SOP Template: Recall Initiation and Decision-Making Authority

This SOP details the **recall initiation and decision-making authority** process, outlining the criteria for initiating a product recall, the roles and responsibilities of key personnel involved, and the authority required to approve recall actions. It ensures a structured and efficient approach to promptly identifying, assessing, and managing product recalls to protect consumer safety and maintain compliance with regulatory requirements.

1. Purpose

To define the procedures and responsibilities related to the initiation and approval of product recalls, ensuring prompt, compliant, and effective action to safeguard consumers.

2. Scope

This procedure applies to all products manufactured, distributed, or sold by [Company Name], and to all employees involved in the recall process at all locations.

3. Definitions

- **Recall:** Removal of a product from the marketplace due to safety, quality, or regulatory concerns.
- **Recall Coordinator:** The individual responsible for managing all aspects of the recall process.
- **Decision-Making Authority:** The person or group with the power to approve recall initiation and major recall actions.

4. Criteria for Initiating a Recall

- Evidence or notification of a potential product defect that may affect consumer safety or regulatory compliance.
- Adverse events, complaints, or regulatory notices indicating potential risk.
- Internal quality audit findings identifying serious nonconformance.
- Direction from regulatory authorities mandating recall action.

5. Roles and Responsibilities

Role	Responsibility
Recall Coordinator	Manages recall assessment, coordination, communications, and documentation.
Quality Assurance Manager	Evaluates reported issues, assesses risk, and makes recall recommendation.
Legal/Regulatory Affairs	Reviews compliance requirements and assists with regulatory notifications.
Recall Committee/Executive Management	Holds decision-making authority to approve recall initiation and closure.
Communications/PR Manager	Prepares communications to regulatory bodies, customers, and public, as required.

6. Recall Initiation Process

1. **Initial Detection:** Any employee who identifies a potential recall situation must notify the Recall Coordinator immediately.
2. **Assessment:** The Recall Coordinator, in consultation with QA and relevant departments, assesses the situation for recall criteria.
3. **Recommendation:** The QA Manager documents findings and recommends recall action (if warranted) to the Recall Committee/Executive Management.
4. **Decision:** The Recall Committee/Executive Management reviews the assessment and authorizes recall if

criteria are met.
5. **Notification:** The Recall Coordinator initiates regulatory notifications and internal communications as required.
6. **Recall Execution:** Product removal and associated actions are managed as per the approved recall plan.

7. Decision-Making Authority

- Recall Committee or designated Executive Management possess sole authority to approve or reject recall initiation and to finalize recall actions.
- All recall actions must be documented, including the rationale for decision and evidence supporting the chosen course.

8. Documentation & Recordkeeping

- Maintain records of all recall-related communications, notifications, assessment reports, and decision approvals as part of the Recall File.
- Ensure traceability and availability of all documentation for internal and regulatory review.

9. References

- [Insert relevant regulations, e.g., FDA, Health Canada, EU MDR, etc.]
- [Insert internal quality policies related to recalls]

10. Revision History

Version	Date	Description	Author
1.0	[YYYY-MM-DD]	Initial release	[Name]