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1. Purpose

This procedure is to define the process for identifying, delivering, and documenting training required to ensure the competency of personnel performing tasks within the [Company] Quality Management System (QMS). This includes training necessary to meet applicable regulatory requirements, ensures compliance, and to maintain the effectiveness of the QMS.

2. Scope

This procedure applies to all personnel involved in activities governed by the [Company] QMS, including but not limited to distribution and storage, labelling and regulatory compliance, complaint handling and recall processes, quality oversight and supplier management.

Job specific training outside of the QMS is not within scope of this procedure.

3. Roles and Responsibilities

Role and/or Title	Tasks and responsibility in this process

Manager	• Coordinates with Process Owners and SME to help determine Quality Management System (QMS) and job-specific training requirements.
	• Ensures that QMS training needs are identified for each associate. Notifies their department of scheduled training and deadlines for completing the training.
	• Ensures that associates are competent and trained to complete their job duties.
	• Addresses their associates' training questions, concerns, or noncompliance in a timely manner.
	• Completes Corrective Action / Preventative Action (CAPA) assigned by Quality & Regulatory and/or the training administrator to address direct reports' QMS training noncompliance.
	• Reviews direct reports' QMS training requirements against their job descriptions at least once per year (annual employee review).
	  o Ensures alignment between associate's current job description, requirements, responsibilities, and assigned training.
	• Notifies Quality Systems Compliance Specialist when an associate:
	  o Has a change in role and/or responsibilities
	  o Is on a leave of absence and needs training paused
	  o Has been terminated
	  o Requires an extension to the deadline for their training

Process Owner	• Coordinates with Managers to help identify associate QMS training requirements based upon job duties and quality process risks associated with job titles.
Subject Matter Expert (SME)	• Team member with whom managers coordinate with to help determine associates' QMS training requirements. • Advises of regulatory requirements that may affect training and coordinates with managers to update training, as needed.

Role and/or Title	Tasks and responsibility in this process
Quality Systems Compliance Specialist (QSC Spec.)	• Performs role of QMS training administrator. • Assign and track QMS training utilizing the training matrix. • Maintains training records and issues QMS training reports. • Escalate overdue training to managers and initiate CAPA when necessary. • Ensures that QMS training is documented.
Associate	• Become familiar with the quality procedures and processes associated with their job responsibilities. • Complete QMS training as assigned by their manager and/or training administrator within the specified timeframe. • Notifies their manager if scheduled training is not delivered or completed.

Add or delete rows as needed.

4. Terms and Definitions

List in alphabetical order

Term or Acronym	Definition
Associate	A [Company] employee, contractor, or member of the contingent workforce.
CAPA	Corrective Action / Preventive Action. Action taken when a non-conformance is issued.
CAPA Request	The Corrective Action / Preventive Action request that initiates the corrective action process. The CAPA Request form is completed as part of the CAPA process.
KPI	Key Performance Indicator. Established measures for steps, or subprocesses, of a quality system process which when collectively analyzed can be used to assess the overall effectiveness and efficiency of an individual Quality System Process, including its inputs and outputs to other processes.
LMS	Learning Management System. A software application for the administration, documentation, tracking, reporting, and delivery of educational courses, training programs, or learning and development programs.
OTJ	On the job training and learning.
Process Owner	Designated team member who is accountable for implementing, maintaining, and improving a particular process or set of processes within QMS scope. Responsible for the outcomes of the process as well as interactions with other processes.
QMS	Quality Management System. A formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency.

List in alphabetical order	
Term or Acronym	**Definition**
SME	Subject Matter Expert. A person who possesses a broad or deep understanding of a particular subject or area of expertise.
Training Record	1. Internal Training: A training record is a list of training activities that have been completed by a given employee. A training record can also be a list of employees who have completed a particular training activity. 2. External Training: A training record is a documented record of results, or statement of results, that outlines the training completed and the outcome received. Training records may be: transcripts or list of vocational education achievements.

Add or delete rows as needed.

5. Process Details

5.1. Skills and Performance

5.1.1. Managers coordinate with the Process Owners and SME to determine the requirements for positions in their department(s) and/or team(s) in terms of job responsibilities, education, and competencies. These requirements are documented in employee job descriptions.

