill finish operating Zones, and specifically in relation to any interventions during fill finish operations.

The closer, longer and more invasive the operator intervention is, in aseptic fill finish operations, the greater is the contamination risk to product.

Reduction of interventions and demonstration of effective airflows are key elements in any aseptic process design.

## The solution- Mactus IRS

Aseptic techniques are required for all interventions and actions in the aseptic processing zone.

Interventions into the process should be eliminated where possible or otherwise minimized.

IRS has unique features designed for consistent compliance to a firms written procedures.

- Records interventions by each operator/supervisor with minimum effort
- Integrates seamlessly with existing filling machine sensors like doors and glove ports
- Supports manual doors and glove ports without any sensors
- Tracks each intervention count and duration and requires approval process to perform any intervention, if it exceeds the maximum permitted count
- Creates batch wise/lot wise/shift wise reports
- Operators will be guided through text and audio messages based on firms operating procedures and adhering to compliance
- Data generated can be processed into an intelligent report which in turn helps in data trending and informed decision making
- Meets 21 CFR part 11/Annex 11 requirements
- Flexibility in configuration in case amendments/changes are to be introduced.
- Client Server Architecture with Web based clients. One Server can support multiple filling lines with common user base



## Usages

Ensure compliance to mandatory requirements

All interventions (routine as well as non routine) can be tracked and trended

Operator can watch SOP documents or any training videos at any time to validate the procedure



## Functionality

User Administration

Analytics and Reporting

Data management

Ease of Configuration

Data Archived for future use

Audit trail enabled



## Benefits

Eliminates risky deviations during aseptic fill finish operations

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 IRS Solution

- Provides high degree of assurance to Patient Safety and enables consistent compliance to
- Sterility Assurance expectation. by strict controlling a key process variables (ie operator intervention)
- Minimises batch rejections and consequently internal failure costs
- Ensures ease of Operational controls and minimises related documentation efforts in clean rooms
- Provides industry with implementation of best practice with several successful installations

## Example screen views

