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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date:** | | |  | | | | | | | |  | | | | **Type of Deviation:** | | | | | | |
|  | | |  | | | | | | | |  | | | | | | | | | | |
| **Deviation Report #:** | | |  | | | | | | | |  | | |  | | **Planned** | |  |  | | **Procedure** |
|  | | |  | | | | | | | |  | | |  | | **Un-planned** | |  |  | | **Policy** |
| **Initiated By:** | | |  | | | | | | | |  | | |  | | **Major** | |  |  | | **Process** |
|  | | |  | | | | | | | |  | | |  | | **Minor** | |  |  | | **Other** |
| **Area:** | | |  | | | | | | | |  | | | | | | | | | | |
|  | | |  | | | | | | | |  | | | | | | | | | | |
| **Original Requirement (s)** | | | | | | | | **Deviation** | | | | | | | | | | | | | |
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| **Reason for Deviation:** | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | | | | | | | | | | | | | | | | |
| **Does this deviation affect Product Quality?** | | | | | **Yes** |  | **No** | |  | | | **If yes, how?** | | | |  | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **Is product disposition affected?** | | | | | **Yes** |  | **No** | |  | | | **If yes, how?** | | | |  | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **CAPA required?** | | | | | **Yes** |  | **No** | |  | | | **If yes, CAPA#** | | | |  | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | |
| **Approval Signatures/Dates:** | | | **(** *all applicable parties* **)** | | | | | | | | | | | | | | | | | | |
| **Department** | **Name** | | | **Title** | | | | | | | **Signature** | | | | | | | | **Date** | | |
| Area Manager |  | | |  | | | | | | |  | | | | | | | |  | | |
| Quality | Deborah Durbin | | | Dir. Of Quality | | | | | | |  | | | | | | | |  | | |
| Operations | Matt Haynes | | | Dir. Of Operations | | | | | | |  | | | | | | | |  | | |
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