

## Deviation Report Form (Ref. SOP QMS-035; MAN-080)

DR Number:	DRX-YYYY	Priority		
Author		Date	Area/Team	
(Reported by)		Reported	Responsible	
DR Type: (fill in appli	icable information)			
DR5 Customer Com	plaint Deviation			
Customer No.:		Delivery Doc. No.:		
Sales Order No.:		Customer Material No.:		
Sold to Party No:				
DR8 Material Compl	laint Deviation			
Vendor No. or		Purchasing Doc.		
Vendor Name:		Number:		
Material Doc. No.:		Vendors Material No.:		
DR1 Process / Proc	edural Deviation		1	
Product code:		Equipment No.		
MI Sheet No.:		Batch (BPN):		
DR4 Audit Deviation	<u>ı</u>			
Audit Ref. No.		Audit Type		
DR2 EHS Deviation				
Deviation Title				
Description (Must b	e filled in for all deviation typ	es)		
1				



## Management Response Tasks

## 1. Area Manager Response Tasks

(Describe the facts, corrective actions taken. If a preventative action is necessary list in the Follow up tasks. Sent the report to Second management response tasks)

Name:	Si	gn:	Date:	
2. Second Management Response Tasks				

(Review area manger's response and justify efficacy of corrective actions taken. If a preventative action is necessary list in the Follow up tasks. Sent the report to QA management response tasks)



## **Deviation Report Form**

3. QA Management Response Tasks QA Manager to evaluate the deviation and assess the potential impact to the product quality, validation and regulatory requirement. Asses efficacy of the actions taken. Approve the DR)						
Name:	Sign:	Date:				
Follow up Tasks						
Task 1:		1				
Assigned To	Planned finished date					
Confirm Task 1 completed:	Sign:	Date:				
Task 2:	1	1				
Assigned To	Planned finished date					
Confirm Task 2 completed:	Sign:	Date:				
QA manager Approval Task						
Confirm follow up tasks completed:	Sign:	Date:				

List all follow up tasks in the QA Metrics Sheet. Place the completed report into completed DR file.