# GMP / CSV Readiness Checklist

This short checklist helps you understand whether your system lifecycle, documentation, and evidence are positioned to support inspections and customer expectations. If you answer No or Unsure to any item, a short consultation can help you determine next steps before issues escalate into findings.

### 1. Governance & Ownership

- Is responsibility for the system formally assigned and understood?
- Are roles for operation, oversight, and maintenance clearly defined?
- Can you demonstrate who approves changes, reviews records, and ensures ongoing suitability?

### 2. Requirements & Process Understanding

- Are system expectations documented in a way that links to intended business use?
- Is there clarity on what the system must do and what risks it must manage?
- Are intended data flows, user activities, and critical operations understood?

### 3. Risk & Impact Considerations

- Is there a rationale for why certain activities are more critical than others?
- Are risks to product, patient, data integrity, or decision-making clearly identified?
- Are risk-reducing controls or mitigations visible to inspectors?

### 4. Data Integrity (ALCOA+)

- Is evidence attributable, traceable, legible, and contemporaneous?
- Are electronic and paper records treated consistently and controlled appropriately?
- Can you demonstrate how data is protected from loss, alteration, or misuse?

### 5. Documentation & Traceability

- Is documentation structured, current, and aligned with how work is actually performed?
- Is it easy to show the connection between intent, risk, controls, and evidence?
- Would an external auditor understand your documentation flow without assistance?

### 6. Testing & Fitness-for-Use

- Is there visible confirmation that the system works as intended for its users?
- Is testing focused on what matters most, rather than indiscriminate steps?
- Is evidence reviewable, complete, and appropriate for the system's impact?

### 7. System Operation & Supportability

- Are routine activities (access, changes, backups, review) clear and sustainable?
- Are users confident in operating the system without workarounds?
- Is there a clear path for continued suitability over time?

### 8. Audit & Inspection Readiness

- Could you walk an auditor through your system lifecycle today without preparation?
- Are there known gaps that would create unnecessary discussion or findings?
- Are roles, records, and decisions explainable and defensible?

### Next Steps

If any area raised uncertainty or a potential gap, a short conversation can help prioritise what matters most before your next audit or customer review.