RxLogix Corporation SOP

SOP Management

Effective Date:	06-Oct-2020
Document Number:	SOP-000
Version:	7.0

RxLogix

Revision History

Version	Author	Date	Description of Change
1.0	Mike Roberts	17-Jul-2015	Initial document
2.0	Linda D. Mier	26-Aug-2016	Revised the SOP as follows: • Added Superseded to the header • Updated the signature page • Added an additional paragraph to Purpose • Updated Scope to identify personnel to follow this SOP • Added section 4.3 Roles & Responsibilities • Revised SOP Policy • Eliminated the requirement for hardcopy SOP maintenance in SOP Storage and Control • Changed Director of QA to a QA representative throughout • Specified that QA approves SOPs in SOP Review & Approval Process Added clarifications to Periodic Maintenance and expanded the periodic review period from 1 to 3 years.
3.0	Linda D. Mier	28-Dec-2016	Revised the SOP as follows: • Replaced Acronyms table with reference to GDL-001 *Glossary.* • Updated References. • Revised Status of Obsolete SOPs from “Superseded/Obsolete” to “Obsolete”. • Renamed “Superseded/Obsolete” folder o “Superseded and Obsolete” throughout. • Added sections on SOP deviations. • Split out separate sections for Training, Review and Approval • Reordered some sections • Some grammar corrections. Spelled out some acronyms the first time used.
4.0	Mustafa Abdallah	07-Jul-2017	Revised the SOP as follows:

			• Reformatted SOP numbering • Changed periodic review of SOPs from annually to every two years. • Changed SOP-001 to QM-001 to Reference table • Added SOPs must be trained on in accordance of role-based training plan to the policy statement Added SOPs hard copies to be stored in fire-proof cabinet
5.0	Vaibhav Misra	17-Mar-2019	Revised guidelines for periodic review and update of SOPs (Ref: Section *Periodic Maintenance*) to facilitate Impact driven periodic review timeframe
6.0	Jayashree P K Acharya	14-Apr-2020	Revised SOP to align with ZenQMS module. Updated SOP to address external audit findings
7.0	Srividhya Sivakumar	22-Sep-2020	Updated for minor changes and ported the document to recent SOP template

Table of Contents

1.0 PURPOSE

The purpose of this SOP is to describe the process for authoring and managing RxLogix Quality Management System (QMS).

The purpose of defining a QMS within RxLogix is to enable a systematic way of working and ensure consistency is established. This SOP describes a systematic approach towards:

- Plan and implement RxLogix Process improvements
- Establish and maintain a set of RxLogix process assets
- Definition, review and approval of QMS artifacts
- Institutionalization of the QMS

2.0 SCOPE

This SOP covers the authoring and management of QMS within RxLogix. The scope of the QMS shall include all aspects of Product development and Services provided by RxLogix to drive business efficiencies and customer satisfaction.

ZenQMS is an electronic QMS (eQMS) implemented at RxLogix. This tool supports overall Document Management, review, approval and roll out of QMS. These are introduced as validated workflows within the eQMS management system.

All latest copies of the QMS is maintained in ZenQMS and is subjected to access control by the Quality Team.

Director-Quality is responsible for overall QMS management. The QMS of RxLogix shall be classified as Internal Use only and strictly proprietary of RxLogix.

3.0 GENERAL

3.1 Definitions

See GDL-001 *Glossary* for the definitions of terms and abbreviations.

SOP-specific terms and abbreviations are defined in the table below.

Term / Abbreviation	Definition
eQMS	Electronic Quality Management System
Draft SOP	A Draft SOP is a 'work in progress' version of a new SOP or an update to an existing SOP.
Approved SOP	An approved version of the SOP which shall be rolled out shortly
Effective SOP	An Effective SOP is the currently applicable version.

Term / Abbreviation	Definition
Obsolete SOP	An Obsolete SOP is an SOP that is either replaced by different SOPs or is no longer relevant to RxLogix business practices. Obsolete SOPs are removed from the set of effective SOPs and may be replaced by a new version.
Approval Date	Date on which the version of the SOP was signed by the last signatory in the approval workflow
Effective Date	Date on which the version of the SOP becomes effective with the stated requirements.

