

A Capstone Project Reportsubmitted In Partial Fulfillment Ofthe Requirements For The Degree Of Bachelor Of Pharmacy

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ABSTRACT

Proper documentation and record maintenance are often a principal step for any of the pharmaceutical trade for producing pharmaceutical product. Documentation provides a radical info of the history then this standing of the producing batches. It provides a basis of what need to be tired future for the advance within the maneuver. If the documentation is effective it provides the required info to the approved personnel for the discharge of the batch.

Specifications or the procedures for producing and management of the drug merchandise are else being provided. Correct documentation and record are often a maintenance tool permanently producing follow (GMP), as a result of management of documentation and record is in among the obligatory a locality of GMP to chop back error and misuses of any documents.

In a GMP setting Documentation need to meet sure necessities to create positive product Quality and merchandise safety. If the directions or record is poorly documented, then the manufacture or management of a product area unit getting to be negatively compact.

Documentation and record helps to know concerning actual image of any company. As importance given to documentation therefore —good documentation practices is needed.

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I. INTRODUCTION

Good documentation and record follow may be a crucial a locality of the standard assurance and such associated with all aspects of fine producing follow (GMP). Clearly written documents forestall errors of assorted activities in pharmaceutical company every and every activity is written in specific documents like SOPs and strictly followed. wise documentation follow describes standards by that documentation is formed and maintained within the pharmaceutical business. All pharmaceutical Biosciences and tending corporations, together as their merchandiser partners, need to observe gross domestic product or face warnings or panalties levied by the Food and Drug Administration. Documentation compliance and ensures traceability of all development, producing, and testing activities. Documentation and record provides the route for auditors to assess the standard of operations among an organization and so the last word product.

Purpose Of Documentation

Defines specifications and procedures for all materials and strategies of manufacture and management.

- Ensures all personnel acknowledge what to undertake to to and once to undertake to thereto
- Ensures that approved persons have all info necessary for undo of product
- Ensures documented proof, traceability, provide records and audit path for Investigation
- Ensures convenience of information for validation, review and maths analysis Some of the necessities
- wise documentation constitutes an important a locality of thestandard assurancesystem.

Output

Clearly written procedures stop errors succeeding from speech , and clear documentation permits tracing of activities performed.

- Documents need to be signed, approved and dated by the suitable competent and approved persons.
- Documents need to be designed, prepared, reviewed, and distributed with care.
- Unambiguous contents is need to in any documents. The title, nature, and purpose ought to be compelled to be clearly declared.

- The documents need to be set get into associate orderly fashion and be straightforward to envision. Reproduced documents need to be clear and truthful.
 - Documents need to be oft reviewed and preserved to the current purpose. once a document has been revised, systems need to be operated to prevent accidental use of superannuated documents.
 - Documentation should not be written, excepts once documents would love the entry of data, these entries is to boot created in clear truthful handwriting employing a applicable ineradicable medium (pencil not accepted). enough house need to be provided for such entries.
 - Any correction created to a document or record need to be signed or initialed and dated. Records need to be unbroken at the time every action is taken and in such the sole approach that every one activities regarding the conduct of diagnosis studies, clinical trials, then the manufacture and management of merchandise are traceable.
 - The storage location need to guarantee adequate protection from loss, destruction, or falsification, and from harm owing to fireplace, water, etc.
 - Records that are crucial to restrictive compliance or to support essential business activities need to be duplicated on paper, microfilm, or electronically, and keep throughout a separate, secure location throughout a separate buildings from the originals.
 - it's notably important that at intervals the amount of retention, the info may even be rendered truthful at intervals associate applicable amount of it slow. If information is changed, it need to be traceable.
- Documentation is associate integral a district of the standard assurance system and may, as such, be associated with all aspects of GMP. the foremost purpose is to spot the necessities for all merchandise then the producing and management methodology, to substantiate that every one producing employees have the data needed to work out whether or not or not or not or to not undo a batch of medicine purchasable and to provide a The specification ought to be compelled to allow America with the microscopic print and every one the specifications that need to be verified by the merchandise or materials used or obtained throughout manufacture. Production formulas, technique and packaging directions ought to be compelled to outline all the beginning materials used, and every one technique and packaging operations ought to be compelled to even be created public. Procedures will contain pointers for such tasks, like laundry, clothes, environmental protection, sampling, testing and operation of kit. Records ought to be compelled to embrace a history of every batch of the merchandise, furthermore as a result of the delivery therefrom, furthermore as of the alternative applicable conditions relevant to the standard of the last word product.
- All written records ought to be compelled to be management therefore as that the info may even be accustomed assess the standard levels of and drug product a minimum of sporadically to see the requirement for enhancements within the requirements or producing or management procedures for the drug product.
- For such assessments, written protocols ought to be compelled to be created public and followed and needs that are applicable need to be included:-
- Examination of the representative vary of batches, one accepted or denied and, wherever applicable, the batch-related documents.
- product came back and saved, and of the inquiries undertaken. An analysis of allegations, recalls, drug.

