|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| CAR № | *Corrective Action Report (CAR)*  *Non-Conformity (NC)* | | | | | | | Date NC Found: | |
| Case where NC is found (if applicable): | | | | | | | | | |
| *1. Non-conformity raised as a result of:* | | | | | | | | | |
| 🞎 Internal audit | | 🞎 Customer complaint | | | |  | | | |
| 🞎 External Audit | | 🞎 Management Review | | | |
| 🞎 Process non-conformity | | 🞎 Other | | | | | | | |
| *2. Non-Conformity: Description of nonconformity, complaint or incident.* | | | | | | | | | |
|  | | | | | | | | | |
| Detected by: | | | | | Date: | | | | |
| *3. Investigative and Root Cause Analysis: Determination of the Root Cause of the nonconformity* | | | | | | | | | |
|  | | | | | | | | | |
| Investigated by: | | | | | Date started: | | | | |
| Date completed: | | | | |
| *4. Corrective Action: Description of action(s) taken to eliminate the cause of the non-conformity.* | | | | | | | | | |
|  | | | | | | | | | |
| Proposed by: | | | Date: | | | | Implementation date: | | |
| *5. Level of Non-Conformity:* | | | | | *6. Type of Error:* | | | | |
| 🞎 Minor (Class I) 🞎 Internal audit  🞎 Medium (Class II) 🞎 FDA Reportable  🞎 Major (Class III)  🞎 Critical (Class IV) | | | | | 🞎 Administrative Error  🞎 Systemic Error  🞎 Technical Error  🞎 Contamination | | | | |
| *6. Verification of the Effectiveness of the Corrective Action:* | | | | | | | | | |
| Corrective action is:  🞎 Effective  🞎 Not effective. Issue new CAR  Remarks: | | | | | | | | | |
| Signature: | | | | | Date: | | | | |