Turton Consulting

Validation Made Clear. Independent CSV and GxP compliance consultancy

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Capability statement

Turton Consulting provides independent computerised system validation, data integrity and GLP, GCP and GCP for Labs (GCLP) compliance support for CROs, clinical trial sponsors and regulated laboratories, and for the software vendors who serve them. Our approach is practical, risk-based and evidence-led: effort proportionate to risk, and documentation teams can maintain.

Services

Computerised System Validation
Proportionate, risk-based validation of clinical, laboratory and quality systems that proves fitness for intended use, without burying your team in paperwork.

Audit & Inspection Support
Independent gap assessments, inspection readiness and CAPA support, so you walk into an audit knowing where you stand.

AI, SaaS & Cloud Validation
Pragmatic approaches to validating SaaS platforms and governing AI tools such as ChatGPT and Copilot in GxP environments.

Vendor & Partner Support
A specialist validation partner for software vendors, engineering firms and consultancies, white-label or co-branded.

Laboratory GxP Assurance
Specialist compliance support for GLP (non-clinical) and GCLP (clinical trial) laboratories: readiness, audits and remediation.

Data Integrity
Practical ALCOA++ assessment and remediation across paper, hybrid and electronic workflows in clinical, laboratory and quality settings.

Training & Coaching
CSV, data integrity, AI-in-GxP and laboratory GxP training that people actually remember, delivered remotely, onsite or blended.

Who we support

CRO / clinical research: Full-service and specialty CROs running GCP-regulated systems and trials.

Clinical lab (GCLP): Central, bioanalytical, biomarker and speciality trial laboratories working to GCP for Labs.

Non-clinical lab (GLP): Toxicology, preclinical and contract safety-testing laboratories.

Pharma or biotech sponsor: Trial sponsors, including GCP oversight of contracted laboratories and CROs.

Software vendor / consultancy: Vendors, engineering firms and partners serving regulated customers.

Medical device / healthcare: Device manufacturers and healthcare organisations.

CDMO / contract testing: Manufacturing and testing partners working to GMP.

Regulations and standards

ICH E6(R3) GCP · GCP for Labs (GCLP) · OECD Principles of GLP · OECD GLP Advisory Documents No. 17 & 22 · EMA guideline on computerised systems and electronic data in clinical trials · ICH M10 · EU Annex 11 · 21 CFR Part 11 · GAMP 5 (Second Edition) · ALCOA++ · GMP

Validation lifecycle

01 **Discover**
System context, intended use, stakeholders and regulatory impact.

02 **Define**
URS, scope, validation strategy and acceptance criteria.

03 **Assess**
Supplier, system, process and data integrity risk assessment.

04 **Validate**
Protocol development, execution, deviation management and traceability.

05 **Release**
Validation report, QA approval and go-live readiness.

06 **Maintain**
Change control, periodic review, audit trail review and retirement.

Engagement models

Advisory support
Hourly or daily expert input for project questions, document review, validation strategy and QA challenge.

Fixed-scope package
Defined deliverables such as a validation plan, supplier assessment, gap analysis, protocol set or training workshop.

End-to-end delivery
Lifecycle support from scoping and requirements through testing, reporting, approval and release.

Retained QA / CSV partner
Ongoing access to validation and compliance expertise for change control, periodic reviews and continuous improvement.

Independent audit or review
Objective assessment of systems, vendors, laboratories, documentation, data integrity controls or inspection readiness.

Partner delivery
White-labelled or co-branded support for vendors and consultancies needing specialist CSV and compliance capability.

Selected case studies

CLINICAL LABORATORY · GCLP
Independent GCLP laboratory audit and readiness support. Practical audit of quality systems, data integrity and CSV status with clear improvement priorities.

GLP · NON-CLINICAL
Strengthening GLP archive and electronic records controls. Archive review and inspection-response support for paper and electronic record control.

CLINICAL RESEARCH · GCP
Building a risk-based CSV governance model for a clinical research organisation. Clearer validation priorities, ownership and senior reporting for a multi-system GCP environment.

All examples are anonymised. More at turtonconsulting.co.uk/case-studies/

About Joe Turton

Joe is a technology and quality leader with a software development background, specialising in building and governing GxP-critical platforms. Before founding Turton Consulting in December 2024, he was QA Manager and CSV Specialist at The Knowlogy, and previously worked on LIMS, bespoke web applications and data integrity at Fera Science Ltd. His work spans CSV programmes, GLP and GCLP laboratory audits, SaaS and AI oversight, and coaching teams to own quality and data integrity by design.

Talk it through

Book a free 30-minute call, or email info@turtonconsulting.co.uk. We typically reply within 1–2 working days.

turtonconsulting.co.uk/contact/

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