Documents with relevance the strategy of intermediates, pharmaceutical active ingredients and finished product ought to be compelled to be ready, checked, approved and circulated in compliance with written procedures. Such records unit of measurement typically paper-based or electronic. Documents need to be accepted, signed and dated by the accountable parties involved. whereas not authorisation and consent, no document unit of measurement typically updated.

The quality management department ought to be compelled to approve and maintain the specifications for raw materials, intermediates, finished product and packaging materials, and frequent revisions of the specifications ought to be compelled to be administered if changes unit of measurement needed.

It is important to watch form of the revision, issuance, superseding, and removal of all records, with the preservation of revision histories. Systems ought to be compelled to be worked on once a document has been updated to avoid the fortuitous use of substituted records. For a tricky and fast amount of it slow, the ex records ought to be compelled to be preserved.

Documentation system specifications

Documents ought to be compelled to own unambiguous content: it is a necessity to obviously state the title, meaning, and intent. they need to be compelled to be ordered out and easy to verify in associate orderly manner. The records that unit of measurement replicated ought to be compelled to be clear and clean. The duplicate methodology of operative documents from master

documents should not allow any mistake to occur throughout the duplicate methodology. Procedures for maintaining all relevant documentation, like development history reports, scale-up reports, technical transition reports, validation methodology reports, employment records, production records, management records and distribution records, ought to be compelled to be developed. It is a necessity to stipulate the retention amount for these records. All records of producing, management and delivery ought to be compelled to be maintained for a minimum of one year once the batch ending date. Records ought to be compelled to be unbroken for active pharmaceutical ingredients with re-test dates for a minimum of 3 years once the batch is totally distributed.

Documents mustn't be ready by hand. Whereas records would have information to be entered, these entries unit of measurement written in straightforward, legible, ineradicable handwriting. For such entries, ample space ought to be compelled to run. Any changes created to the entry on a document ought to be compelled to be signed and dated, the revisions ought to be compelled to vary the first details to be scan, then the justification for the modification ought to be compelled to be registered. The first or copies of the documents ought to be compelled to be promptly gettable throughout the preservation amount at the establishment wherever the events listed in such records befall. The type of records which is able to be retrieved instantly by electronic or completely totally different means that from another location unit of measurement applicable.

Data is to boot recorded by electronic method systems or photographic or completely totally different reliable means that, however the ornate procedures with connexion the system in use got to be gettable and therefore the accuracy of the records got to be checked. Any of the documentation that is handled by electronic method ways in which within which, alone approved person got to be ready to enter or modify information among the personal computer, and therefore the changes and deletion got to be recorded. Specifications for raw materials, intermediates whenever necessary and active pharmaceutical ingredients, yet as for labelling and packaging materials got to be developed and registered. Specifications is to boot necessary for a few completely totally different product which might have a serious result on potency, like technique aids, gas kits or completely totally different materials used throughout the manufacture of intermediates or active pharmaceutical ingredients.

Classification of Documentation

- Documentation for organization and personnel.
- Documentation for buildings and facilities.
- For Equipments.
- For packaging and labeling management.
- For production and technique management.
- For handling of R.M and P.M.
- For holding and distribution.
- For laboratory management.
- For records and reports.
- For return and salvaged finished product

Types of Documents utilized in prescription drugs

Specifications: - Specifications as per MHRA describe well the needs thereupon the merchandise or materials accustomed obtained throughout manufacture have to be compelled to modification. These can operate a basis of quality analysis.

