Pharmaceutical GMP Audit Checklist

28 Jun 2023 / Herman Lucio

Complete

Score	98.89%	Flagged items	2	Actions	1

Site conducted	Unanswered
Conducted on	28 Jun 2023 09:34 PST
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Flagged items & Actions

2 flagged, 1 action

Flagged items

2 flagged, 1 action

General Controls / Organizational & Management Responsibilities

Does a Quality Assurance unit (department) exist as a separate organizational entity?

No

Currently not yet. Will request for this to be prioritized ASAP.

To Do | Priority High | Due 5 Jul 2023 09:58 PST | Created by SafetyCulture Staff

Prioritize creation of QA unit

General Controls / Organizational & Management Responsibilities

Does the Quality Assurance unit alone have both the authority and responsibility to approve or reject all components, drug product containers and closures, in-process materials, packaging materials, labeling and drug products?

No

Other actions

0 actions

General Controls 2 flagged, 1 action, 95.46%

Organizational & Management Responsibilities

2 flagged, 1 action, 83.33%

Does this facility/business unit operate under a facility or corporate quality policy?	Yes
Does a Quality Assurance unit (department) exist as a separate organizational entity?	No

Currently not yet. Will request for this to be prioritized ASAP.

To Do | Priority High | Due 5 Jul 2023 09:58 PST | Created by SafetyCulture Staff

Prioritize creation of QA unit

Does the Quality Assurance unit alone have both the authority and responsibility to approve or reject all components, drug product containers and closures, in-process materials, packaging materials, labeling and drug products?	No
Does the QA department or unit routinely review production records to ensure that procedures were followed and properly documented?	Yes
Are adequate laboratory space, equipment, and qualified personnel available for required testing?	Yes
If any portion of testing is performed by a contractor, has the Quality Assurance unit inspected the contractor's site and verified that the laboratory space, equipment, qualified personnel, and procedures are adequate?	Yes
Are all QA procedures in writing?	Yes
Are all QA responsibilities in writing?	Yes
Are all written QA procedures current and approved? (Review log of procedures)	Yes
Are the procedures followed? (Examine records to ensure consistent record- keeping that adequately documents testing.)	Yes
Are QA supervisory personnel qualified by way of training and experience?	N/A
"Are other QA personnel, e.g., chemists, analysts, laboratory technicians)	Yes
qualified by way of training and experience?"	Yes

Document Control Program

100%

Does the QA unit have a person or department specifically charged with the responsibility of designing, revising, and obtaining approval for production and testing procedures, forms, and records?

Yes

Does a written SOP, which identifies how the form is to be completed and who signs and countersigns, exist for each record or form?

Yes

Is the production batch record and release test results reviewed for accuracy and completeness before a batch/lot of finished product is released?

Yes

Employee Orientation, Quality Awareness, and Job Training

100%

Circle the types of orientation provided to each new employee: (1) Company brochure (2) Literature describing GMP regulations and stressing importance of following instructions. (3) On-the-job training for each function to be performed (before the employee is allowed to perform such tasks). (4) Other: enter in notebook.

Yes

Does each employee receive retraining on an SOP (procedures) if critical changes have been made in the procedure?

Yes

Indicate how on-going, periodic GMP training is accomplished.

There are monthly trainings for GMP compliance done in the SafetyCulture app and all data is forwarded to the right leaders for tracking. Even if there are no changes in procedures, this is done.

Is all training documented in writing that indicates the date of the training, the type of training, and the signature of both the employee and the trainer?

Yes

Are training records readily retrievable in a manner that enables one to determine what training an employee has received, which employees have been trained on a particular procedure, or have attended a particular training program?

Yes

Are GMP trainers qualified through experience and training?

Yes

Are supervisory personnel instructed to prohibit any employee who, because of any physical condition (as determined by medical examination or supervisory observation) that may adversely affect the safety or quality of drug products, from coming into direct contact with any drug component or immediate containers for finished product?

Yes

Are employees required to report to supervisory personnel any health or physical condition that may have an adverse effect on drug product safety and purity?	Yes
Are temporary employees given the same orientation as permanent employees?	Yes
Are consultants, who are hired to advise on any aspect of manufacture, processing, packing or holding, of approval for release of drug products, asked to provide evidence of their education, training, and experience?	Yes
Are written records maintained stating the name, address, qualifications, and date of service for any consultants and the type of service they provide?	Yes

Plant Safety and Security

100%

Does this facility have a facility or corporate safety program?	Yes
Are safety procedures written?	Yes
Are safety procedures current?	Yes
Do employees receive safety orientation before working in the plant area?	Yes
Is safety training documented in a readily retrievable manner that states the name of the employee, the type of training, the date of the training, and the name of the trainer and the signature of the trainer and the participant?	Yes
Does this facility have a formal, written security policy?	Yes
Is access to the facility restricted?	Yes
Describe how entry is monitored/restricted:	Yes
Is a security person available 24 hours per day?	Yes