5.1.2. The QMS job-specific training needed to prepare associates to fulfill their job requirements as they relate to the QMS is documented in the training matrix and is in alignment with their role and job title.

5.1.3. The associates' direct manager is responsible for ensuring that associates are aware of the relevance and importance of their training activities and how they contribute to the achievement of the quality objectives.

5.1.4. Associates' performance and ability to meet job requirements is tracked and assessed by their direct manager.

5.2. New Associate Training

5.2.1. Shortly after onboarding, each associate will be trained on the QMS procedures that apply to their job title and duties to be performed.

- Department managers and Process Owners identify positions and roles that affect product quality or that are needed to fulfill Quality Management System (QMS) requirements.
- Based upon roles and responsibilities, procedures that align to the associate's job title and responsibilities are identified for training.
- QMS training is assigned, tracked, completed, and documented by the QMS training administrator.

- Associates are responsible for completing all assigned training by the specified due date.
- Depending upon the type and method of training, documentation may be completed through the Learning Management System (LMS) software or through a manual Training Record (QF-12).

5.2.2. Training on topics and tasks beyond the QMS documented processes will be determined and provided by the associate's direct manager in coordination with other trainers, as needed.

5.2.3. Assigned training will be proportionate to the risk associated with the work or action being performed.

5.2.4. Managers will be responsible for determining the competence of their direct reports.

- See "Evaluating Training Effectiveness".

5.3. Ongoing and Recurring Training

5.3.1. If training is required due to review, audit, or other considerations, the manager will ensure that the affected associates are trained, and that applicable training documentation is completed.

5.3.2. When required, and within 14 calendar days after a procedure change has been documented and released to the QMS, each associate will be assigned training on the revised procedure(s) that applies to their job title and responsibilities.

- Training assignments must be completed within defined due dates.
- Training to procedural changes will be documented.

5.3.3. Associates are trained as required on quality procedures that apply to their job title:

- During the onboarding process.
- When their responsibilities or job title changes.
- If job performance indicates further training is required.
- When a new or revised procedure or work instruction is issued.
  - Exceptions made for when a revision does not affect the content or process, such as a formatting change, spelling or grammar corrections, etc.
- When a process or function has a specific requirement for training to be performed on a regular schedule (e.g.: annually).

5.3.4. Associates are notified of required training needs and the due date by which training needs to be completed.

- Unless otherwise specified, training is due 30 calendar days after assignment.
- Associates' vacation time, leave of absence, or other circumstances that affect the assigned due date will be taken into consideration and an extension may be granted, if required.

- Length of extension to be determined based upon risk, circumstances, and on a case-by-case basis.
- See also: “Overdue Training” section.

5.3.5. QMS procedural training is reviewed and updated as applicable to reflect the changes in procedures as they are released to the QMS.

5.3.6. Based upon roles and responsibilities, associates may be provided additional QMS training to include, but not limited to:

- On the job training (OTJ)
- Classroom training
- Webinars and/or online training
- Off-site training

5.3.7. The QMS training administrator assigns and tracks QMS training.

- The QMS training administrator is not responsible for assigning or tracking training outside of the QMS (e.g.: training on use of equipment, external training, etc.).

5.3.8. All QMS training is planned, tracked, and documented.

5.4. Additional Training Assignments

5.4.1. Managers who have a change in associate assignments, or have new hires, communicate with the Process Owners and QMS training administrator to identify QMS training needs.

5.4.2. The QMS training administrator will update the Training Matrix and assign training accordingly.

- Depending upon the role or responsibility of the associate, training requirements may include additional training outside of their current job title.
  - e.g.: Associates who are in process of growing their position and take on additional roles and responsibilities but have not yet advanced to a new title.

5.4.3. Instructor/SME’s training records on a given subject or process must be completed prior to their providing training to others on that subject or process. Instructors/SMEs who lead training sessions shall not sign as instructor and attendee on the same training record.

5.4.4. Associates who take on additional roles and responsibilities throughout the year may identify and request additional training.

- Associates may coordinate with their direct manager for the additional training assignments.
- Managers will coordinate with the Process Owners and QMS training administrator to have additional training assigned.

