Standard Assessment

Document Assessed: Record Retention and Destruction x Site Document Handling Guideline

Section	Original Content	Recommended adjustments	Summary and Rationale
1. Procedure (5.2) Document Placement	5.2.1. Documents that contain process procedures, design approval documents, governance meeting notes, Procurement documents that do not involve CRB, and BProject documents are to be stored in the Project Box Folder in the appropriately labeled folders. 5.2.2. Documents that pertain to Operational Readiness, Project Risk Register, Site Leadership Team, Program Committee, and general departmental documents are to be stored in Sharepoint in the appropriately labeled folders. 5.2.3. Engineering documents relating to the facility that will be turned over at capital project completion are to be stored in the Engineering Document Management System. 5.2.4. Quality documents such as SOPs, Work Instructions, technical reports, Forms, GxP training records, Deviation Records, CAPA records, Change Control records, compliance records, supplier management records, audit/inspections records, Site Quality Risk Register, and Regulatory Drawings are to be stored in the Veeva Vault Quality system. 5.2.5. Factory Acceptance Test (FAT) documents, Site Acceptance Test (SAT) documents, Commissioning documents, Installation Qualification/Operational Qualification (IQ/OQ) documents, Performance Qualification (PQ) documents, and equipment drawings are to be stored in the ValGenesis system. 5.2.6. Project documents which may include but are not limited to CRB Procurement documents, P&IDs, AF&IDs, design models, blueprints, design reports, schedules, design meeting minutes and process specifications will be stored in Autodesk Construction Cloud.	5.3 Document Storage (Electronic) 5.3.1. Documents may be stored electronically on human readable media, such as Veeva Quality Documents or cloud-based services, e.g., Box, OneDrive, or SharePoint, which are regularly backed up in accordance with requirements established by Information and Communication Technology (ICT) Department in consultation with the Legal Department and centrally managed. 5.3.2.If documents are archived using electronic or optical media, the methods for transferring the data to/from these media are qualified and a suitable backup strategy implemented to prevent loss or destruction of data. There must be a possibility to generate hard copies throughout the document retention period. 5.3.3. Electronic records shall be maintained in accordance with 21 CFR Part 11 (FDA) and other applicable regulations, ensuring data integrity, security, and backup procedures.	• Create a new section called "Document Storage (Electronic)" • Revise 5.1.2 for media types to match the services to clearly align with 21 CFR Part 11 (FDA), for example, VQD is cloud-based along with Box, OneDrive, and SharePoint). Recommended revision: Documents may be stored on human readable media, such as a cloud-based service. Cloud-based system repositories being used include but are not limited to: 1. Veeva Vault Quality System 2. ValGenesis 3. Box 4. OneDrive 5. SharePoint 6. Autodesk Construction Cloud The Information and Communication Technology (ICT) Department, in consultation with the Legal Department, centrally manages repositories and ensures regular backups. • The Legal Department and the ICT Department need to be in both the Definitions list and the Roles and Responsibilities section.