Specifications needed for –

1. Active and Inactive materials
2. Primary written and packaging materials
3. Intermediate and semi finished product
4. Finished product

SOPs:- These unit of measure written, approved purposeful instruction used as a reference by the writer for performance and area unit used for work new operators among the performance of the procedure.

Test method:- usually{this will be} typically a written and approved documents, and it'll describe the ornate testing procedure.

List:- Documents contain a catalog of any object like list of Equipments.

Certificate of Analysis:- it's associate authentic documents show the analytical reports and call of acceptance and rejections.

Label Records Organ gram
Job description

Batch producing records:-

These unit of measure important document issued for each batch of product to assure, review and record keeping of any product batch.

Some of the foremost Batch producing Records content:

1. Generic name, power, product name, shelf life, date of expiration and date of production.
2. an entire list of the ingredients to be issued with the full definition, codes and consistency.
3. a sort of theoretical yield and reconciliation argument.
4. A declaration for location and instrumentality methodology.
5. Complete MFG and management directions, the maneuver for sampling and checking, criteria and precautions to be taken
6. technique or association to the set up of action to be used for the preparation, together with laundry, installation, activity and sterilisation, of essential instrumentality.
7. Time and dates of all operations.
8. Procedure for line clearance in every 0.5.
9. Regulation of labelling and sample committal to writing in primary , secondary and tertiary packaging materials.
10. Record of deviation and results of review created.

Golden rules of GMP:—

Get the flexibility thought right from the start

Validation of Processes

productive protocols and follow the write Identifying world organization agency is doing what Holding wise records

Train and grow personnel

Practice wise hygiene

Maintain installations and services

Develop consistency through the whole product lifecycle

Conduct periodic audits

Preparation, problems and Uses of Documents

To avoid misuse, each document have to be compelled to be strictly and logically written. and every one necessary Information's have to be compelled to be written properly. every document is apparent and processed therefore as that documents signed by a involved individual square measure readable and discharged to purpose a confirmed issue. If a correction is completed, it have to be compelled to be clearly cut with one signature and date line, don't write. every paper have to be compelled to have ample area and a written fili have to be compelled to be used for ball ink pen

Each document contains:—

1. Name of Business
2. Intent and title of papers
3. Revision No and Registration No.
4. Authorization Date
5. Test Date
6. Signature ready by, confirmed and accepted by
7. List of delivery
8. On page No.
9. the principle for the examination have to be compelled to be acknowledged.
10. Relation and Abbreviation

Hierarchical document system

A company is in control of the subsequent laws (E.G, USFDA / EU GMP / ICH / schedule M, etc.) have to be compelled to be at the simplest of the pyramid of the document and might regulate the sub-level directives.

Level one documents:- (E.G., the standard Manual) have to be compelled to break the foundations into elements specific to those needed to be followed by the corporate. These documents have to be compelled to commenced general principles and tips for the means that the corporate plans to develop and implement a Ccmp- Compliant Quality System for documentation.

Level a strive of of Documents:- The pyramid have to be compelled to any break down the weather of the laws into specific subjects or subjects throughout this documentation system. therefore on check that consistency across departments, these documents (E.G., company policies) have to be compelled to establish tips thereupon all subordinate level procedures have to be compelled to adapt.

Level a strive of documents mustn't give specific directives or knowledge documentation forms, however have to be compelled to give the intentions and tips for necessary programmes or systems, what's additional as explanations for the rationale and styles of the programme. These have to be compelled to be applied at intervals a GMP-Compliant company to any or all departments.

Documents Level 3:- These level papers have to be compelled to be specific to the department or specific to the perform.

Documents at Level 4:- (E.G., Batch record, take a look at ways that during which, validation procedures) This level of documents is that the foremost specific in nature. They apply to a selected department, product, machinery, or process. Such documents give step-by - step directions for tasks and activities associated with production, what's additional as provides a way of documenting such tasks.

In Level four documents specific to a selected technique, the directions named in Level three documents, that unit of measurement of a general nature, would possibly even be overridden.

