SOP TITLE: **DOCUMENT AND DATA CONTROL MANAGEMENT**

1. **Objective:**

The objective of this document is to establish a standard procedure for document management and data control in order to ensure that all the GMP related documents are systematically reviewed, approved prior to issue, available at the appropriate locations, and changes to documents are authorized and recorded. Data is filled timely and correctly / accurately and reviewed before finalized.

1. **Scope:**

This Standard Operating Procedure (SOP) is applicable to all documents and data that will be prepared and generated at the formulation plant of PharmEvo (Pvt.) Ltd. All the changes of this version shall be applicable to all existing documents and data at the time of their review and revision.

1. **Reference:**
   1. WHO TRS-986, Annexure 2: Good Manufacturing Practices for Pharmaceutical Products.
   2. Pakistan Standard General Requirements for Halaal Health Care Products PS: 5442-2019
   3. Drug Act 1976, Schedule B-II, Section 10
   4. ISO-9001: 2015 (Quality Management System)
2. **Responsibility:**
   1. Manager QA (ISO/Halal/Doc.) is responsible to prepare, revise and follow the SOP.
   2. All HoDs shall be responsible to ensure the compliance of this SOP for maintaining control on all documents and documented data or records.
   3. Quality Assurance shall be responsible to maintain the documents as per this SOP and shall review the GMP documents for compliance with the relevant documentation procedures.
   4. QA Head or designee shall be responsible for compliance of this SOP.
   5. QA Department is responsible for controlling of this SOP.
3. **Definitions:** 
   1. SOP - Standard Operating Procedure
   2. SMF - Site Master File
   3. VMP - Validation Master Plan
   4. Master Copy - The Original Approved copy of Document
   5. Controlled Copy - Photocopy of Master Copy that retrievable when supersedes
   6. Un-Controlled Copy - Photocopy of Master Copy and no retrieval is required
   7. Obsolete Copy - Master Copy that is no longer in use or superseded by newer

Version

1. **Materials & Equipment:**

N/A

1. **Precautions:**

N/A

1. **Procedure:**
   1. All documents prepared shall be identified and traced by a unique document number.
   2. Any allotted document number must not be allotted to any other document.
   3. Issued approved documents may be corrected manually by Head of QA with a pen and sign for minor corrections, (only if the correction is formed by virtue of any grammatical / typographical / spelled error); and correction shall be carried out in the next revision.
   4. No hand written documents shall be considered as master document.
   5. All master copies shall be kept in Quality Assurance Department.
   6. **Generation of Documents:** 
      1. All the documents shall be prepared or generated as per their respective SOP.
   7. **Master Copies of documents:**
      1. Master copy shall be an approved original copy of the documents and shall be prepared by stamping “MASTER COPY” with stamp in “Red Color” on each page of the documents at left side upper corner position without obscuring any text.
      2. Master copy shall be kept in the custody of QA under the supervision of authorized person of QA.
      3. No department is allowed to keep the master copy of any document except QA Department.
   8. **Controlled copies of Documents:**
      1. Controlled copy shall be prepared by photocopy of master copy with stamping of “CONTROLLED COPY” stamp in “Blue Color” along-right-side of “Master Copy”.
      2. QA Documentation shall assign & write copy number with sign initial on each page of the document as per distribution list.
      3. Ensure the retrieval of all obsolete controlled copies of documents before distributing of newer version of document.
      4. Log the activity in “Document Distribution & Retrieval form” (Document No.QAG/5/002)
   9. **Un-controlled copies of Documents:**
      1. Un-controlled copy shall be prepared by photocopy of master copy with stamping of “Un-CONTROLLED COPY” stamp in “Green Color”.
      2. Uncontrolled copy of any document may also be prepared by scanning and inserting uncontrolled stamp in watermark in PDF which can be shared via email as soft copy to avoid taking print outs.
      3. Un-controlled copy may be issued on need as a reference copy for internal / external audits, external regulators and concerns.
      4. No record shall be maintained for issuance & retrieval of uncontrolled copy.
   10. **Obsolete copies of Documents:**
       1. All obsolete Master copy of documents will be stamped with “OBSOLETE COPY” in RED INK at any suitable place and retained for as per their retention period.
       2. All obsolete controlled copies of documents will be retrieved before distributing copy of newer version. All obsolete controlled copies shall be destroyed.
   11. **Level & Code of Documents:**

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| --- | --- | --- |
| **Level** | **Code** | **Type of Document** |
| I | 1 | Policies and Manuals |
| II | 2 | SOP |
| III | 3 | Layouts, Plans and Lists |
| 4 | Site Master File |
| 5 | Formats, Forms, Logbooks, protocols. |

