

Pharmaceutical

Control systems that run every batch as approved and keep your data beyond question.



Pharmaceutical manufacturers answer to regulators, Qualified Persons and, in the end, patients. Their control systems must run each batch as approved, keep records whose integrity is beyond question and stay validated through years of change, with every step documented for an MHRA or FDA inspector.

YOUR PRIORITIES

What matters most

Validated, and staying so

Systems validated, and kept that way through change.

Data integrity

Complete, secure records with full audit trails.

Right first time, every batch

Every batch run to the approved recipe.

Change under control

Change that never puts supply or compliance at risk.

STANDARDS

Standards we work to

ISPE GAMP 5 (Second Edition)

A risk-based approach to compliant GxP computerised systems, from specification to retirement.

EU GMP Annex 11 and Annex 15

GMP rules for computerised systems and for qualification and validation, applied in the UK by the MHRA.

FDA 21 CFR Part 11

US rules for electronic records and electronic signatures, for sites that supply the US market.

MHRA GXP Data Integrity Guidance

The MHRA's expectations for complete, consistent and accurate data, summed up as ALCOA+.

ISA-88 (IEC 61512) batch control

Models and terms for batch control: recipes, procedures and the equipment that runs them.

IEC 62443

Security for industrial automation and control systems.

HOW WE DELIVER



Systems we engineer

- Batch process control and recipes
- Weighing, dispensing and blending
- Purified water and clean utilities
- CIP and SIP control
- Electronic batch records and audit trails
- Environmental and equipment monitoring

Why Matrix

- **Standards first.**
- **You own the system.**
- **Tested before site.**
- **Multi-vendor.**
- **In it for the long term.**

ISO 9001 certified • Cyber Essentials • CHAS • Constructionline • SafeContractor

Talk to us about your project

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