3.2 References

Document ID	Document Title
GDL-001	Glossary
QM-001	Quality Manual
RxL-TMP-SOP-001	SOP template
SOP-002	Internal and External Audits
SOP-003	Corrective and Preventive Action (CAPA)
SOP-014	Training
SOP-022	Document Management Plan
SOP-032	Record Retention
WI-006	Approving SDLC documents in ZenQMS

3.3 Roles and Responsibilities

Role	Responsibilities
Process SME	• RxLogix staff designated to scribe or modify the QMS artifact such as SOP, Policy , Template , Work Instruction etc • Is a SME in the said Process area virtue of corporate experience or academics • Accountable for writing or updating various Process Areas. • Should be experienced in the subject and/or have taken training to ensure relevance, usability and integrity of the procedure. • When needed support in trainings with respect to the Process Area and represent RxLogix in front of Customers • Provide process consultancy and support process roll outs • Ensure compliance to QMS documentation standards
Function Head	• Reviews the SOP for technical accuracy and completeness and approves it for implementation. • Provide Process consultation and suggest improvements • Approve changing the status of an SOP to Obsolete.
Quality Assurance (QA)	• QA must approve each SOP prior to release for adequacy, completeness, and compliance requirements. • QA approves changing the status of an SOP to Obsolete. • Overall Access authorization to ZenQMS • Perform periodic user access management reviews for ZenQMS

4.0 Policy

- RxLogix shall maintain a QMS covering all aspects of Product development and Services provided by organization to drive business efficiencies and customer satisfaction.
- Only latest copies of the QMS shall be made available for use.
- All employees shall be trained on the latest version of QMS before they are made effective.
- Trainings shall be rolled out in accordance with the Training Competency matrix.
- The QMS shall be reviewed periodically for adequacy once every 2 years.
- External parties – such as Customers and Regulatory Agencies – may be granted access to view selected SOPs on request, at the discretion of RxLogix management.

5.0 Procedure

5.1 Triggers to QMS changes

The following may be inputs to creation or modification of RxLogix QMS artifacts:

- Internal Continual Improvement initiatives
- Internal Audits
- External Audits
- Root cause Analysis outcomes
- Suggestion from RxLogix staff
- Alignment to industry standards
- Management directions
- Periodic reviews

5.2 SOP Creation Procedure

Based on the above inputs, if a gap is identified in QMS, the Quality Team shall work with the appropriate Function Head. The Function Head shall nominate a Subject Matter Expert from his/her team.

1. SOP Scope definition:
    a. The Head of the relevant business unit(s) and QA shall agree upon the scope and intention of the new SOP.
    b. During this phase, the proposed SOP ID shall be generated, and the electronic SOP Master List shall be updated to include a 'placeholder' for the new SOP.
        i. See SOP-022 *Document Management Plan* for the conventions to use for SOP document IDs.
2. SOP Draft:
    a. The SME shall author a draft SOP with the assistance of QA based on input from the business unit(s) using SOP Template RxL-TMP-SOP-001.
    b. The draft SOP shall be uploaded for review.
    c. The draft SOP shall contain a proposed Effective Date for the new SOP.
3. SOP Review & Approval:
    a. The SOP shall be reviewed and approved as described in section 5.5 SOP Review & Approval Process.
4. SOP Training:
    a. See section 5.6 SOP Training for information about the training for the new SOP.
5. SOP Becomes Effective:
    a. The SOP becomes effective on the specified Effective date.
    b. The draft SOP workflow up till becoming effective is entirely managed in ZenQMS
    c. The SOP Master List is updated

5.3 SOP Revision Procedure

The following procedure is used to update an SOP:

1. SOP Change scope definition.
    a. Based on the identified change, the Quality Team and the Function Head come together and perform an impact assessment
    b. As part of this assessment, the outcomes could be – agreement to change, assess the details of change, identify SME to update the change, associated QMS artifacts, training needs and roll out steps.
    c. The Function Head and QA shall agree on the scope and intent of the change.

