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.

VQ DESK

Vendor questionnaires, answered from your own knowledge.

AI-assisted vendor and customer questionnaire responses grounded in the documents and approved knowledge your team provides.

THE CONTROLLED WORKFLOW

01

Draft review-ready answers from supplied documents

02

Keep supporting sources visible for every answer

03

Leave unsupported questions clearly for human review

04

Build a reusable approved-answer knowledge library

BUILT FOR

Quality assurance, vendor qualification and customer-response 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.