5.5. Evaluating Training Effectiveness

5.5.1. The method used to evaluate training effectiveness will be proportionate to the risk associated with the work or task for which the training is being provided.

5.5.2. The effectiveness of training may be measured by knowledge checks (quizzes, etc.), debriefing with the trainer, job performance review, and daily observations.

5.5.3. Other methods may be used to check the effectiveness of training which may include, but are not limited to:

- "Tell, Show, Do" hands-on training evaluation
- Effect on measured Key Process Indicators (KPI)
- Impact to quality objectives

5.6. Training Records, Storage, and Retention Period

5.6.1. Training records are maintained in a combination of the Learning Management System (LMS) and/or in the training records file location within the QMS.

5.6.2. Training records are retained as specified in Documents and Records procedure (QP-01).

5.7. Overdue Training

5.7.1. Monthly QMS training reports will be sent to managers who show direct reports with incomplete training.

5.7.2. Unless otherwise specified, training is due 30 calendar days after assignment.

- Any exception to the due date must have a rationale provided and the risk created by the postponement or delay assessed.
- The rationale must be documented. It may be provided via email, documented in the LMS report, or noted on the training record.

5.7.3. Training notifications will be sent:

- Initial: When training is assigned.
- Reminder: At least one week before training completion due date.
- Final Reminder: Day training completion is due.

5.7.4. Any associate whose training assignments are not completed by the due date will receive an Overdue Training notice to which their direct manager may be copied.

- This notice will be sent within 15 calendar days of the date the training becomes overdue.

5.7.5. Any associate who has a training assignment that is more than 30 calendar days past the assigned due date, and a valid rationale for the extra time required cannot be provided, the training administrator may:

- Contact the associate's direct manager to discuss the overdue training and associated risks.
- Issue a CAPA and assign to the associate's manager if:
  - Repeat or significant noncompliance occurs with an individual
  - Multiple individuals on a manager's team show overdue training
- If corrective action is not taken by the specified CAPA due date, then the CAPA will be escalated to the next higher level of management.
- If more time is needed or there are extenuating circumstances, the manager responsible for completing the CAPA must contact the QMS training administrator to ask for an extension. Failure to do so will result in escalation of the CAPA.