Internal Quality/GMP Audit Program

100%

Does this business unit/facility have a written quality policy?	Yes
Is a copy of this quality policy furnished to all employees?	Yes
Is training provided in quality improvement?	Yes
Does a formal auditing function exist in the Quality Assurance department?	Yes

Does a written SOP specify who shall conduct audits and qualifications (education, training, and experience) for those who conduct audits?	Yes
Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?	Yes
Does a written SOP specify the distribution of the audit report?	Yes

Quality Cost Program

100%

Does this facility have a periodic and formal review of the cost of quality?	Yes
Does this facility have the ability, through personnel, software, and accounting records, to identify and capture quality costs?	Yes
Does this facility make a conscious effort to reduce quality costs?	Yes

Facility Control	100%

Facility Design and Layout

100%

Are all parts of the facility constructed in a way that makes them suitable for the manufacture, testing, and holding of drug products?	Yes
Is there sufficient space in the facility for the type of work and typical volume of production?	Yes
Does the layout and organization of the facility prevent contamination?	Yes

Environmental Control Program

100%

The facility is NOT situated in a location that potentially subjects workers or product to particulate matter, fumes, or infestations?	Yes
Are grounds free of standing water?	Yes
Is lighting adequate in all areas?	Yes
Is adequate ventilation provided?	Yes
Is control of air pressure, dust, humidity and temperature adequate for the manufacture, processing, storage or testing of drug products?	Yes
If air filters are used, is there a written procedure specifying the frequency of inspection and replacement?	Yes
Are drains and routine cleaning procedures sufficient to prevent standing water inside the facility?	Yes
Does the facility have separate air handling systems, if required, to prevent contamination? (MANDATORY IF PENICILLIN IS PRESENT!)	Yes

Facility Maintenance and Good Housekeeping Program

100%

Is this facility free from infestation by rodents, birds, insects and vermin?	Yes
Does this facility have written procedures for the safe use of suitable, (e.g. those that are properly registered) rodenticides, insecticides, fungicides, and fumigating agents?	Yes

Is this facility maintained in a clean and sanitary condition?	Yes
Does this facility have written procedures that describe in sufficient detail the cleaning schedule, methods, equipment, and material?	Yes
Does this facility have written procedures for the safe and correct use of cleaning and sanitizing agents?	Yes
Are all parts of the facility maintained in a good state of repair?	Yes
Is sewage, trash and other refuse disposed of in a safe and sanitary manner (and with sufficient frequency?)	Yes

Outside Contractor Control Program

100%

Are contractors and temporary employees required to perform their work under sanitary conditions?	Yes
Are contractors qualified by experience or training to perform tasks that may influence the production, packaging, or holding of drug products?	Yes

Equipment Design and Placement 100%

Design and Placement 100%

Is all equipment used to manufacture process or hold a drug product of appropriate design and size for its intended use?	Yes
Are machine surfaces that contact materials or finished goods non- reactive, non-absorptive, and non-additive so as not to affect the product?	Yes
Are design and operating precautions taken to ensure that lubricants or coolants or other operating substances do NOT come into contact with drug components or finished product?	Yes
Fiber-releasing filters are NOT used in the production of injectable products?	Yes
Asbestos filters are NOT used in the production of products?	Yes
Is each idle piece of equipment clearly marked ""needs cleaning"" or ""cleaned; ready for service""?"	Yes
Is equipment cleaned promptly after use?	Yes
Is idle equipment stored in a designated area?	Yes
Are written procedures available for each piece of equipment used in the manufacturing, processing or holding of components, in-process material or finished product?	Yes
Do cleaning instructions include disassembly and drainage procedure, if required, to ensure that no cleaning solution or rinse remains in the equipment?	Yes

Equipment Identification 100%

Are all pieces of equipment clearly identified with easily visible markings?	Yes
Are all pieces of equipment also marked with an identification number that corresponds with an entry in an equipment log?	Yes
Does each piece of equipment have written instructions for maintenance that includes a schedule for maintenance?	Yes
Is the maintenance log for each piece of equipment kept on or near the equipment?	Yes

