Control of Non-conforming Product – A Checklist Approach

Products that do not adhere to standards or specifications are considered nonconforming products. But it is not only the product that can be non-conforming, process nonconformances are also common. Plus, products might become nonconforming as a result of nonconforming processes.

According to 21 CFR Part 820.90 Nonconforming products, "Each manufacturer shall establish and maintain procedures to control products that do not conform to specified requirements". This checklist will help you understand the requirements and implement them in a systematic manner.

S.NO.	CRITERIA	RESULT	REMARKS
CONTROL OF NON-CONFORMING PRODUCT			
1	Manufacturer has established and maintain procedures to control product that does not conform to specified requirements.	☐ Compliant ☐ Non-Complaint	
2	The procedure is able to identify, document, evaluate, segregate, and dispose of nonconforming product.	☐ Compliant ☐ Non-Complaint	
3	The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.	☐ Compliant ☐ Non-Complaint	
4	The evaluation and any investigation shall be documented.	☐ Compliant ☐ Non-Complaint	
DISPOSITION OF NON-CONFORMING PRODUCT			
5	Manufacturer has established and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product.	☐ Compliant ☐ Non-Complaint	
6	The procedures shall set forth the review and disposition process.	☐ Compliant ☐ Non-Complaint	
7	Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.	☐ Compliant ☐ Non-Complaint	
8	The organisation shall have procedures for issuing advisory notices in accordance with applicable regulatory requirements.	☐ Compliant ☐ Non-Complaint	
REWORK			
9	Manufacturer shall establish and maintain procedures for rework including retesting and re-evaluation of the nonconforming product after rework.	☐ Compliant ☐ Non-Complaint	
10	Rework shall ensure that the product meets its current approved specifications and regulatory requirements.	☐ Compliant ☐ Non-Complaint	
11	Rework and re-evaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.	☐ Compliant ☐ Non-Complaint	

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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.

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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