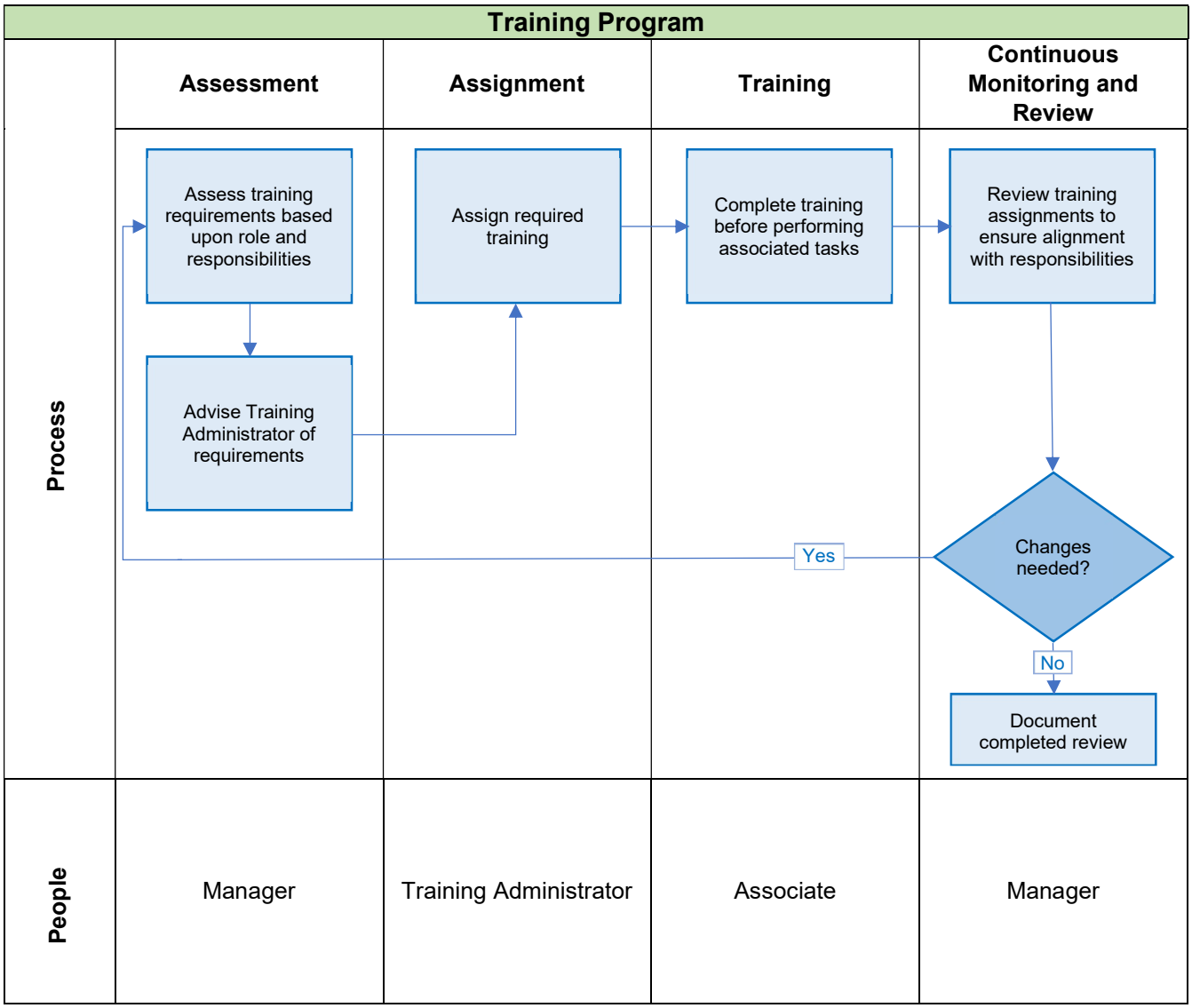
6. Appendix A – Training Matrix

- The Training Matrix is located in the Quality Records Index (QR-01).
- The Training Matrix tab is linked to the Procedure and Work Instruction tabs so the revision levels and effective dates for the documents listed on the Training Matrix update automatically when associated tabs are updated.
- Training effective date, listed below document effective date, is manually updated:
  - Aligns with document effective date if training is required for that revision.
  - Previous revision's effective date will remain when training is transferred over from previous revision and the cell is filled with a brighter blue to indicate training transfers.
- Training assignment dates and completion dates are monitored through the Learning Management System (LMS) reports.

Training Matrix – QMS Documents

Parent Procedure: QP-16												
Last Updated: **28-Jun-2024**			Doc. ID #:	QM-001	QP-01	QP-02	QP-03	QP-04	QP-05	QP-07	QP-09	QP-
QMS training only - See Supplemental tab for GMP, DSCSA, etc.			Current Revision:	15.0	12.0	5.0	4.0	5.0	8.0	11.0	13.0	11.
			Doc. Effective Date:	09-Feb-2023	27-Mar-2024	08-Mar-2022	24-Jul-2023	09-Apr-2024	10-Jan-2023	26-Mar-2024	08-Jan-2024	16-Jun-
			Training Effective Date (if transferred from previouse revision)	04-Sep-2021	27-Mar-2024	08-Mar-2022	24-Jul-2023	09-Apr-2024	10-Jan-2023	30-Jan-2024	08-Jan-2024	16-Jun-
Area / Reporting Org	**Workday Title**	**Team Member Name**		Quality Manual	Documents and Records Control	Regulatory Communication	Canada Device Classification and Licensing Process	Canadian Device License	Medical Device Reporting	Recall & Market Withdrawl	Customer Complaints	Corrective Action
Marketing: Private Label and General	Marketing Specialist II	[redacted]		Required	N/A	N/A	Required	Required	N/A	N/A	N/A	N/A
Quality & Regulatory	Quality Sys Compl Spec II	[redacted]		Required	Required	Required	Required	Required	Required	Required	Required	Requi
Distribution - Canada	FC Manager I	[redacted]		Required	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Distribution - Canada	Department Manager	[redacted]		Required	N/A	N/A	N/A	N/A	N/A	N/A	Required	Requi
Technical Services – USA	Sr Mgr Proc & Ops Improvement	[redacted]		Required	N/A	N/A	N/A	N/A	N/A	N/A	Required	Requi

