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.

APQR

APQR documents, drafted from batch records.

Generate Annual Product Quality Review documents from Master Batch Records with generative AI assistance and human review.

THE CONTROLLED WORKFLOW

01

Extract relevant information from Master Batch Records

02

AI-assisted first-draft preparation

03

Structured review-ready APQR output

04

Human review remains central before approval

BUILT FOR

Quality assurance teams preparing recurring Annual Product Quality Reviews.

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.