Audit Readiness Checklist

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Management Responsibility and Quality System

- Are your organization's Quality Policy and Quality Objectives documented?
- Does your organization have a Quality Manual documenting the quality system and its implementation?
- Is the Quality function separate from the Production function?
- Are quality procedures and responsibilities documented?
- Does QA have the authority for all quality matters?
- Is the suitability and the effectiveness of the quality system reviewed by management at defined intervals?
- Does your organization have a documented plan for recovery and return to operations following a disaster?
- Does your organization have written procedures for handling customer complaints?
- Do procedures ensure that root causes of customer complaints are investigated and resolved, and effectiveness of corrective and preventative actions are verified?

Documentation and Records

- Are procedures available for the control of documents and records?
- Do these procedures address the handling of document changes?
- Are there written manufacturing or service instructions?
- Is there a process for the approval of procedures/service instructions?
- Is there a system for record retention?
- Are records retained in accordance with the applicable regulatory requirements?

Facilities

Infrastructure — Are the requirements defined for the infrastructure needed to:

- Achieve conformity to product requirements
- Prevent product mix-up and
- Ensure orderly handling of product
- Is there a security system to assure there is no entry by unauthorized persons?
- Is there a written preventative maintenance program for all equipment and critical utilities?
- Is there a pest control program including approved insecticides and areas applied?

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Equipment

- Are manufacturing and lab equipment and critical utilities qualified according to the written protocols and industry standards?
- Is equipment maintained and calibrated according to a preventive maintenance schedule?
- Are the calibration maintenance intervals based on the manufacturer's specified frequencies?
- Are records maintained for maintenance and calibration operations?
- Are there written procedures for cleaning, specifying cleaning agents and methods?
- Is there data and cleaning validation reports to show that the residuals left by the cleaning and/or sanitizing agent are within acceptable limits when cleaning is performed in accordance with the approved method?
- Is there an adequate system to assure that unclean instruments, equipment and machines are not used?
- Is there proper storage of cleaned instruments and equipment so as to prevent contamination?
- Is there an adequate system for controlling changes to methods, documents related to equipment, machines?
- Are changes authorized and approved through quality?
- Is re-qualification or re-validation performed post any major changes to the equipment and/or machine?

Purchasing Controls and Materials

- Is there a system in place to ensure that materials are only purchased from approved suppliers?
- Has each supplier of material or component been inspected, evaluated or audited for proper manufacturing controls?
- Are batch records used to document the material, equipment, machine and process(es) used in the production?
- Are there written procedures for the receipt, testing and release for use of all materials?
- Are incoming materials inspected?
- Are incoming material/components quarantined until approved for use?
- Are rejected components, material and containers quarantined and clearly marked to prevent their use?
- Is there a segregated area for non-conforming product?
- Is a final inspection performed on the completed product?

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- Is there a system for handling non-conforming product materials or test results to prevent reoccurrence?
- Is each lot within each shipment of material or components assigned a distinctive code so material or components can be traced through manufacturing and distribution?

Production

- Have any of your manufacturing processes been validated?
- Does your facility have design control for any products manufactured?
- Are planned and unplanned deviations documented?
- Is there a procedure for the documentation and investigation of non-conformances?
- Is production data reviewed for potential trends in non-conforming product?
- Are adverse trends addressed and is appropriate management notified?
- Does your firm subcontract the assembly and/or packaging of the product?

Laboratory Controls

- Do you have an on-site laboratory to test incoming materials and finished product?
- Is there a procedure for investigation of out-of-specification (OOS) test results to assure that a uniform procedure is followed to determine why the OOS result occurred and that corrective actions are implemented?
- Are non-conformances tracked and trended?
- Are all your contract labs/manufacturers qualified?
- Do your contract labs/suppliers follow current good manufacturing practice /good laboratory practice requirements?
- Is there a written specification on how to qualify contract labs/manufacturers?

Field Actions/Recalls

- Have any field alerts, recalls or market withdrawals been issued, are procedures in place?

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Change Control / Notification

- Is there a system in place to manage process changes? If yes, is this process detailed in a written procedure?
- Do you routinely notify customers of changes that potentially affect the quality of the product or service provided?
- Do you routinely notify customers of key business changes (e.g. acquisitions, manufacturing location changes, etc.)?
- Do you notify customers in advance of significant changes to processes/materials? What is the notification process?

Corrective and Preventive Action

- Are procedures in place for Corrective and Preventive Action?
- Are corrective and preventive actions assigned and tracked to closure?
- Are records maintained for corrective and preventive actions?
- Are corrective and preventive actions reviewed for effectiveness?
- Are corrective actions periodically reviewed by top management?

Internal Audits/Supplier Management

- Is there a documented internal audit program in place at your organization?
- Are internal audits performed on a schedule and corrective actions taken as appropriate?
- Are internal audits periodically reviewed by top management?
- Does your organization maintain an approved supplier list?
- Does your organization have a procedure/process outlining the selection and monitoring of suppliers providing critical products and/or services?

Training

Are trainings being conducted?

- Internal QMS training
- Job specific training
- Are employee training records maintained in compliance with Control of Records?
- Are personnel qualifications, skills in accordance with the job performed and job descriptions available?

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