2. SOP Draft:
    a. The QA team or SME shall be using the SOP to create a new version of the SOP, with status of Draft, based on input from the business unit(s).
        i. The draft SOP shall be in accordance with SOP Template RxL-TMP-SOP-001.
    b. The draft SOP shall be uploaded with changes and routed for review.
    c. Reviewers would typically include practice teams' representatives as nominated by the Director-Quality or Function Head.
    d. The draft SOP shall contain a proposed Effective date for the new version of the SOP.

3. SOP Review & Approval:
    a. The new SOP version shall be reviewed and approved as described in section 5.5 SOP Review & Approval Process.
4. SOP Training:
    a. See section 5.6 SOP Training for information about the training for the new SOP version.
5. SOP becomes Effective:
    a. The new SOP version becomes effective on the specified Effective date.
    b. QA shall ensure changes to the update are in alignment with the company standards for documentation
    c. At this point the following updates are made:
        i. The version of the SOP being superseded is chosen to be retired in ZenQMS
        ii. New workflow is launched identifying the Reviewer and Approvers to e-sign the document
        iii. The new version of the SOP is then treated as effective post training on the set Effective date
        Note: QA Team to ensure the date between Approved version to Effective version is a minimum of two weeks. This window of two weeks provides team members to acclimatize with the changes and get back to QA team if there are any clarifications.
        iv. The SOP Master list is updated with information about the new version of the SOP.

5.4 Process for Obsolete QMS artifacts

Over time few of the QMS artifacts may become outdated, either because of the objective being clarified, or defined in other artifacts of newer business drives etc.

In such an instance the Director Quality shall discuss with the designated Function Heads of the process and term such artifacts as OBSOLETE. QMS Artifacts shall be marked OBSOLETE in ZenQMS and archived.

Note: Virtue of revisions to SOPs, the earlier versions of the SOP will be deemed consider as superseded and shall not follow the above steps.

5.5 SOP Review & Approval Process

The following process shall be used to review new SOPs and updates to existing SOPs:

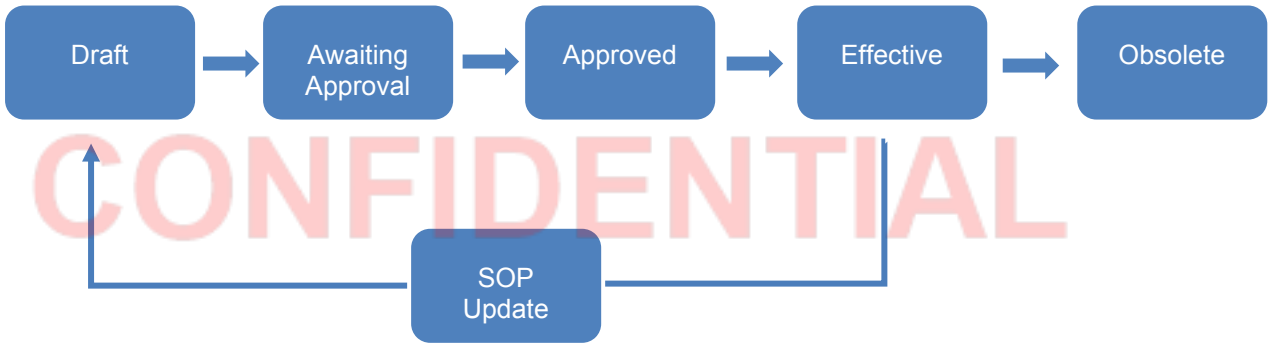
1. The appropriate SME(s) from the relevant functions and QA will review the draft SOP and submit comments (if any) to the author.
2. Comments shall be reviewed, discussed with the SME(s) and QA, and incorporated as deemed.
3. Approval workflow shall already be pre-defined in ZenQMS based on category selection.
4. The approvers shall receive the notification in ZenQMS under dashboard, if any procedure has been assigned to them for sign off.