One way of organising the documents of an organization is that the document Hierarchy pyramid.

Coordination of gross domestic product with restrictive desires (Harmonized requirement)

A brief document among the style of a 'Site master file' have to be compelled to be ready by the manufacturer, containing specific and factual GMPs on the manufacture and management of the pharmaceutical producing processes allotted among the permits.

There is the subsequent description (some of the information)

1. Temporary details regarding the firm
2. Pharmaceutical production operations, as authorised by the Licensing Authority
3. If any of the choice production activities unit of measurement gift, the permits jointly square measure allotted.
4. Product sorts approved for producing, with flowcharts description the procedure and flow of processes
5. reasonably producing staff, control, storage and distribution
6. Use, in affiliation producing and analysis, of out of doors scientific, analytical or totally different technical facilitate
7. Short description of the firm's quality management system
8. Elaborated merchandise registered with foreign countries

1. Personnel:-

- structure diagram showing quality assurance arrangements, beside management of production and quality.
- Qualification, experience, and duties of key employees.

2. Equipment:—

- Description of major instrumentation employed in producing and laboratories for management.
- Description of the regular preventive instrumentation maintenance programmes and collectively the audio system

- Qualification and standardization, beside recording systems, and processed system validation arrangements.

3. Sanitation:—

- Written specifications and cleanup procedures for producing areas and facilities.

4. Documentation:—

- variety of the arrangements for document preparation, revision, and distribution

- required producing documentation and thus the various documentation relating to product quality that's unlisted (e.g. microbiological management of air and water).

5. Production:—Production

- Production activities pattern realizable flow sheets and diagrams specifying key parameters

- Sampling, quarantine, release, and storage arrangements embrace arrangements for the handling of beginning materials, packaging materials, and bulk and finished merchandise.

- Description of substantiating the maneuver

6. Management of quality:—

- Description of the standard management system and/or the tasks of the department of management, procedures for cathartic finished product

7. Manufacture of the Loan Certificate and Licensee:-

- Definition of the means that among that GMP human action ought to be evaluated by the loan businessperson

8. Distribution, grievances, and recall of products:-

- Arrangements and methodology of recording for distribution
- Arrangements for observance reports and remembers of product

9. Self-Inspection:—

- Short define of the arrange of action of self-inspection, beside whether or not or to not incorporate AN impartial and arduous external knowledgeable in assessing the compliance the producer with GMP altogether areas of production.

10. Drug exports: —

- things shipped to individual countries
- Complaints, if any of constant, and merchandise recall.

11. Equipment cleanup and use record

The date, period, product, and batch style of every batch processed within the instrumentation and collectively the name and signature of the one World Health Organization assigned the cleanup and maintenance ought to be indicated within the records of the foremost necessary instrumentation used, cleaning, cleanup or sterilisation, and maintenance. Those people global organization agency perform the cleanup and maintenance assay ought to date and sign or initial the log, indicating that the work has been done.

Reasonable technological or organisational steps ought to forestall cross-contamination, such as:

- o method in sequestered areas (required for merchandise like antibacterial drug, live vaccines, live preparations of microorganism AND bound varied biological products) or through AN adequate cleanup campaign.

- the• Minimizing chance of pollution caused by untreated or insufficiently treated air recirculation or re-entry.

acceptable air locks and extractions for air. • Providing

- Keep protecting instrumentation in sq. measureas wherever product ar ready-made with a particular risk of cross-contamination.

clarification for cross contamination is that• A common the employment of non-efficient cleanup and removal techniques, as within the effective cleanup of kit and Use a closed production methodology.

- and• Residue checking collectively the employment of cleanup standing marks on devices.

If instrumentation is devoted to the manufacture of 1 intermediate or active pharmaceutical ingredient, then there is not any want for individual instrumentation records of varied activities like laundry, repair, batch log, etc., on condition that this information is entirely traceable within the batch record. low value cleanup protocols ought to be developed for the manufacture of formulations to substantiate the elimination of any contamination from the previous product.

