



Market Complaints Management

Audit Readiness Checklist

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I. DOCUMENTATION

	Yes	No	NA
Complaint Handling Procedures			
• Are there documented procedures for managing market complaints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are procedures easily accessible to relevant personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Complaint Records			
• Are all market complaints recorded promptly and accurately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Do complaint records include detailed descriptions of the complaint, including product details and customer information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigation Records			
• Are investigations conducted for all market complaints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are investigation records complete and thorough?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CAPA Documentation			
• Are corrective and preventive actions (CAPA) identified and implemented for each market complaint?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are CAPA records documented and reviewed regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

II. PROCESS AND SYSTEM REVIEWS

Complaint Reviews			
• Are market complaints reviewed by a designated quality control unit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are complaints categorized based on severity and impact?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Yes No NA

Root Cause Analysis

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| • Are root cause analyses conducted for all market complaints? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are findings from root cause analyses documented and approved? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Training

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| • Are personnel trained on market complaint handling and investigation procedures? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are training records current and complete? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



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III. REGULATORY COMPLIANCE

Regulatory Guidelines

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| • Are market complaints evaluated for compliance with relevant regulatory guidelines (FDA, EU GMP, etc.)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are regulatory bodies notified of significant market complaints as required? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Quality Risk Management

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| • Are market complaints integrated into the quality risk management system? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| • Are risks associated with market complaints documented and managed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

IV. PRODUCT AND CUSTOMER COMMUNICATION

	Yes	No	NA
Customer Communication Procedures			
• Are procedures in place for communicating with customers regarding complaints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Is customer feedback collected and analyzed for trends and patterns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Product Recall Procedures			
• Are procedures established for initiating product recalls if necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are recall notifications issued promptly and effectively?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Follow-Up With Customers			
• Is follow-up conducted with customers regarding complaint resolution?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are customer satisfaction surveys conducted to assess complaint handling effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

V. COMMUNICATION AND COORDINATION

Complaint Management Team Preparation			
• Is the complaint management team aware of their roles and responsibilities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are relevant stakeholders involved in the complaint management process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Complaint Review Meetings			
• Are regular meetings held to review and discuss market complaints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Are meeting minutes documented and actions tracked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Yes No NA

Pre-Audit Review

- Is a pre-audit review conducted to ensure complaint management readiness?
- Are potential issues identified and addressed before the audit?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

VI. FOLLOW-UP AND MONITORING

Post-Investigation Review

- Are market complaints reviewed after investigation to ensure they are resolved?
- Is there documented evidence of the review and its findings?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Monitoring and Reporting

- Are market complaints monitored to ensure CAPA effectiveness?
- Are recurring complaints analyzed for patterns and trends?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continuous Improvement

- Are lessons learned from market complaints documented and used for continuous improvement?
- Are complaint management procedures reviewed and updated based on audit findings?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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