| **Item #** | **Task** | **Comments**  (Task objective or important details) | **Owner**  (A single individual should be named for accountability) | **Status**  (Not Started, In-Process, Complete, or NA) |
| --- | --- | --- | --- | --- |
|  | Quality manual | complete, accurate, and formally approved |  |  |
|  | Organizational chart | complete, accurate, and formally approved |  |  |
|  | Job descriptions | complete, accurate, and formally approved |  |  |
|  | CVs | Are located in the employee files or with the training records |  |  |
|  | Training SOP and Training curriculum or plan | Items 2,3,4,&5 are connected. The name and title on the org chart should align with the title on the job description, and the required experience and education demonstrated by the CV and training records. These records should all align.  The training curriculum or training plan should address what training is required for a specified function. Ask yourself, “If you were to hire someone tomorrow what training would be required? “ |  |  |
|  | Training Records | Accurate, complete and up to date with all training requirements. Every employee should have a training record. |  |  |
|  | Drawings | Facility layout drawing, process flow drawing or material flow drawing (as applicable) |  |  |
|  | Complaints | Prepare the last 2 years or any complaints that remain open.  You must have access to all complaints for the life of the product. |  |  |
|  | CAPAs, NCRs, SCARs, Non-Conformance Investigations | Prepare the last 2 years or any that remain open. For any trends or recurring nonconformances a CAPA should be opened. |  |  |
|  | Recall Records | Prepare the last 2 years. You must have access to all recall records for the life of the product.  Make sure you have a formal closure letter for any completed recalls. |  |  |
|  | Batch Records or Manufacturing records (Device History Record / Device Master Record) | Make sure that what you are producing (or testing) aligns with the current test methods, validated parameters, and approved specifications. If you are operating beyond a CPP or outside the validated range be able to explain why. |  |  |
|  | Specifications | Raw material specifications, Final Product specifications, packaging and labeling |  |  |
|  | CPPs and CQAs | If your specifications (or batch records) do not clearly indicate critical process parameters or critical quality attributes then create a document that clearly defines these as well as the normal operating ranges. |  |  |
|  | Test & Inspection Steps | If your process flow diagram does not indicate where *all* test and inspection steps are occurring then either add these or create a separate document (process description). This needs to be clearly explained during an audit. This includes in-process and final release testing. |  |  |
|  | Testing to support lot release or in-process testing | Formally documented testing. Defined test acceptance criteria. Validated methods. Instruments or tools are qualified, Calibrated, PMed and appropriately labeled. Test data is appropriately recorded and stored. Quality review is conducted for final release testing. |  |  |
|  | Management Review / Annual Product Review | Last 2-3 years. FDA cannot formally request internal audits or management review records but notified bodies and other regulatory agencies may. FDA will also ask for the inputs and outputs of management review. |  |  |
|  | Procedures, Work Instructions, and Forms | Have the current and legacy versions available. All documents should have a complete change history (or revision history). |  |  |
|  | Internal audits | Prepare the internal audit plan or schedule. Demonstrate how all the elements of your quality system will be covered. Be able to explain any open audit findings and how these are tracked to closure. |  |  |
|  | Approved Supplier List (ASL) | Prepare the ASL and ensure that it is complete and accurate. Review critical vendors/suppliers to be sure they are on the ASL. |  |  |
|  | Material qualification and incoming material Testing | Be able to demonstrate how materials were qualified and why they are appropriate for your product. Be able to explain your rationale behind incoming material testing (testing each lot, testing each year, etc.) |  |  |
|  | Supplier files (Qualification Records) | Prepare and update supplier files. Files should demonstrate supplier evaluation, supplier qualification and continued monitoring. |  |  |
|  | Validation and Qualification records | Locate and re-familiarize yourself with the most current qualification and validation records that support your existing products. (Do not focus on legacy or discontinued products unless these are leveraged) |  |  |
|  | Maintenance Records including calibration and PM | Last 2 years  Investigations for any equipment found out of calibration or not working properly. |  |  |
|  | EM Data | Review all EM data if you are working with clean utilities or in classified spaces. Review and trend data to action and excursion limits. Review investigations for last 2 yrs as applicable. |  |  |
|  | Pest Control and facility maintenance records | Layout drawing with location of traps indicated. Pest control Log. Approved pest control vendor. Investigation into pest sightings inside of the building or in critical spaces. Facility Cleaning records last 2 years. |  |  |
|  | Cleaning (cleanrooms) | Cleaning validation reports, material qualification for cleaning agents (sporacides), coupon tests, etc. |  |  |
|  | IT Systems | Validation of cGMP IT systems, 21 Part CFR part 11 compliance, and especially Data Integrity for ERES |  |  |
|  | Warehouse and material storage | Inventory management, FIFO, ability to reconcile all materials stored. Complete traceability of materials incoming and outgoing. Controlled Quarantine area. Temperature controlled/mapped as appropriate. Review of any T, RH excursions that could impact product.  What happens when an inventory check (or cycle count) shows a discrepancy? Are these investigated? |  |  |
|  | Product traceability | Be able to demonstrate product (and component) traceability from manufacture through customer receipt |  |  |
|  | Labels | Review labeling and IFUs. Have examples materials for the auditor |  |  |
|  | Product DEMO | Prepare a “demo” product and make sure it is appropriately labeled |  |  |
|  | Submissions | Review submissions and filings for impacted products or facilities. If your submission doesn’t match exactly with what is happening in the facility, there is a problem. |  |  |
|  | Tour | Tour tour tour!! Tour the facility 2 months out, 2 weeks out, 2 days out and again every morning prior to starting the audit. Tour should include warehouse, laboratories, manufacturing spaces and any other CGP/GLP/GMP areas |  |  |
|  | Formal Tour Routes | Formalize tour routes and tour guides in writing (I like to highlight a facility layout drawing with the exact tour route and share this with senior leadership & department managers) |  |  |
|  | Subject Matter Experts (SMEs) | Prepare department managers, engineers, maintenance staff, operators and technicians for interviews. |  |  |
|  | Company, product and facility history | Know your company history and the history of your products.  Know the compliance history of your key vendors. (Recalls, 483s, Warning Letters, Untitled Letters, Consent Decree, etc.) |  |  |
|  | Records Accessibility | Electronic and paper records are easily accessible during the audit. Archived records can be retrieved within 24 hours of a formal request. |  |  |
|  | Staff Availability | Vacations for key personnel should be minimized. Travel schedules and vacations should be communicated and backup persons should be designated. |  |  |
|  | Vendor/ Customer Availability | Don’t forget to communicate to your key vendors (and customers) that you are anticipating an inspection. Most Quality Agreements require notification and updates at the conclusion of the audit. Ensure that key person are available to assist with questions remotely. |  |  |
|  | Lists | If you have the luxury of time I always like to create lists in advance of the audit. Recalls last 5 years, Complaints last 2 years, CAPAs last 2 years, lots manufactured last 2 years and current status. List of countries or regions which products are shipped to, list of all product types with part numbers. Keep these lists in Excel or other editable file so that you can sort during the audit. You can always print an abbreviated list for the auditor as needed. |  |  |