12. Records of Raw materials, Intermediates, Labeling, and packaging materials:-

Records got to be protected in an exceedingly} very manner that includes:

- The name of the manufacturer, the identity and quantity of each consignment of each batch of raw materials, intermediates or marking and packaging materials, the name of the supplier, the management vary of the supplier (if any) or the opposite identification, the number assigned upon receipt and conjointly the date of receipt,

- Results of any analysis or analysis distributed and conclusions drawn from the take a glance at,
- Records tracing the employment of materials,
- Documentation of the review and analysis of labelling and packaging materials for compliance with the needs printed,

• so the final word judgement on raw materials, intermediates, or labelling and packaging materials that area unit declined.

It is acceptable to mark starting materials that ar among the hold properly. The specifics that a mark got to bring with them ar as follows:

- elite product name and connection the inside code, where applicable,
- The batch vary issued by the supplier and if given by the manufacturer, the management or batch vary upon receipt, ought to be recorded to substantiate traceability.
- Material standing (e.g. on quarantine, on examination, released, refused, returned, revoked etc.)
- AN finish date or a date once that re-testing is required, if necessary,

Mater production Instructions/ master production and management records (MPCR)/ master formula card (MFC):-

Master production directions for intermediate or active pharmaceutical ingredients/finished product got to be prepared, dated and signed by one person and severally verified, dated and signed by someone among the standard units to substantiate uniformity from batch to batch. The content and delivery within the firm of directions and Master Formulas got to be the responsibility of qualified persons virtuoso in production and control. These got to be signed and dated duly. The superannuated master formulas got to be withdrawn but unbroken for reference. it's a necessity to prepare copies of master formulas in an exceedingly} very approach that removes the prospect of transcription errors.

The master formulas that need to be changed in some things, like among the initial production runs following pilot development, as an example. Any amendments ought to be formally accepted and signed by the individual concerned. At the earliest probability, the revised text got to get replaced by a freshly prepared master formula.

In accordance with the master formula, method got to be distributed. directions for Master

Development got to include

- The name of the manufactured intermediate/API/formulation and an distinctive document reference code, if applicable,
- A full list of raw materials and intermediates (designated by sufficiently descriptive names or codes for the identification of any specific quality characteristics)
- AN precise statement of the number or quantitative relation, furthermore because the unit of live, of each staple or intermediate to be used. The estimate for each batch size or output rate got to be capsule if the number is not set. Whenever even, variations in amounts got to be capsule.
- A full list of raw materials and intermediates (designated by sufficiently descriptive names or codes for the identification of any specific quality characteristics)
- The place of manufacture and major production instrumentality to be used
- careful directions for output, including:

4. Sequence to be pursued

5. half parameter ranges to be used

6. ways that to be used for the preparation of vital instrumentality e.g. washing, assembly) or connection ways that

7. Sampling pointers and technique controls, with their approval desires, if applicable,

8. limits for individual method steps and/or the complete technique to be completed, if necessary

9. Excluded yield levels at the required method or time points.

Special notations and measures to be taken, or cross-references to those, where applicable, Instructions for storing intermediate or API/semi-finished formulations to substantiate that they are safe to be used, labelling directions (sample labels and packaging materials, and special storage desires with limits, if applicable) got to be protected.

Batch production records / batch production and management records (BPCR) / batch manufacturing record (BMR)

For each intermediate and active pharmaceutical ingredient/formulation, batch production records got to be prepared and complete details with regard to the assembly and management of each batch got to be capsule. until supplying, the batch production record got to be reviewed to substantiate that it is the right version that the required master production instruction is legibly accurate. If the batch production record is made from a special section of the master document, a connection this master production directions obtaining used got to be capsule in that document. A review got to be conducted and registered before any fairly method starts to substantiate that the instrumentality and computing machine are free of previous things, documents or materials that do not appear to be needed for the planned technique that the instrumentality is clear and ready to be used. These records got to be numbered and once written, dated and signed with a specific batch or identification range. The product code beside the date and time will operate the distinctive image ceaselessly in development until the final word range is assigned.

In a record or electronic process device, the batch vary got to be recoded sort of a shot. Dates of allocation, product identity, and batch size got to be capsule among the record.

The following reports got to embody the completion of and essential introduce the batch production records (batch production and management records):

- Dates and times

Identity of major installations used (e.g. reactors, dryers, factories, etc.)