5.6 SOP Training

1. The Function Head and QA must agree on the level of training required and the training audience for the new SOP. This could be a classroom session, On Job Training or by self-reading through the SOP changes.
2. Will also identify any new Teams that may need to be trained if deemed felt applicable.
3. The applicable training shall be developed and delivered as per SOP-014 *Training*.
4. The Function Head and QA are responsible for ensuring that the SOP training is delivered to relevant personnel per the training plan prior to its effective date.
5. Any new SOP that is introduced in the QMS, will be subjected to mandatory assessment prior to being effective.

5.7 SOP Review and Approval Workflow

1. An SOP can have one of the following states:
    a. Draft
    b. Awaiting Approval
    c. Approved
    d. Effective
    e. Superseded
    f. Obsolete



5.8 Deviations from SOPs

Deviations from an SOP may be planned in advance or unplanned.

5.8.1 Planned Deviations or Approved Process Tailoring

The Project Manager proposes the Planned Process Deviation in advance by writing an email to the QA Team and Function Head. The request shall also include the justification to either tailor or deviate from the process and if there are any other alternate process adoptions, such as Customer QMS or templates etc.

The QA Team and the Function Head shall discuss and may either approve or disapprove the proposed deviations. All such deviations shall be documented in the Validation Test Summary Report.

Prior to implement the approved deviation, the associated Project Manager shall raise a Memo and document the description of the deviation and the rationale. This approved memo will have a unique ID. The QA team shall maintain a list of all such Memos.

5.8.2 Unplanned Deviations

Unplanned deviations could be either disclosed by the team, identified during Root Cause Analysis, Internal Reviews or Internal Audits. They are treated and termed as Non-Conformances

For unplanned deviations with a significant impact and identified as Critical, a Corrective and Preventive Action (CAPA) shall be opened and managed in accordance with SOP-003 Corrective and Preventive Action (CAPA).

5.8.3 SOP Deviations and Updates in Exceptional Situations

In an exceptional case where a large number of SOPs need to be updated at the same time (e.g. triggered by a major company reorganization, major change to a business process or an external/internal audit finding) a staggered update process or remediation plan may be followed by prioritizing the SOP updates to ensure that the most critical SOPs are updated first and that high priority processes are in compliance with the SOPs at the time of the change.

When an exceptional case occurs, QA shall discuss the necessary SOP changes with the Function Heads and prepare a summary SOP update plan outlining the update priorities to present to management and the business area heads.

6.0 Templates

Below listed controlled templates shall be utilized with respect to this SOP:

Template ID	Template Name
RxL-TMP-SOP-001	SOP Template
RxL- TMP-GDL-001	Guideline Template
RxL-TMP-WI-001	Work Instruction Template
RxL-TMP-MEM-001	Memo Template
RxL-TMP-MEM-002	Memo Tracker

7.0 Annexure A

Prior to rolling out a QMS artifact on ZenQMS, the Author(s) shall ensure the following criteria are met and verify the same before hosting as part of the QMS

1) Author to ensure that all changes have been accepted in the document.
2) There shall be no open comments or highlighted texts.
3) To ensure that effective date is updated as per criticality of the document. As per SOP-014 - Training: Section 4.3, generally, 15 calendar days shall be provided to the employees for getting trained on new/revised RxLogix procedures. However, this timeline could be reduced or relaxed, depending on the criticality and the targeted Effective date for the QMS artifact.
4) The date in revision history is updated to current date of hosting in ZenQMS
5) The document status in Header of the document is updated to “Effective” and the same status is reflected across all pages.
6) The font size and number shall be Arial , 10 inside all the sections of the document.
7) The table of contents shall be updated before hosting in ZenQMS and there are no page number issues
8) Details like Title, Effective date and page number are the same across all pages of the document
9) Ensure page numbering sequence is appropriate and is reflected correctly in the headers of all pages

REVISION HISTORY

Version 05 Effective on 08-Apr-2019
None

Version 06 Effective on 28-Apr-2020
Periodic update and inclusion of Zen QMS

Version 07 Effective on 06-Oct-2020
v7.0

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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Required Workflow Steps for this Category

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