

THE ESSENTIAL ISO 22716 Owner's Checklist

Manage and track everything you need for compliance in
one, easy place

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TERMS

XLS

ISO 22716 Owner's Checklist

ITEMIZED LIST OF AREAS TO CHECK

NOT STARTED

IN PROGRESS

CHECKLIST ITEMS

Documentation Review

GMP Documentation:

Are all GMP-related documents, such as SOPs, work instructions, and records, up-to-date and readily accessible?

Complete

Is there a process in place for regular review and approval of GMP documents?

In Progress

Are records of all GMP activities, including batch production, quality control, and audit reports, complete and properly archived?

On Hold

Supplier Documentation:

Have you obtained and reviewed all necessary documentation from suppliers, including Certificates of Analysis (COAs) for raw materials?

Waiting To

Are supplier agreements in place that specify GMP requirements and expectations?

Not Started

Is there a process for evaluating and approving new suppliers based on their compliance with GMP?

Complete

Facility Inspection

Cleanliness and Hygiene:

Is your manufacturing facility clean, organized, and free from contaminants?

Are there documented cleaning procedures for all areas, including production, storage, and common areas?

Are cleaning schedules adhered to, and are records of cleaning activities maintained?

Equipment Maintenance:

Are all equipment and tools properly maintained, serviced, and calibrated at regular intervals?

Are there documented procedures for equipment maintenance, and are logs kept for all maintenance activities?

Are there contingency plans in place for equipment breakdowns to minimize production disruptions?

zoning and Layout:

Is your facility layout designed to minimize the risk of contamination, with clearly defined zones for different stages of production?

Are there adequate controls in place to prevent cross-contamination, such as air filtration systems and proper storage?

Is there a flow chart or map of the facility that details the movement of materials and personnel?

Raw Material Control

Incoming Material Inspection:

Are all raw materials inspected upon receipt to ensure they meet specified quality standards?

Are there procedures for sampling, testing, and approval of raw materials before they are used in production?

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Minjie Lin

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