7. Appendix B – Training Flow Overview



8. Appendix C – LMS basic QMS course formats

Course Title	QMS BU, Doc Title, Doc ID#, Rev. (Effective Date) [Rev X training transfers] If applicable **Examples**: QMS [COMPANY], Freeze Sensitive Products, WI-031, Rev 2.0 (2023-Mar-31) [Rev 1.0 training transfers] QMS | BU | Doc Title | Doc ID# | Rev | Effective date | If previous training transfers QMS [BU 1] Documents and Records Control, QP-01, Rev. 13.0 (2024-Aug-01) QMS [BU 2] Statistical Techniques, QP-24, Rev. 2.0 (2023-Feb-28) [Rev 1.0 training transfers] QMS [BU 3] Documents and Records Control, A01, Rev. 12.00 (2023-Dec-18)
Course Number	QMS, BU, Doc ID# **Examples**: QMS [BU 1] A01 QMS [BU 2] QP-01 QMS [BU 3] QP-24
Description	Use the text in the Purpose section of the QMS document.
Contacts	List the members of the QMS team responsible for assigning training.
Document Lesson Title	Use the title of the QMS document.
Document Lesson Description	List where the document may be found on the QMS. If the document is in more than one language, include translation. **Examples**: Training on the QMS procedure. Procedures, work instructions, and forms are located on the QMS SharePoint. *French / Français:* Formation sur la procédure SMQ. Les procédures, les instructions de travail et les formulaires se trouvent sur le QMS SharePoint.
Training Acknowledgement Lesson Title	Training acknowledgement If the document is in more than one language, include translation: Training acknowledgement / Reconnaissance de la formation
Training Acknowledgement Lesson Description	Add guidance, as needed. If the document is in more than one language, include translation. **Examples**: Please close the window after receiving your notification of completion or passing test score in order to return to Workday. *French / Français:* Veuillez fermer la fenêtre après avoir reçu votre notification d'achèvement ou de réussite au test afin de revenir à Workday.

9. Appendix D – Training Assignment Alert Emails

Training assigned – First notification (example)	
Send to	All associates who are assigned the training.
Priority	Normal
Subject Line	Workday Learning Assignment - <Insert Doc # and Title -or- Subject (GMP, etc.)>
Email Body	Hello [Company] team members. You are receiving this email because you have been assigned training in Workday Learning <or applicable LMS>: <LINK> Please log into your Workday Learning account and complete the assigned training at your earliest convenience. Due date: **<Bold and Highlighted>** ***Training is not only a regulatory requirement, it contributes to your professional growth, skill set, and the achievement of [Company]'s quality objectives.*** We understand that all of our days can get very busy, and priorities are often juggled. We **greatly appreciate** your time and helping [Company] to remain compliant by completing this required training. If you have any questions or concerns regarding training, please feel free to reach out to your manager or the learning admins. ***Thank you for helping [Company] to live our value of continuous improvement!***
Training coming due – Reminder (example)	
Send to	All associates who are assigned the training and do not yet show as completed.
Priority	High
Subject Line	Coming Due: Workday Learning Assignment - <Insert Doc # and Title -or- Subject (GMP, etc.)>
Email Body	Hello [Company] team members. You are receiving this email because our records show that you have training coming due in Workday Learning <or applicable LMS>. Training needs to be completed within **30 calendar days** of assignment unless otherwise stated. Please log into your Workday Learning account and complete the assigned training at your earliest convenience. Due date: **<Bold and Highlighted>** ***Training is not only a regulatory requirement, it contributes to your professional growth, skill set, and the achievement of [Company]'s quality objectives.*** **It is important to note that we can be issued a nonconformance (NC) audit finding for overdue training in a regulatory audit**. In order to avoid a potential *major* NC, **all training must be completed by the assigned due date**. We understand that all of our days can get very busy, and priorities are often juggled. We **greatly appreciate** your time and helping [Company] to remain compliant by completing this required training. If you have any questions or concerns regarding training, please feel free to reach out to your manager or the learning admins. ***Thank you for helping [Company] to live our value of continuous improvement!***

