Leucine

Document Management

Audit Readiness Checklist

I. Document Governance & Lifecycle Control

	Yes	No	NA
SOP Development & Review			
Are documentation practices reviewed and updated regularly?			
Do current SOPs include clear, step-by-step instructions that ensure consistency?			
Is there a formal procedure for the development, review, and revision of SOPs involving end-users?			
Are personnel involved in SOP development and review adequately trained?			
Do SOPs undergo cross-departmental review for consistency?			
Are SOPs reviewed and updated regularly to ensure they reflect current practices?			
Do SOPs include detailed descriptions for sampling procedures and locations?			
Are SOPs for analytical methods reviewed and updated regularly?			
Is there a periodic review schedule for all SOPs?			
Are deviations from SOPs properly documented and justified?			

	Yes	No	NA

SOP Compliance & Version Control

Is version control maintained for all SOPs?			
Is there a robust system for managing and updating SOPs?			
Are SOPs customized to reflect operational practices?			
Are all SOPs and batch records verified for completeness and accuracy?			
Is there a mechanism to ensure SOP updates are communicated and understood by staff?			
Are SOPs accessible to all relevant personnel?			
Is there a system for tracking changes in SOPs?			
Are SOPs aligned with regulatory requirements (FDA, EMA, WHO)?			
Are SOP updates including verification steps for labeling and counts?			
Are SOP-related deviations reviewed during audits?			

II. Controlled Document Issuance & Management

	Yes	No	NA
Issuance & Tracking			
Are all controlled documents issued and tracked appropriately?			
Is a controlled copy issuance log maintained for GMP documents?			
Are documents captured and managed within the EDMS system?			
Are checks in place to ensure documents are entered into EDMS before destruction?			
Is a logbook maintained for all documents placed for shredding?			
Are document issuance and control procedures adequately defined and followed?			
Is there a system for electronically managing document access and reconciliation?			
Are document revisions tracked and recorded?			
Are controlled GMP forms reconciled at the end of each batch?			

	Yes	No	NA
Document Security & Storage			
Are GMP documents stored in a controlled and secure manner?			
Is access to master records restricted to authorized personnel?			
Is there a digital backup system for GMP records?			
Are document retrieval processes efficient and timely?			
Is electronic document storage validated for compliance?			
Are obsolete or outdated documents clearly identified?			
Is searchability maintained in EDMS for controlled documents?			
Are retrieval requests logged and tracked?			
Are archived records indexed for quick retrieval?			
Are retention and disposal policies enforced consistently?			
Are destroyed documents logged with QA oversight?			

III. Training & Competency

	Yes	No	NA
Training Implementation			
Are personnel trained in document management procedures?			
Are employees trained in proper document handling and compliance?			
Is routine training conducted on document management procedures?			
Are QA staff trained on proper documentation procedures?			
Are staff trained on GDP correction procedures?			
Are new employees trained on document SOPs before assignment?			
Are refresher trainings provided when SOPs are updated?			
Are training programs refreshed periodically?			
Is staff competency evaluated after training?			
Are training records updated in real time?			

	Yes	No	NA
Competency Evaluation & Oversight			
Are training records complete and up to date?			
Are training records audited periodically for compliance?			
Are overdue training records flagged and corrected?			
Do reviewers have training records proving competence?			
Are training responsibilities documented within SOPs?			
Are cross-functional trainings conducted where relevant?			
Is there supervisory oversight for training quality?			
Are refresher trainings documented and reviewed by QA?			
Are staff periodically re-certified on GDP practices?			
Is training effectiveness evaluated against compliance audits?			

IV. Quality Oversight & Audit Readiness

	Yes	No	NA
QA Oversight & Review			
Are all QC unit responsibilities and procedures documented and accessible?			
Are investigation and CAPA details accurately documented?			
Are production/testing documents reviewed by QA before release?			
Is QA approval required for document disposal?			
Are all GMP documents reviewed and approved by QA?			
Are QA personnel consistently following documented procedures?			
Is QA oversight ensured during document issuance and distribution?			
Are QA reviewers part of the SOP lifecycle process?			
Are QA responsibilities included in quality agreements?			
Does QA review cover labeling and packaging documents?			

