



INDUSTRY BRIEF

Pharmaceutical

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

[::]MATRIX



What matters most

Validated, and staying so

Computerised systems must be validated before use and kept in a validated state through every upgrade and change, with documents an inspector can follow from requirement to test.

Data integrity

Records must be attributable, legible, contemporaneous, original and accurate, with audit trails, controlled access and electronic signatures that will stand up to an MHRA or FDA inspection.

Right first time, every batch

Every batch has to follow the approved recipe and procedure, with deviations caught, alarmed and recorded so they can be reviewed before the batch is released.

Change under control

New products, upgrades and fixes have to be introduced through your change control, without putting qualified equipment, licensed processes or the supply of medicines at risk.

The standards that shape your project

Standard	What it covers
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.

The standards listed are those most often relevant to control-system work in this sector. Which apply to your project, and how, is agreed with you at specification stage.

From specification to long-term support



We work within your quality system: your validation plan, change control and document templates. Specifications trace through to tests, and our factory and site acceptance tests are written to support your IQ, OQ and PQ. Logic is proven against a simulation first, so time on site goes on qualification, not debugging.

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

PLATFORMS WE WORK WITH

Siemens TIA Portal, S7 and PCS 7 • Rockwell • ABB • Schneider • Mitsubishi • Beckhoff • Emerson DeltaV • Honeywell • GE • WinCC, Ignition, AVEVA (Wonderware), FactoryTalk, iFIX and Citect SCADA

The evidence you receive at handover

✓ Functional design specification

✓ I/O list and cause-and-effect

✓ Alarm list and HMI interface

✓ FAT and SAT records

✓ As-built drawings and source code

✓ Method statements for common faults

Why customers choose us

Standards first

An ISO 9001 certified quality system, designing to the standards your sector demands, plus any you specify.

You own the system

Clear structure, open interfaces and complete documentation, so you can support it yourself or with any vendor.

Tested before site

Control code is version-controlled and tested against a simulated plant before factory and site acceptance.

Multi-vendor

Siemens, Rockwell, ABB, Schneider, Mitsubishi, Beckhoff, Emerson, Honeywell and GE platforms.

In it for the long term

For us a project is not finished until the control system is decommissioned. 24/7 support is available under a support agreement.

OUR PROMISE

Standards-led, fully documented control systems that you own and can support.

GET IN TOUCH

Talk to us about your project

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