FDA Audit Prep Checklist

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The items on this checklist include many of the most-frequently cited observations in FDA-regulated industry. Therefore, a thorough review of all of the items below, with zero findings, should signal a sufficiently robust system. This checklist is intended for use for all types of medical products, but will not include checklist items for product types with specialized regulatory requirements.

☐ Verify that management provides adequate material, personnel and direction and to assure conformity to the requirements of the quality management system.
Verify that responsibilities and procedures applicable to the quality control unit are in writing and fully followed

☐ Verify that laboratory controls include scientifically sound and appropriate Specifications (including rationale and linkage to critical processing parameters and critical quality attributes) for

- components
- drug product containers
- closures, and
- in-process materials

☐ Verify that laboratory controls include scientifically sound and appropriate Standards (sourced from a national or international standard, if possible or well-documented internal standard) for

- components
- drug product containers
- closures, and
- in-process materials

☐ Verify that laboratory controls include scientifically sound and appropriate Sampling Plans (including statistical rationale) for

- components
- drug product containers
- closures, and
- in-process materials

☐ Verify that laboratory controls include scientifically sound and appropriate Test Procedures (including validation/verification) for

- components
- drug product containers
- closures, and
- in-process materials

☐ Verify that testing and release of products for distribution include appropriate laboratory determination of satisfactory conformance to the [final specifications, (e.g. identity and strength of each active ingredient) prior to release.

☐ Verify that procedures are established for investigation of discrepancies, and possible escalation to CAPA, and records are present to demonstrate conformity to procedures.

☐ Verify that all unexplained discrepancies, such as the failure of a batch or any of its components to meet any specification, whether or not the product has been already distributed, are investigated, and appropriate corrective and preventive action (including effectiveness checks) are taken to prevent recurrence.

☐ Verify that controls are established and followed to monitor and validate (i.e. IQ/OQ/PQ;PV) the performance of manufacturing processes or cleaning that could causing adverse variability in the characteristics of in-process material and final product.

☐ Verify that procedures designed to prevent microbiological contamination of products purporting to be sterile are established, written, followed, and appropriate.

☐ Verify that written procedures are present for production and process controls, to ensure that products have the identity, strength, quality, purity, or other performance attributes that they are represented to possess.

☐ Verify that historical manufacturing records are available for review and document the processes followed, the individuals involved, and such documentation is complete and error-free.

☐ Verify that appropriate controls are exercised over computers or related systems to assure that changes in quality records are instituted only by authorized personnel.

☐ Verify that all records are legible and are made using indelible ink.

☐ Verify that aseptic processing areas are appropriately monitored for environmental conditions, including validation/verification of controlled facilities/utilities or other environments.

☐ Verify that a written testing program designed to assess the stability characteristics of drug products is established and followed for every product.

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☐ Verify that procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have been established and encompass a documented evaluation decision of whether the product failed to meet specifications, whether the complaint represents and adverse patient event, and a formal decision of whether to open an investigation on the complaint and/or to report as an adverse event.

☐ Verify that all purchased or otherwise received product and services (including services by logistics providers, post-manufacture) conform to specified requirements have been established, including a procedure for supplier evaluation, and incoming materials inspection.

☐ Verify that the level of inspection is commensurate to the risk of the material to the safety of the final product.

☐ Verify that all processes whose output cannot be evaluated through inspection and/or test are validated.

☐ Verify that procedures are in place and implemented for an internal audit program, including training for auditors, and audits scheduled at appropriate intervals to assure continued success of the quality management system.

☐ Verify that processing equipment and utensils are cleaned, sanitized and maintained at appropriate intervals (including verification of hold times [i.e. cleaning validation]) to prevent malfunctions and/or contamination] that would alter the safety, identity, strength, quality, purity sensitivity, precision, size, resolution, or other key characteristic(s) of the product.

☐ Verify (for devices) that procedures for Design Controls and process for product Design Change are appropriately documented in a Design History File, identifying design inputs, design, outputs, design validation/verification, and design reviews at key points in the product design process. Each design phase shall trace back to requirements identified earlier in the design process.

☐ Verify that routine calibration, inspection, and maintenance of automated or measurement equipment used in the manufacturing, testing, or data storage is performed according to a written program (traceable to an identifiable standard).