ASEPTIC INTERVENTION TRACKING FOR ANNEX 1

Aseptic Intervention Compliance System (AICS)

Automated recording of every intervention — type, duration, frequency, personnel, and location — via a dedicated cleanroom interface.

OVERVIEW

On paper, operators complete the intervention log after the event, from memory. AICS records it while it happens.

WHY TEAMS CHOOSE GAMP AICS

Recorded where the work happens

Interventions captured automatically on a cleanroom interface, and visible in real time so QA can review while the batch is still running.

Justified against the science

Records are tied to the qualification evidence behind each intervention, and protocols are standardised from what historical batches actually show.

Investigate with the full picture

High-risk interventions and abnormal patterns flagged as they occur, with complete traceability behind any deviation investigation that follows.

CAPABILITIES

- ✓ Automated intervention recording on Cleanroom TAB
- ✓ Real-time visualisation for immediate QA review
- ✓ Linked to smoke studies, airflow patterns, and media fills
- ✓ Standardised protocols from historical batch data
- ✓ High-risk intervention and abnormal pattern alerts
- ✓ Complete traceability for deviation investigations

ON THE ASEPTICONE PLATFORM

- Single sign-on across modules, managed through one administration layer
- Active Directory integration
- Audit trail, electronic signatures and role-based access
- Cloud, on-premises or hybrid deployment
- Built for 21 CFR Part 11 and EU Annex 11
- Designed around EU GMP Annex 1

THE COMPLETE SYSTEM

- **Glove-port sensors**
- **Door sensors**
- **Existing line sensors**
- **Cleanroom TAB**

AICS works with GAMP sensors or the ones already on your line. Connecting another maker's hardware is an integration project, carried out with that manufacturer and your team. Hardware is supplied by GAMP Services Limited, our parent company; the Cleanroom TAB is sourced from compatible vendors.

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