* 1. **Issuance & Control of Documents:**
     1. All documents shall be issued and controlled by QA Department. The custodian of Master Copy of any document shall be the QA Department.
     2. All rubber stamps shall be kept under lock and key.
     3. Issuance of formats and BDRs/BMRs/BPRs/BYSs shall be described in their respective SOP (SOP Doc # QAD/2/0023).
  2. **Review and Revision of Documents:**
     1. All the controlled documents shall be reviewed within one month after “review date” assigned on the concern document.
     2. Any document can be reviewed and revised as and when required however during its review process the older version of said document shall be considered as valid.
     3. Change in existing document or new document shall be reviewed and approved by QA Head or designee who will assess the nature of new and proposed change in the document.
     4. During assessment, if identified change is observed to impact cGMP activity or equipment, it shall be initiated by “Change Management”. (Document No.: QAG/2/033)
     5. QA Head shall intimate to the concerned department for initiating the “Change Management” procedure.
     6. During review, if identified changes do not impact cGMP activity or equipment, then QA Head shall forward the document onward for its approval to the competent authorities.
  3. **Distribution & Retrieval of Documents:**
     1. All the controlled documents shall be distributed and retrieved by QA Documentation.
     2. Distribution and retrieval of the document shall be done by using the form “Document Distribution and Retrieval Record” (Document No.QAG/5/002).
     3. Additional controlled copies of the documents, if required, shall be requested through a form titled “Requisition for Additional copy”. (Document No.: QAG/5/103)
     4. QA shall issue additional controlled copy only after receiving / checking the completed form.
     5. The retrieved controlled copies of the document shall be destroyed by QA Documentation.
  4. **Retention of documents:**
     1. Records, superseded documents shall be preserved and retained for the period as described below:

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| --- | --- | --- | --- | --- |
| **S. No.** | **Type of Document Retention Period** | **Retention Period** | **Method of Destruction** | **Reference / Justification** |
| 01. | Organograms, quality manual, site master file, Laboratory information file / SOPs / JDs/ Policies / Artworks | Last one obsolete version | Shredded in tiny pieces | In-house – revisions are in place with document history |
| 02 | Vendor audit reports and quality agreement |
| 03 | Routine personal medical record |
| 04 | Pharmaceutical waste management record | Two years | Shredded in tiny pieces |
| 05 | Internal audit records | Three years | Shredded in tiny pieces |
| 06 | Management Revie Meeting (agenda and minutes) |
| 07 | Cleaning and utilization logs of instruments, equipment / machines and facility | Six Years | Shredded in tiny pieces | EU GMP, Chapter 04, Volume 04 (Clause 4.12) and ICH Q7 (GMP Guide) |
| 08 | Monitoring records (Environment, pH, Temperature) |
| 09 | Log book (Sampling logbook, Document number assigning logbooks, documents issuance and distribution log books etc) |
| 10 | Master batch documents (BDR, BMR, BPR) / Testing methods and specifications / Facility layouts | Ten Years | Shredded in tiny pieces |
| 11 | Change Control Records |
| 12 | Deviation record |
| 13 | OOS/OOT records |
| 14 | Complaint records |
| 15 | Training records |
| 16 | Calibration records |
| 17 | Lists/plans/schedules |
| 18 | Batch Records (BDR, BMR, BPR)/Laboratory record/Post marketing stability reports/APR reports/Warrantor samples and their correspondence | Expiry plus one year | Incinerated through outsource vendor |
| 19 | Regulatory inspection records/Layouts approved from regulatory/Drug manufacturing license/Wholesale license and registration record | Life time | Not applicable | In-house |
| 20 | Personal Qualification Record |
| 21 | Maintenance record (Utilities, QC instruments, Production equipment/machine and facility) |
| 22 | Product Development record | Throughout product life cycle | Not applicable | In-house |
| 23 | Qualification / initial validation records |
| 24 | Stability Records (Premarketing/commitment batches) |

Note: The retention period shall start after superseded of documents.

* 1. **Controlling of Layouts, Plans, Lists, Policies and Manuals:**
     1. **Layouts**
        1. All layouts / drawings of facilities, areas, utilities, or any other GMP related activities shall be controlled through QA.
        2. Concerned department shall submit the required number of copies of the layouts according to the distribution list. One copy shall be marked as master copy containing Red Color stamp while rest of the copies shall contain the Blue Color stamp of controlled copy.
        3. Concerned department shall be responsible to submit the current and updated version of layouts in QA alongwith signatures of Prepared By, Reviewed By and Approved by. The controlled layouts shall remain valid until its newer version is submitted in QA. These can be reviewed and updapted as and when required, hence, no next review date shall be assigned to the layouts.
        4. All layouts shall be reviewed by relevant HoD and approved by QA Head or Quality Head. All copies of the layout shall be signed and dated manually.
        5. QA Documentation shall control the submitted layout as per aforementioned defined procedure and past the label title “Layouts Controlling Label” (QAG/5/281) on the back of the master copy and distribution copies of the layout.
     2. **Plans & Lists**
        1. All GMP related lists and plans shall be controlled through QA. Responsible departments shall prepare the plan or list on prescribed format namely “Format for Plans / Lists” (Doc # QAG/5/283) and submit in QA after approval signatures.
        2. Concerned department shall ensure that the blank format of list/plan is controlled through the relevant SOP, however, their versions will be maintained independently.
        3. QA Documentation shall control the submitted list / plan as per aforementioned defined procedure and distribute as per the list of distribution.
     3. **Policies**
        1. All departmental and other policies shall be controlled through QA. Concerned department shall prepare the policies on prescribed format namely “Departmental Policy” (Doc # QAG/5/015) and submit in QA after approval signatures for control and distribution.
     4. **Manuals**
        1. All manuals e.g. Quality Manual, Halaal Manual shall be controlled through QA. Responsible departments shall prepare the manual on prescribed format namely “Format for Manuals” (Doc # QAG/5/282) and submit in QA after approval signatures.
     5. **Header:**

