VALIDATION + GXP SOFTWARE

Reduce compliance risk. Remove operational friction.

PharmaEddge helps regulated teams validate computerized systems, improve inspection readiness and replace fragile manual workflows with purpose-built software.

RISK-BASED

Validation effort matched to system risk

AUDIT-READY

Evidence written for inspection

FLEXIBLE

Remote or on-site, worldwide

WHAT WE DELIVER

Validation & Compliance

- CSV and CSA
- IQ/OQ/PQ protocols
- Data integrity assessments
- Audit readiness

Custom GxP Software

- Regulated workflow design
- Controlled records and approvals
- Access control and audit trails
- Validation support

Consultation & Advisory

- Fractional QA support
- Remediation roadmaps
- Inspection coaching
- Documentation strategy

COMMON REGULATORY FRAMEWORKS

GAMP 5

21 CFR PART 11

EU ANNEX 11

ALCOA+

PIC/S

CSA

Start with the pressure point.

CALIBRATION & MAINTENANCE

Schedules that keep equipment ready.

Plan calibration and preventive maintenance, track due dates and retain completion records in one controlled system.

THE CONTROLLED WORKFLOW

01

Calibration and preventive-maintenance schedule planning

02

Due, upcoming and overdue visibility

03

Equipment-wise service and completion history

04

Controlled records supporting inspection readiness

BUILT FOR

Engineering, instrumentation, laboratories and quality teams.

WHY PHARMAEDDGE SOFTWARE

CONTROL

Replace side spreadsheets and informal tracking with one governed workflow.

TRACEABILITY

Keep status, history, decisions and evidence connected.

ADOPTION

Give users a practical interface aligned to the work they perform.

VALIDATION

Implementation and validation support from the team that builds it.

See it against your real process.