Standard Operating Procedure (SOP)

Final Approval and Product Release Documentation

This SOP details the process for **final approval and product release documentation**, encompassing the review and verification of product quality, compliance with regulatory standards, approval workflows, documentation accuracy, and authorization protocols. The objective is to ensure that all products meet established specifications and quality criteria before being officially released for distribution, maintaining product integrity and regulatory compliance.

Document #	[Insert Number]	**Effective Date**	[Insert Date]
Revision #	[Insert Revision]	**Prepared by**	[Name & Title]
Reviewed by	[Name & Title]	**Approved by**	[Name & Title]

1. Purpose

To define the procedure for the final review, approval, and release of products, ensuring all quality and regulatory requirements are satisfied prior to distribution.

2. Scope

This SOP applies to all finished products manufactured and/or packaged at [Company Name] prior to release for sale or distribution.

3. Responsibilities

- **Quality Assurance (QA):** Coordinates the review and release process, reviews documentation, and authorizes product release.
- **Quality Control (QC):** Provides necessary test data and verification reports.
- **Production:** Prepares product and associated documentation for final review.
- **Regulatory Affairs:** Ensures compliance with applicable regulations.
- **Authorized Approver:** Signs off on the final product release documentation.

4. Procedure

1. **Completion of Manufacturing/Packaging:** Production complete; compile batch records and label samples.
2. **Review of Batch Documentation:**
    - QA reviews completed batch records and supporting documentation (e.g., test results, deviations, investigations).
    - QC ensures all testing and analytical requirements are met; results are documented and compliant.
3. **Verification of Regulatory Compliance:**
    - Regulatory Affairs verifies product conforms to relevant standards and market-specific regulations.
4. **Quality Review & Authorization:**
    - QA Lead performs final quality review checklist.
    - If all criteria are met, QA completes and signs the Product Release Authorization form.
    - Any non-conformances are logged and investigated prior to release.
5. **Final Approval:**
    - Authorized Approver (per signature matrix) reviews documentation and provides final sign-off for product release.
6. **Product Release:**
    - Upon authorization, QA notifies Warehouse/Logistics for product distribution.
    - All release documentation is archived according to document control procedures.

5. Documentation

- Batch Production Records (BPR)
- Certificate of Analysis (CoA)

- Deviation and Investigation Reports (if applicable)
- Product Release Authorization Form
- QA Release Checklist
- Regulatory Compliance Certificates

6. References

- Good Manufacturing Practices (GMP) Guidelines
- [Applicable Regulatory Standards & Guidelines]
- Document Control SOP

7. Revision History

Version	Date	Description of Change	Changed By
1.0	[Insert Date]	Initial SOP release	[Name]