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.

COLUMN MANAGEMENT

Every chromatography column, accounted for.

Controlled column lifecycle management for regulated pharmaceutical QC laboratories, from receipt to destruction.

THE CONTROLLED WORKFLOW

01

Column master, receipt, issuance and return records

02

Usage and system-suitability performance history

03

Status, location, periodic review and retirement control

04

Role-based access and complete audit trail

BUILT FOR

QC laboratories using HPLC or GC columns.

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.