Specific identification of each batch, furthermore as raw materials, intermediates, or any reprocessed materials used throughout method, furthermore as weights, measurements, and batch numbers.

Real findings for essential technique parameters according

- Any sampling distributed

Signatures of the success of the individual and conjointly the direct oversight or management of each essential introduce the activities.

Results of technique and laboratory studies True yield at applicable stages or times Packaging and label outline Representative label

Any deviation determined, assessment and investigation distributed or reference to that investigation is Outcomes of unhitch observance All batch-related analytical documents, or a reference which is able to modify their retrieval

A decision to unhitch or reject the batch, with the date and signature of the writer of the selection

- Analysis of the assembly record

As a neighborhood of the approval a part of batch unhitch, output and control records need to be checked. it is necessary to fully examine any disruptions and failure of a batch to attain its wants. it's therefore necessary to expand the inquiries to various multitudinous constant product and various things which may area unit connected with a particular failure or discrepancy.

The details that need to be registered at the time each action is taken is as follows:

The product name, the number of the batch and additionally the amount of the merchandise to be repacked, more as a result of the quantity really obtained and additionally the reconciliation.

Date and time of the packaging activities

Name of the responsible person conducting the operations of packaging

The Initials of the operators of the varied important steps

Identity tests and compliance with the package directions, additionally because the outcomes of technique controls, Information of the packaging operations that area unit done, at the side of references to the instrumentality and packaging lines used and pointers for keeping the merchandise unpacked among the cargo area. The periodic review for the correctness of the printing and sample samples obtained, if necessary, Notes or various specific problems, additionally as specifics of any deviation from the packaging directions, with the suitable person's written authorization, the range and reference variety or identity of all written packaging materials and bulk things that area unit issued, used,

destroyed or came back to stock and additionally the quantity of the merchandise learned ought to be properly reconciled.

Laboratory management records

Full information extracted from all experiments performed need to be encircled in laboratory management records to verify

Compliance with the needs and standards developed, additionally as examinations and tests, as defined, As follows:

A description of samples that area unit collected for testing, additionally because the name or offer of the content.

Batch number and/or supplier; various distinctive code, sample date taken and where, as an alternate. The quantity of the sample and additionally the date the sample was collected for testing were acceptable.

A declaration of or reference to any take a glance at methodology used.

A declaration of the load or live of the sample used as printed by the strategy for each test.

Data on or mention to reference specifications, reagents and reagents, preparation and testing commonplace alternatives.

A full record, to boot to tables, graphs and charts, of all information created throughout each take a glance at Laboratory instrumentation spectra, all properly printed to represent the relevant material checked and additionally the batch.

A record of all the test-related calculations, along side as associate example, units of units of

Measurement, conversion variables, and equivalence variables.

A declaration of the results of the analysis and therefore the method they compare with acceptance criteria.

The signature of the one that assigned each take a glance at and additionally the date(s) on it the tests were conducted.

A second person's date and signature, suggesting that the initial documents were checked for accuracy, completeness, and conformity with standards that area unit developed.

Complete records need to even be maintained for. Any modification to academic degree existing methodology of analysis. Periodic activity of laboratory materials, instruments, gauges, and recorder All stability tests assigned on APIs/formulations are Out of inquiries of parameters.

Full records of all laboratory reference analysis and standardisation need to be preserved.

Standards, reagents, and commonplace solutions; periodic activity of activity need to even be endured record.

Laboratory facilities, apparatus, gauges and recorder.

Batch production record review

For the analysis and approval of batch production and laboratory management documents, along side packaging and marking, written protocols need to be printed and followed to check compliance of the intermediate or API with established requirements before the batch is written or distributed.

For the analysis and approval of batch manufacturing and laboratory management documents, along side packaging and marking, written protocols need to be printed and followed to check compliance of the intermediate or API with established requirements before the batch is written or distributed. Before the batch is free, all deviation, inquiry, and OOS reports need to be reviewed as a neighborhood of the batch record analysis.

The quality unit(s) may delegate the responsibility and authority for cathartic intermediates to the assembly unit, with the exception of those shipped on the way aspect the management of the producing company.