	Yes	No	NA

Internal Audits & Compliance

Is there an internal audit mechanism to monitor document management?			
Are documentation practices regularly audited for compliance?			
Are deviations from SOPs documented and reviewed during audits?			
Are audit findings logged and tracked to closure?			
Are periodic audits conducted to review document practices?			
Are document issuance and access controls audited?			
Are audit outcomes linked to corrective/preventive actions?			
Are CAPAs generated for audit issues and tracked?			
Are audit results communicated to relevant teams?			
Are audit responsibilities clearly documented?			

V. Data Integrity & GDocP Compliance

	Yes	No	NA
Good Documentation Practices (GDP)			
Is there a system in place to ensure documentation completeness and accuracy?			
Is there evidence that staff follow GDP practices?			
Are corrections made with single-line, initial, and date?			
Are documentation errors investigated and resolved?			
Are GDP violations tracked and escalated?			
Are handwritten entries legible, dated, and signed?			
Are GDP refresher trainings documented?			
Are deviations from GDP documented in quality records?			

	Yes	No	NA
Data Control & Accuracy			
Are all forms version-controlled?			
Are laboratory notebooks reviewed regularly?			
Are environmental monitoring records complete and accurate?			
Are calibration and testing records traceable?			
Are discrepancies in sample data reconciled promptly?			
Are laboratory records independently verified by QC?			
Are validation and retest records updated promptly?			
Are FTIR and other data files named/organized per SOP?			
Are deviations documented in quality documents?			
Are all test results accurately recorded before approval?			
Are second-person verifications conducted where required?			

VI. Retention, Archiving & Retrieval

	Yes	No	NA
Document Retention			
Are documents retained and available for inspection?			
Is there a clear and enforced policy for retention/disposal?			
Are retention periods aligned with 21 CFR Part 211?			
Are obsolete documents identified and segregated?			
Are destroyed documents logged with justification?			
Are retention policies periodically reviewed?			
Are video/audio records retained per SOP?			
Are compounded product reports retained as required?			
Are BPDR-related records retained for mandated periods?			
Are retention responsibilities assigned to QA?			

	Yes	No	NA

Retrieval & Traceability

Are retrieval processes efficient and documented?			
Are records indexed for fast access?			
Is searchability maintained in EDMS?			
Are retrieval requests logged and tracked?			
Are retrieval tests conducted before inspections?			
Are archived records protected from unauthorized use?			
Is retrieval responsibility defined within SOPs?			
Are retrieval processes validated during audits?			
Are retrieval times benchmarked for efficiency?			
Are electronic backups accessible for retrieval testing?			

VII. Record Management in Manufacturing & QC

	Yes	No	NA
Manufacturing Records			
Are production and process control records maintained per SOP?			
Are batch records filled contemporaneously?			
Are operator initials captured accurately?			
Are manufacturing steps recorded sequentially?			
Are cleanroom activities logged hourly?			
Are deviations in production explained in records?			
Are acceptance measurements for equipment documented?			
Are equipment cleaning/validation activities documented?			

	Yes	No	NA

QC & Laboratory Records

Are QC test results verified by a reviewer?

Are chromatograms traceable to sample IDs?

Are deviations explained in QC result sheets?

Are analyst initials/times documented?

Are instrument logs attached to QC reports?

Are laboratory logs maintained accurately?

Are stability study data reviewed and archived?

Are laboratory incidents reported and managed per SOP?

Are impurity profiles reviewed and approved?

Are all QC observations logged in controlled forms?

Are master batch records reviewed and approved?

VIII. Policy & Governance Compliance

	Yes	No	NA
Governance Alignment			
Are governance roles defined in quality agreements?			
Are QC/QA procedures documented and accessible?			
Are governance policies harmonized with global standards?			
Are governance documents reviewed annually?			
Are deviations escalated to senior management?			
Are governance KPIs monitored and reported?			
Are governance roles communicated across functions?			
Are oversight responsibilities aligned to CAPA processes?			
Are governance documents updated with regulatory changes?			
Are governance procedures reviewed during internal audits?			