SOP Template: Complaint Handling and Root Cause Analysis Workflows

This SOP defines the **complaint handling and root cause analysis workflows**, detailing the systematic process for receiving, documenting, investigating, and resolving customer complaints. It ensures prompt identification of underlying issues through thorough root cause analysis, enabling effective corrective actions and continuous improvement. The SOP aims to enhance customer satisfaction, maintain regulatory compliance, and prevent recurrence of problems by fostering transparent communication and structured problem-solving methodologies.

1. Purpose

To establish a standardized procedure for handling customer complaints and conducting root cause analysis, ensuring efficient resolution and improvement of processes, products, or services.

2. Scope

This SOP applies to all employees involved in receiving, documenting, investigating, and resolving customer complaints within the organization.

3. Responsibilities

Role	Responsibilities
Customer Service	Receive, document, and acknowledge complaints.
Complaint Handler	Investigate complaints, coordinate with relevant departments, document findings.
Quality/Compliance Team	Perform root cause analysis and verify effectiveness of corrective actions.
Management	Review complaint trends, approve escalation and corrective actions, allocate resources as needed.

4. Definitions

- **Complaint:** Any expression of dissatisfaction from customers regarding products or services.
- **Root Cause Analysis (RCA):** Methodical approach to identify the underlying cause of a problem.
- **Corrective Action:** Steps taken to fix the root cause and prevent recurrence.

5. Workflow

5.1 Complaint Handling

1. **Receipt:** Receive complaints via email, phone, website, or in-person.
2. **Acknowledgement:** Confirm receipt of the complaint to the customer within 1 business day.
3. **Logging:** Record all relevant details in the complaint management system/log.
4. **Initial Assessment:** Evaluate severity, categorize, and assign to a responsible complaint handler.
5. **Investigation:** Gather facts, interview stakeholders, collect supporting evidence.
6. **Interim Action:** If immediate risk, implement temporary containment action and inform affected parties.
7. **Communication:** Keep customer updated throughout the handling process.

5.2 Root Cause Analysis

1. **Assemble RCA Team:** Include cross-functional members relevant to the issue.
2. **Data Review:** Analyze complaint data, process records, and historical issues.
3. **Root Cause Analysis Tools:** Apply methods such as 5-Whys, Fishbone (Ishikawa), or FMEA as appropriate.
4. **Identify Root Cause:** Document the primary contributing factor(s).

5.3 Resolution & Follow-up

1. **Corrective Actions:** Develop and implement corrective/preventive actions to address root causes.
2. **Verification:** Evaluate effectiveness of actions and monitor outcomes over a defined period.
3. **Closure:** Close the complaint formally in the system, with detailed documentation.
4. **Customer Notification:** Communicate the resolution and preventive measures taken to the customer.
5. **Trend Analysis:** Periodic review of complaint trends for continuous improvement.

6. Documentation

- Complaint Log/Database
- Investigation Reports
- RCA Worksheets
- Corrective Action Records
- Customer Communication Records
- Management Review Minutes

7. References

- [Relevant regulatory guidelines or standards, e.g., ISO 9001, FDA CFR, etc.]
- Internal policies on quality and customer service

8. Revision History

Version	Date	Description	Author
1.0	2024-06-22	Initial Release	Quality Manager