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.

EIGHT PURPOSE-BUILT PRODUCTS

Software for regulated quality, laboratory and operations teams.

Controlled workflows, practical adoption and validation support from the team that builds each product.

VQ DESK

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

COLUMN MANAGEMENT

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

LMS

Role-based learning, assessments and controlled training records for regulated teams.

DOCUMENT MANAGEMENT SYSTEM

Document workflows, approvals, master copies and version management across different document types.

ERP

A modular business operations platform for pharma teams, available as a complete ERP or selected modules.

PHARMA QR CODE

Create QR-enabled pharma labels and standard labels using controlled templates for varied packaging and operational needs.

APQR

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

CALIBRATION & MAINTENANCE

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

VALIDATION, COMPLIANCE AND ADVISORY

Right-sized rigor for computerized systems.

Risk-based services structured around practical evidence that can withstand internal review and regulatory inspection.

Computer System Validation

- Validation planning and strategy
- Risk assessment and GAMP categorisation
- URS, FRS and traceability
- IQ/OQ/PQ protocol and report support

Data Integrity & Compliance

- Part 11 and Annex 11 assessment
- ALCOA+ controls and audit trail review
- Gap assessment and remediation
- SOP and governance documentation

Custom Software & Advisory

- Bespoke GxP workflow applications
- Validation package aligned to the build
- Fractional QA support
- Audit preparation and inspection coaching

START WITH A FREE CONSULTATION

Bring the system, workflow or audit pressure point.

We will give you a practical view of the risk, an appropriate scope and the clearest next step - whether or not that step involves us.

01 Describe the current process

Share the system, records, users and immediate concern.

02 Clarify the compliance need

We map the applicable risk, regulatory expectation and business outcome.

03 Receive a right-sized route

You receive a clear recommendation for validation, software or advisory support.

PHARMAEDDGE SOLUTIONS

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