Equipment Maintenance & Cleaning 100%

Are written procedures established for the cleaning and maintenance of equipment and utensils?	Yes
Are these procedures followed?	Yes
Does a written procedure assign responsibility for the cleaning and maintenance of equipment?	Yes
Has a written schedule been established and is it followed for the maintenance and cleaning of equipment?	Yes
Has the cleaning procedure been properly validated?	Yes
If appropriate, is the equipment sanitized using a procedure written for this task?	Yes
Has a sufficiently detailed cleaning and maintenance procedure been written for each different piece of equipment to identify any necessary disassembly and reassembly required to provide cleaning and maintenance?	Yes
Does the procedure specify the removal or obliteration of production batch information from each piece of equipment during its cleaning?	Yes
Is equipment cleaned promptly after use?	Yes
Is clean equipment clearly identified as "clean" with a cleaning date shown on the equipment?	Yes
Is clean equipment adequately protected against contamination prior to use?	Yes
Is equipment inspected immediately prior to use?	Yes
Are written records maintained on equipment cleaning, sanitizing, and maintenance on or near each piece of equipment?	Yes

Measurement Equipment Calibration Program

100%

Does the facility have approved written procedures for checking and calibration of each piece of measurement equipment? (Verify procedure and log for each piece of equipment and note exceptions in notebook with cross reference.)	Yes
Are records of calibration checks and inspections maintained in a readily retrievable manner?	Yes

Equipment Qualification Program

100%

Verify that all pieces of equipment used in production, packaging, and quality assurance are capable of producing valid results.	Yes
When computers are used to automate production or quality testing, have the computer and software been validated?	Yes
Have on-site tests of successive production runs or tests been used to qualify equipment?	Yes
Were tests repeated a sufficient number of times to ensure reliable results?	Yes
Is each piece of equipment identified to its minimum and maximum capacities and minimum and maximum operating speeds for valid results?	Yes
Have performance characteristics been identified for each piece of equipment? (May be provided by the manufacturer, but must be verified under typical operations conditions.)	Yes
Have operating limits and tolerances for performance been established from performance characteristics?	Yes

Material/ Component Control	100%

Material/Component Specification and Purchasing Control

100%

Although purchasing is not specifically addressed in the current GMP regulation, incumbent upon user of components and materials to ensure quality of product, material or component.	Yes
Has each supplier/vendor of material or component been inspected/audited for proper manufacturing controls? (Review suppliers and audits and enter names, material supplied, and date last audited in notebook.)	Yes

Material/Component Receipt, Inspection, Sampling, and Laboratory Testing

100%

Does the facility have current written procedures for acceptance/rejections of drug products, containers, closures, labeling and packaging materials?	Yes
Is each lot within each shipment of material or components assigned a distinctive code so material or component can be traced through manufacturing and distribution?	Yes
Does inspection start with visual examination of each shipping container for appropriate labeling, signs of damage, or contamination?	Yes
Is the number of representative samples taken from a container or lot based on statistical criteria and experience with each type of material or component?	Yes
Is the sampling technique written and followed for each type of sample collected?	Yes
Is the quantity of sample collected sufficient for analysis and reserve in case retesting or verification is required?	Yes
Verify that the following steps are included in written procedures unless more specific procedures are followed:	Yes
Containers are cleaned before samples are removed.	Yes
Stratified samples are not composited for analysis.	Yes
Containers from which samples have been taken are so marked indicating date and approximate amount taken.	Yes
Each sample container is clearly identified by material or	Yes

component name, lot number, date sample taken, name of person taking sample, and original container identification.	
At least one test is conducted to confirm the identity of a raw material (bulk chemical or pharmaceutical) when a Certificate of Analysis is provided by supplier and accepted by QA.	Yes
If a Certificate of Analysis is not accepted for a lot of material, then additional testing is conducted by a written protocol to determine suitability for purpose.	Yes
Microbiological testing is conducted where appropriate.	Yes

Material Component Storage and Handling

100%

Verify that materials and components are stored and handled in a way that prevents contamination, mix-ups, and errors.	Yes
Are incoming material and components quarantined until approved for use?	Yes
Are all materials handled in such a way to prevent contamination?	Yes
Are all materials stored off the floor?	Yes
Are materials spaced to allow for cleaning and inspection?	Yes
Are labels for different products, strengths, dosage forms, etc., stored separately with suitable identification?	Yes
Is label storage area limited to authorized personnel?	Yes
Are rejected components, material, and containers quarantined and clearly marked to prevent their use?	Yes

Inventory Control Program

100%

Are inventory control procedures written?	Yes
Does the program identify destruction dates for obsolete or out-dated materials, components, and packaging materials?	Yes
Is stock rotated to ensure that the oldest approved product or material is used first?	Yes
Is destruction of materials documented in a way that clearly identifies the material destroyed and the date on which destruction took place?	Yes

Vendor (Supplier) Control Program

100%

Are vendors periodically inspected according to a written procedure?	Yes
Is the procedure for confirming vendor test results written and followed?	Yes