The merchandise record need to be unbroken and may embrace the batch selection, the quantity created, the customer's name, address and speak to information, the quantity delivered and additionally the date of delivery.

Policy for implementation

The following 'documentation and records' approach is useful for pharmaceutical manufacturers to fulfil the strain of various restrictive agencies.

Write smart procedures and follow them

Think about what happens in associate extremely work if there are no written processes out there. therefore on inform them how to try and do stuff and then do their work from memory, people take into account further senior staff. this may be nice for a company producing garden pots, but not thus smart once prescribed drugs or the product being manufactured and may even cause death.

It is important that smart protocols are in place to verify a regulated and reliable output among the food, drug associate degree medical device industry; it's associate integral a neighborhood of GMP. Procedures need to be straightforward, succinct, and logical. consider hiring a competent technical author to do to to the task. They skills to jot well not like permanent employees, and may conduct usability testing to verify that the documents work. academic degree freelance party's review of procedures additionally can facilitate to strengthen the operation.

Before you start writing the tactic, outline the task. Build a quick breakdown of the relevant task-related steps and key points; a flow chart could also be a useful gizmo. Note that people sometimes do not scan procedures from begin to finish; they wish to hunt for keywords among the text. Break the processor into chunks to make it easier to digest and follow details, and use the following Headings Tables Bullet points Diagrams

One need to try to imagine the individual administrative body will follow the procedure once writing out any procedure. exploitation language which will be understood by the person. do not offer associate excessive quantity of detail, or deficient. Increase the instructions' readability by exploitation short sentences associated writing in an extremely conversational manner. Most organisations have a 3-year review quantity for his or her documents; however, this may be calculated on the concept of the possibility of improvement among the tactic thereto the document relates.

Following procedures

It's all fine to possess wonderful written protocols in place, but they need to be enforced to verify a managed and consistent performance; it's a GMP necessity. Sometimes, it cannot appear that the measures created public in associate extremely written procedure are the foremost victorious approach of operational. Taking shortcuts can save time or build the task easier, but whereas not the permission of a manager or the quality department, one need to never deviate from a written protocol.

For this there are two key reasons:

Many shortcuts can generate pitfalls which is able to ultimately be expensive. Each section has been encircled for a reason in associate extremely procedure

While it shouldn't be instantly obvious the principle of a specific move, it ought to area unit placed there as a check for an extra stage of the tactic. Improvement proposals ought to be welcome, but whereas not evaluating the impact on the complete technique, they're doing not alter procedures.

Keep smart records

Good records alter one to look at, from the receipt of raw materials to the last word unleash of the merchandise, all activities performed throughout batch manufacture; they provide a history of the batch and its delivery. Holding elaborate records could be a important a neighborhood of GMP, associate degree it helps to talk the message throughout associate audit that protocols are being followed. It to boot shows that the mechanisms underneath stood and are beneath regulation.

Remember

Immediately record all relevant details upon completion of a mission. Never trust the memory or write results on loose paper bits.

Write your name in ink legibly. Note that you {just} just are certifying that the record is true by linguistic communication documents that you've got completed the task as per the required procedure.

Draw one line between any errors and additionally the first and correction date. Have a corrective reason at the lowest of the page

When you deviate from the protocol, document information. Contact your boss or the department of quality for steering if there need to be a deviation.

Do not record the work of anyone else unless you are appointed to do to to thus or qualified.

Never presume that unsupported work has been done properly-if it isn't written down, then it isn't happened!

Documents/ SOPs required

To satisfy the preceding specifications, the following documents and procedures need to be prepared. The data created by these procedures need to be preserved therefore on demonstrate compliance with the needs listed more than.

To outline the quality commitments of the management, prepare apex documents like quality policy, quality manual, web site file, validation program, etc.

Defining the duties and obligations of all staff used among the corporate

Prepare policies for periodic document analysis. End, make certain that this industrial practises and assortment criteria ar complied with by this text versions

SOP for document preparation, analysis, acceptance, training, delivery, control, and retention (SOPs, MPCR, BPCR, validation/qualification protocol, formats).

