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1 Approvals

1.1 Author

Brandon Patterson	Sr. Process Engineer		
Printed Name	Title	Signature	Date


1.2 Approver

N/A	N/A	N/A	N/A
Printed Name	Title	Signature	Date

1.3 Quality Approver

Justin Pawlik	VP Midwest Operations		
Printed Name	Title	Signature	Date

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2 Version History

Version	Changes
1	New Document
2	Rewrite

3 Purpose

This Standard Operating Procedure (SOP) describes the processes and documentation procedures that establish a document control system compliant with current Good Manufacturing Procedures (cGMPs).

4 Scope

4.1 This procedure applies to all GMP activities and associated documentation at GMPPENS.

5 Responsibilities

5.1 It is the responsibility of the Quality Assurance group to:

5.1.1 Ensure that this SOP complies with all standards of record-keeping and all associated activities

5.1.2 Review all GMP documents to ensure they are consistent with this procedure.

5.1.3 Review and update this procedure as necessary.

5.2 It is the responsibility of all employees and contractors involved in GMP documentation to follow the procedures outlined in this SOP.


6 Definitions (Abbreviations)

6.1 GMP - Good Manufacturing Practices

6.2 QA - Quality Assurance

6.3 SOP - Standard Operating Procedure

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7 Referenced Documents

7.1 SOP-001-FORM-01: Master Signature Log

7.2 SOP-001-FORM-02: Master Document List

8 Procedure

8.1 All GMP documents will be assigned a unique identification number.

8.2 All GMP documents will be subject to revision control.

8.3 All GMP documents must be approved prior to becoming effective.

8.3.1 The minimum required approvers are:

8.3.1.1 Document author

8.3.1.2 Quality Assurance

8.3.2 Quality Assurance is responsible for identifying any other approvals that are necessary.

8.3.3 Quality Assurance must sign after all other approvers.

8.3.4 Signatures will be captured in approval blocks on the front page of GMP documents.

8.3.5 Approvals will include the name of the approver, the capacity in which they are approving the document, signature, and date.


8.3.6 The approval block is a permanent part of the record and must be kept on file, but printed versions of approved documents do not need to display the signatures; they can refer to the master file of the document.

8.4 The following steps are performed to prepare the document for approvals

8.4.1 Effective dates are assigned and typed onto the Word document.

8.4.1.1 In the event that approval is not achieved before the effective date, the document must be re-approved because the change of effective date is considered a material and significant change to the document that has been approved.

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8.4.2 The Word document is converted to PDF.

8.4.3 The PDF is printed.

8.4.4 The document is routed for approval signatures.

8.5 The following document types are used by GMPPENS.com:

8.5.1 Standard Operating Procedures – these are defined procedures or series of actions that are involved in GMP activities. All SOPs will be assigned a document number beginning with “SOP-“

8.5.2 Forms – these are working documents that capture information as required by another document such as an SOP. They are an attachment to that document, but may be printed and used separately from the document. Forms will be assigned a unique document number that begins with the number of the document to which they are attached, followed by “-FORM-“ and a unique number.

For example, forms attached to SOP-001 would be numbered “SOP-001-FORM-01,” “SOP-001-FORM-02,” etc.

8.5.2.1 Forms may be bound into logbooks. The logbook is treated as a single working document.

8.5.2.2 All pages of a logbook must be marked with “Page X of Y.”

8.5.2.3 The cover of the logbook must be labeled with the title of the form, the number of the form, and the date the logbook was created.

8.5.2.4 When a logbook is retired, the end date of that logbook must be recorded on the front of the logbook.

8.5.2.5 Retired logbooks must be stored in a secure location.


8.5.2.6 Forms must be reviewed by Quality Assurance when they are filled up.

8.6 Document Master File

8.6.1 A master file for each document must be created and stored in a secure location.

8.6.2 The master file must include the approved version and original signatures for all revisions of that document.

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8.7 Document Master List

8.7.1 SOP-001-FORM-02 must contain a master list of all approved documents, including the document numbers and revision numbers.


8.7.2 SOP-001-FORM-02 shall be maintained by the Quality Assurance department.


8.8 Electronic Documents


8.8.1 Electronic copies of documents may be uploaded to the GMPPENS KymaPRO website.


8.8.2 There shall be a separate placeholder for each document number.

8.8.3 The placeholders shall contain the following files.

8.8.3.1 PDF of the approved version with an “Approved Version” watermark to distinguish it from any superseded or unofficial versions of the document. The PDF shall be identified with the formally approved status icon .

8.8.3.2 Word document of the approved version. The Word document shall be identified with the approved status icon .


8.8.3.3 Word documents of the superceded versions. These Word documents shall be identified with the superceded status icon .


8.8.3.4 Word documents of draft versions. These Word documents shall be identified with the draft status icon .

8.8.4 When a new revision of a document is approved, or when a document is retired:


8.8.4.1 Retain the Word documents for all previous versions.



8.8.4.2 Delete the PDF document for the “Approved Version” of the previous version.

8.8.4.3 Change the status of the Word documents of the previous “Approved Version” to the superceded icon .

8.8.4.4 Upload the Word documents of the new approved version and change the status to the approved icon .

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- 8.8.4.5 Create the “Approved Version” PDF by converting the approved Word documents to PDF. Add the “Approved Version” watermark in red to the PDF.
- 8.8.4.6 Upload the “Approved Version” PDF documents and change the status to the formally approved icon .
- 8.8.4.7 Optional – All previous versions and drafts may be archived.
- 8.8.5 Drafts of the documents may be created by copying the approved Word documents.
 - 8.8.5.1 The file names shall include “draft”.
 - 8.8.5.2 Draft versions may be used to incorporate proposed changes to the document.
 - 8.8.5.3 The draft copies must not be used for GMP activities.
 - 8.8.5.4 If draft copies are uploaded to the GMPPENS KymaPRO website the status icon shall be changed to the draft icon .
- 8.9 Working Copies of documents shall be created by photocopying the original signed document or by printing the “Approved Version” PDF.
- 8.10 Records Retention
 - 8.10.1 All working documents shall be retained for a minimum of seven (7) years from the date they were completed.
 - 8.10.2 All working documents must be reviewed by Quality Assurance for completeness and compliance.
 - 8.10.3 All approved documents must be stored in a secure location.
- 8.11 A Master Signature Log shall be maintained on form SOP-001-FORM-01. This log shall ensure traceability of all initials and signatures on GMP documents.
 - 8.11.1 Any signatory who has not filled out this form shall print their name and signature on each document they sign.

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