Training overdue - less than 30 days past due (example)	
Send to	All associates who are assigned the training and show overdue by less than 30 days.
Priority	High
Subject Line	Overdue Training – Please complete
Email Body	Hello [Company] team members. You are receiving this email because our records show that you have overdue training in Workday Learning <or applicable LMS>. Training needs to be completed within 30 calendar days of assignment unless otherwise stated. Once training becomes 30 days or more past the original due date, managers will be contacted to discuss the overdue training, associated risks, and potential actions. Please log into your Workday Learning account and complete the assigned training at your earliest possible convenience. Due date: **ASAP** **It is important to note that we can be issued a nonconformance (NC) audit finding for overdue training in a regulatory audit**. In order to avoid a potential *major* NC, all overdue training must be completed ASAP and all future training must be completed by the assigned due date. ***Training is not only a regulatory requirement, it contributes to your professional growth, skill set, and the achievement of [Company]'s quality objectives.*** We understand that all of our days can get very busy, and priorities are often juggled. We greatly appreciate your time and helping [Company] to remain compliant by completing this required training. If you have any questions or concerns regarding training, please feel free to reach out to your manager or the learning admins. ***Thank you for helping [Company] to live our value of continuous improvement!***
Training overdue - 30 days or more past due (example)	
Send to	The managers of all associates who are assigned the training and show 30 days or more overdue.
Priority	High
Subject Line	Direct Reports with Overdue Training – We need your help
Email Body	Hello [Company] Managers. You are receiving this email because our records show that you have direct reports with overdue training in Workday Learning <or applicable LMS>. Please see the attached report which can be filtered by name. Please assist your direct reports with signing into their Workday Learning account and completing the assigned training at the earliest possible opportunity. **It is important to note that we can be issued a nonconformance (NC) audit finding for overdue training in a regulatory audit**. In order to avoid a potential *major* NC, all overdue training must be completed ASAP and all future training must be completed by the assigned due date. If repeat instances occur without a valid rationale for the extra time required, a CAPA may be assigned to your team in order to satisfy regulatory requirements. ***Training is not only a regulatory requirement, it contributes to our professional growth, skill set, and the achievement of [Company]'s quality objectives.*** We understand that all of our days can get very busy, and priorities are often juggled. We greatly appreciate your time and helping [Company] to remain compliant by helping your direct reports to complete their required training. If you have any questions or concerns regarding training, please feel free to reach out to the Quality & Reg Sys Prog Mgr (training process owner) or the learning admins. ***Thank you for helping [Company] to live our value of continuous improvement!***

10. Appendix E – Training Attestation Standard Text

The following is an example of the standard text used for “Read and Understand” training assignments.

Please acknowledge you have read and understood the procedure. If you have any questions, please reach out to your manager, the Learning Administrator, or a member of their team. Thank you.

- QMS procedures, work instructions, and forms are located on the QMS SharePoint page.
- By selecting “Yes” and completing this training record, you acknowledge that you have read, understood, and agree to comply with the processes outlined.
- If you select "No", please contact your manager or the process owner for further assistance.
- Please close the window after receiving your notification of completion and/or test score to return to the Learning Management System (LMS).

11. References

Document ID	Title
ID #	Quality Manual
ID #	Training Matrix
ID #	Training Record Form
ID #	Management Review SOP
ID #	Document and Record Control SOP

Add or delete rows as needed.

12. Revision History

Rev.	Revision date	DCR #	Description of change(s)
A	07-Nov-2023	DCR-XXX-001	Initial creation

Add or delete rows as needed.

13. Approval

Approvals for this document are maintained digitally using the electronic signature (e-signature) functionality of the validated 21 CFR Part 11 compliant e-signature system.

Individuals who approve QMS documents:

1. Are accountable for the integrity of the entire document with emphasis on their area of expertise.
2. Confirm they have reviewed the document and find it to be adequate, complete, and correct.

Name, signature, and date	Title
	Approver
	Reviewer
	Author / Editor

Add or delete rows as needed.