Operational Control	100%

Material/Component/Label Verification, Storage, and Handling

100%

Do written procedures identify storage time beyond which components, containers, and closures must be reexamined before use?	Yes
Is release of retested material clearly identified for use?	Yes
Are retesting information supplements originally obtained?	Yes
Do written procedures identify steps in the dispensing of material for production?	Yes
Do these procedures include (1) release by QC, (2) Documentation of correct weight or measure, and (3) Proper identification of containers?	Yes
Does a second person observe weighing/measuring/dispensing and verify accuracy with a second signature?	Yes
Is the addition of each component documented by the person adding the material during manufacturing?	Yes
Does a second person observe each addition of material and document verification with a second signature?	Yes
Does a written procedure specify who is authorized to issue labels?	Yes
Does a written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies?	Yes
Do written procedures call for destruction of excess labeling on which lot or control numbers have been stamped or imprinted?	Yes

Equipment/Line/Area Cleaning, Preparation, and Clearance

100%

Do written procedures detail how equipment is to be checked immediately prior to use for cleanliness, removal of any labels and labeling from prior print operations?	Yes
Do written procedures detail any disconnection and reassembly required to verify readiness for use?	Yes

Operational Process Validation and Production Change Order Control

100%

Have production procedures been validated? (Review selected procedures for validation documentation. Adequate?)	Yes
Does the process control address all issues to ensure identity, strength, quality, and purity of product?	Yes
Does the procedure include formulation that is written to yield not less than 100% of established amount of active ingredients?	Yes
Are all weighing and measuring preformed by one qualified person and observed by a second person?	Yes
Have records indicated preceding policy been followed by presence of two signatures?	Yes
Are actual yields calculated at the conclusion of appropriate phases of the operation and at the end of the process?	Yes
Are calculations performed by one person? Is there independent verification by a second person?	Yes

In-Process Inspection, Sampling, and Laboratory Control

100%

Are written procedures established to monitor output and validate the performance of manufacturing procedures that may cause variability in characteristics of in-process materials and finished drug products?	Yes
Are in-process materials tested at appropriate phases for identity, strength, quality, purity and are they approved or rejected by Quality Control?	Yes
Are there laboratory controls including sampling and testing procedures to assure conformance of components, containers, closures, in- process materials, and finished product specifications?	Yes

Reprocessing/Disposition of Materials

100%

Do written procedures identify steps for reprocessing batches?	Yes
Are quality control review and approval required for any and all reprocessing of material?	Yes

Does testing confirm that reprocessed batches conform to established specification?	Yes
Does a written procedure outline steps required to reprocess returned drug products (if it can be determined that such products have not been subjected to improper storage conditions?)	Yes
Does Quality Control review such reprocessed returned goods and test such material for conformance to specifications before releasing such material for resale?	Yes

Finished Product Control	100%

Finished Product Verification, Storage, and Handling

100%

Do write procedures indicate how and who verifies that correct containers and packages are used for finished product during the finishing operation?	Yes
In addition, do written procedures require that representative sample of units be visually examined upon completion of packaging to verify correct labeling?	Yes
Are expiration dates stamped or imprinted on labels?	Yes
Are expiration dates related to any storage conditions stated on the label?	Yes
Are all finished products held in quarantine until QC has completed its testing and releases product on a batch to batch basis for sale?	Yes
Is finished product stored under appropriate conditions of temperature, humidity, light, etc.	Yes

Finished Product Inspection, Sampling, Testing, and Release for Distribution

100%

Has the formulation for each product been tested for stability based on a written protocol? (Containers must duplicate those used in final product packaging.)	Yes
Are written sampling and testing procedures and acceptance criteria available for each product to ensure conformance to finished product specifications?	Yes
Is a quantity of samples equal to at least twice the quantity needed for finished product release testing maintained as a reserve sample?	Yes
Are sterility and pyrogen testing performed as required?	Yes
Are specific tests for foreign particles or abrasives included for any ophthalmic ointments?	Yes
Do controlled release or sustained release products include tests to determine conformance to release time specification?	Yes

Distribution Controls

100%

Does a written procedure manage stocks to ensure that oldest approved product is sold first?	Yes
Are deviations to the policy above documented?	Yes
Does a written procedure identify the steps required if a product recall is necessary?	Yes
Is the recall policy current and adequate?	Yes

Marketing Controls

100%

The current regulation does not address marketing controls per se except that all finished products must meet their specifications.	Yes

Complaint Handling and Customer Satisfaction Program

100%

Are complaints, whether received in oral or written form, documented in writing and retained in a designated file?	Yes
Are complaints reviewed on a timely basis by the Quality Control Unit?	Yes
Is the action taken in response to each complaint documented?	Yes
Are decisions not to investigate a complaint also documented and the name of the responsible person documented?	Yes
Are complaint investigations documented and do they include investigation steps, findings, and follow-up steps, if required? Are dates included for each entry?	Yes

Completion

Final Notes

Create and formally document the establishment of a dedicated QA team ASAP.

Sign off

Herman Lucio
28 Jun 2023 10:17 PST