Requirements for Complaint Handling Procedure

In general, organizations must establish and maintain robust and detailed procedures for receiving, reviewing, and evaluating complaints by an assigned department to ensure complaint processing is uniform and carried out in a timely manner.

Documentation must detail the receipt, investigation and evaluation of Complaints to determine if failure investigation and/or the submission of a medical device report (MDR) is required. Make sure to consider the below mentioned points while evaluating your existing procedure or preparing a new one:

S.NO.	CRITERIA	RESULT	REMARKS
1	The organization has documented robust and up to date complaint handling procedure.	☐ Compliant ☐ Non-Complaint	
2	The procedure includes requirements and responsibilities for receiving, reviewing, and recording information by a formally assigned department/person.	☐ Compliant ☐ Non-Complaint	
3	All complaints, be it written, oral or electronic, are processed in a uniform and timely manner.	☐ Compliant ☐ Non-Complaint	
4	The procedure has provision for documenting complaints upon receipt.	☐ Compliant ☐ Non-Complaint	
5	The complaint handling procedure evaluates information to determine if the feedback is a complaint.	☐ Compliant ☐ Non-Complaint	
6	The procedure includes requirements and responsibilities for investigating complaints.	☐ Compliant ☐ Non-Complaint	
7	All complaints are evaluated to determine whether the complaint is an event that need to be reported to the appropriate authorities.	☐ Compliant ☐ Non-Complaint	
8	The procedure addresses the handling of complaint-related product.	☐ Compliant ☐ Non-Complaint	
9	The procedure determines the need to initiate corrections or corrective actions.	☐ Compliant ☐ Non-Complaint	
10	All complaints are reviewed and evaluated to determine if any investigation is needed.	☐ Compliant ☐ Non-Complaint	
11	When no investigation is made, justification for the same is provided and a record containing the reason for no investigation is maintained.	☐ Compliant ☐ Non-Complaint	

12	If an investigation against a complaint is made, a record of the investigation is maintained by a formally assigned department/person.	☐ Compliant ☐ Non-Complaint	
13	Correction or corrective action arising from complaint handling process is recorded.	☐ Compliant ☐ Non-Complaint	
14	If any activities outside the organization contributes to the complaint, relevant information is exchanged between the organization and the external party or stakeholder.	☐ Compliant ☐ Non-Complaint	
15	Complete and detailed records of complaint handling are maintained.	☐ Compliant ☐ Non-Complaint	

With ComplianceQuest Complaint Management, quality assurance leaders can automate the process of Complaint intake and handling.

Automating the complaints management process can not only help with providing greater visibility into the complaints management workflow but also enable the automation of key parts of the process, severely decreasing errors and associated costs.

Use ComplianceQuest's Complaint Management Solution to automate your workflow end-to-end and also integrate/connect with your CRM.

Watch Demo

REFERENCE:

A. TITLE 21 CFR -Food and Drugs CHAPTER I-Food and Drug Administration, Department of Health and Human Services, SUBCHAPTER H - MEDICAL DEVICES, PART 820 -- QUALITY SYSTEM REGULATION, Subpart M - Records, Sec. 820.198 Complaint files.

B. ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes; Clause 8.2.2 Complaint handling.

C. MDSAP AUDIT APPROACH; Document No: MDSAP AU P0002.007, Revision Date: 2022-04-15; CHAPTER 3 - Measurement, Analysis and Improvement.

For a truly successful quality culture in your enterprise, empower various key stakeholders including the Quality team, IT team, Senior Management and others to take ownership of the quality function and move it from just regulatory compliance to a competitive advantage.
Share this checklist with your quality colleagues and other relevant teammates to bring them up-to-speed with what ComplianceQuest's next-gen EQMS solution could do for your enterprise!

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About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product, Quality and Safety management platform, built on Salesforce. Our connected suite of solutions helps businesses of all sizes increase quality, safety and efficiency as they bring their products from concept to customer success. Our intelligent data-driven platform comes with best-in-class integrated processes to mitigate risks, protecting your employees, suppliers and brand reputation, and to increase innovation, compliance, profit and customer loyalty. ComplianceQuest is pre-validated and easy to implement, use, and maintain, allowing for streamlined communication and collaboration across the product value chain.

For more information, or to request a demo with a ComplianceQuest expert, contact ComplianceQuest today:

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