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| --- | --- | --- |
|  | **Title** | Title of the document. Font type “Normal Text” |
|  | **Document No.** | As per master document list, Font type “Normal Text”. |
|  | **Version No.** | Consists of 02 numerical character which starts from “00” with increment of 1 on each version. “00” indicates the first version of the document. |
|  | **Page No.** | Page X of Y |
|  | **Issue Date** | It is the date from which the document shall be prepared. The date format will be DD-MM-YYYY, where DD indicates the date, MM indicates the month & YYYY indicates the year (e.g. 01-01-2024). Date shall be stamped / hand-written. |
|  | **Effective Date** | It is the date from which the document shall be approved (e.g. 01-01-2024). |
|  | **Next Review Date** | It is the date on which the document shall be reviewed according to the document requirements. |

* + 1. **Bottom:**
       1. All plans, lists, policies and manuals shall have the distribution list and document history at the end of document as per following form:

**Distribution List:**

**Document History:**

* + 1. **Footer of the document:** 
       1. Mention version number of the document at the right alignment.
       2. Provide top border line of the text of footer.
  1. **Numbering System (Layout/Plan/List/Policies/Manual):**
     1. Each document shall have a unique numbering system. Once a number is allocated to a document, the same number shall not be repeated to other document.
     2. Each Document No. consists on nine (09) alphanumeric characters (i.e. XXX/9/999). For example, first plan prepares for APQR in QA shall be numbered as QAI/3/001.
     3. First three characters indicate department & section. (i.e. QA which shows Quality Assurance and “I” shows In-Process Control Section).
     4. Fifth character indicate level of the document. (i.e. 3 indicates the document is either layout, plan or list).
     5. Last three numeric characters indicate serial number of particular document.
     6. For departmental codes and section / functional codes, vide para 8.2.6.7 and 8.2.6.8 of SOP for “preparation, review and retrieval of SOP”, Doc. No. QAG/2/056.
  2. **Handling of documents:**
     1. QA shall maintain the “Master List of SOPs” (Doc # QAG/5/004)
     2. QA shall maintain the “Master List of Formats” (Doc # QAG/5/273).
     3. QA shall maintain the “Master List of Job Descriptions” (Doc # QAG/5/274).
     4. QA shall maintain the “Master List of Organograms” (Doc # QAG/5/275).
     5. QA shall maintain the “Master List of Layouts/Plans/Lists” (Doc # QAG/5/276).
     6. QA shall maintain the “Master List of Policies and Manuals” (Doc # QAG/5/277).
     7. QA shall maintain the above master lists through QA Doc. Portal according to the specimen formats are attached with this SOP.
  3. **Destruction of Documents and Records:**
     1. QA Documentation shall destroy the records by using paper shredder machine or manually or through incineration and the relevant recording shall be done on the form “Document Distribution and Retrieval Record” (Document No.QAG/5/002).
     2. After completion of retention period “OBSOLETE MASTER COPY” shall be destroyed by QA Documentation using paper shredder machine or manually or through incineration.
     3. QA Documentation shall record the details of destruction of obsolete master copies / documents in “Document Destruction Records” (Document No.QAG/5/106).

1. **Training:**

Training will be provided to concern personnel prior to implementation of SOP and will be recorded on Document No. QAG/5/142.

1. **Attachment:**
   1. Controlled Document Distribution & Retrieval form - QAG/5/002
   2. Master List of SOPs - QAG/5/004
   3. Departmental Policy – Format - QAG/5/015
   4. Requisition for Additional Copy - QAG/5/103
   5. Document Destruction Records - QAG/5/106
   6. Master List of Formats - QAG/5/273
   7. Master List of Job Descriptions - QAG/5/274
   8. Master List of Organograms - QAG/5/275
   9. Master List of Layouts / Plans / Lists - QAG/5/276
   10. Master List of Policies and Manuals - QAG/5/277
   11. Layouts Controlling Label - QAG/5/281
   12. Format for Manuals - QAG/5/282
   13. Format for Plans / Lists - QAG/5/283
2. **Distribution List:**
3. **Document History:**