Procedure for protecting the past of revisions

Management, pursuit and preservation of records old-hat or obsolete

Procedure for record installation and retrieval

Handling, archiving, storage and preservation of electronic documents/records

Procedure for electronic signature management Cleaning of buildings and hygiene procedures Issuance and management of logs for instrumentation

Report explaining the steps taken to prevent cross-contamination and records of their employment

Master plan of cleanup validation

Procedure for the cleanup and verification of batch-to-batch and product-to-product to verify the

elimination of previous batch/product residues.

Records for incoming raw materials and materials for packaging

SOP for technique validation protocol planning and reports

SOP for the preparation of btch documents for development and management

- SOP for batch selection allocation

Calibration program and reports for activity

- technique for batch unleash

SOP for QC info Sheet preparation and management

SOP for analytical management selection distribution

- Procedure for analytical info analysis

SOP for OOS outcomes inquiry

SOP need to be routed via impact analysis and alter management protocol for amendment management, revision of any technique or documentation, or upgrading of facility or instrumentation.

SOP for deviation method theme

- Corrective and preventive action SOP (CAPA)

- SOP for checking stability

SOP offered of product and its regulation

Document management

The Department of Interest initial prepares the paper whereas the Department reviews the draught and draught. the highest and Final Draft shall be submitted to the QA Department, that shall rework the draught into a final document reviewed and approved by the authorised person. management copies are given to the Department and records of provision are command once approval of documentation like Sops quality assurance, all users/concern department ought to be trained before finishing up the sops records of such work. {a work|a training} organiser is answerable for coordinating the coaching, ideally the highest of the user department or totally different appointed individuals. once victorious implementation of work on any SOPs, Initial Sops are sealed with loss as "MASTER COPY"; the master is kept beneath oversight and additionally the master photocopy is properly sealed in Blue as "CONTROL COPY". For provision records, Sops list got to be preserved, modification in Sops ought to be initiated to change request and each one issue copies got to be retrieved and new copies enforced with work.

Record management

The GDP procedure can define the forms of workbooks/notebooks which will be used-these are generally hard-covered with sown/sturdy binding; as pages are removed, avoid spiral bound workbooks or logbooks.

In academic degree emergency, if there isn't any official means out there to report academic degree observation, then:

1. Original, date and have a investigate the observation paper record and connect it as presently as accomplishable to the official hardcopy record.
2. Transcribe and transfer the most points and annotate 'transcribed, see connected original' to the official record. The transcription ought to be signed by the preparer and dated, and filed/stored beside the initial document.
3. the data ought to be reviewed by a second worker for accuracy.

4. Investigate why at the time a political candidate record wasn't out there. Implement corrective steps demonstrate that constant condition does not occur over again, e.g. manufacture a record kind, alter the procedure, modification the mechanism so as that the record is electronically recorded, etc.

Using true copies

1. usually a reproduction of an inspired document or record has to be used, E.G. Attaching a reproduction of a study to a record of non-conformance. it's clear, then that the record is not the original:

2. On the front of the derived documentation, stamp or write, 'Real Copy'.

3. Sign and date the modification to 'Real copy'. Modifying records in associate passing compliant Manner

How info or entries are additionally amended got to be stipulated inside the corporate GDP procedure. this might provide data on

1. E.G. 'Not Applicable'(NA Or N/A) Etc. was used for all commonplace abbreviations.

2. Unacceptable activities, E.G To imply constant entry as beyond, exploitation 'Ditto' Marks('), deed empty fields in associate passing type, etc.

3. UN agency is liable over time for reviewing record changes or general GMP

Compliance with record pages.

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II. CONCLUSION

Implementation of an honest Documentation observe for pharmaceutical merchandise can facilitate compliance with GMP and restrictive Bodies. The Goal of higher documentation and records is to stipulate the makers system of knowledge and management, to chop back the danger of interpretation and errors inherent in oral or nonchalantly written communications, to supply higher procedures to be followed to supply conformation of performance.

Pharmaceutical manufacture and regulation is clearly a world business with the increasing stress on Harmonization efforts and customary setting, what's a lot of as mutual recognition agreements, data of foreign laws and documentation and record laws is additionally a got to each for understanding the long approaches . it's once more stressed that documentation is additionally a major aspects of GMP and may enhance the visibility of the standard assurance perform.

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