	UGEE CHEMICALS Plant General SOP	SOP Standard Operating Procedure

MANAGING DEVIATIONS AND EXCEPTIONS

SOP No: UCL/IBDPSG/CD/Q/09.0	Issuance Date:	As at Last Signature	
	Revision Date:	Maximum 2 years from Effective Date	
	Effective Date:	20 working days from the issuance date	Page 1 of 9

PURPOSE

To provide a standard way of Managing Deviation and Exceptions with appropriate management review.

SCOPE

This SOP is to be used in Ibadan Plant to document and reconcile any deviation or exception to normal operating procedure, validated process, standards, starting materials and finished product handlings and methods or specifications in all areas.

RESPONSIBILITY

Process Owner (Initiator): responsible for initiating a thorough investigation following the attachment 2 format for any of the following reasons, get all required QA approval & fully document the deviation associated with in the batch records or packaging records:

Known deviations from Standard Operating Procedures (SOPs), manufacturing or packing standards. Failure of a component (raw material), packing material, intermediate or product to meet any of its specifications or in-process control tolerances.

Any variance or process which may have influenced the quality of a component, packaging material, intermediate, bulk lot or finished product; e.g., sanitation or mix-up.

Equipment malfunction which could directly affect the quality of an intermediate, bulk or finished product.

Potential cross-contamination

The QA Manager: reviews deviations & exceptions and approves/disapproves as deem fit.

The Deviations System Owner: logs in all local deviations/exceptions and tracks they are investigated and actions are completed on time. Assigns deviation number to deviation/exception forms and keeps the deviation master file for all paper approved deviations.

PROCEDURE:

SOP OWNER	QA APPROVAL	HS&E APPROVAL	AUTHORISATION
---------- Adio Sakiru Date: 4th Aug. 2022	----------NA-------- Date:	----------NA---------- Date:	---------- Alawode Olujide Site QA: Date: 11-08-2022

2. For all deviations, the Site Deviation System owner assigns deviations number to all deviation or exception. The process owner channels such for appropriate approval.
3. On those occasions where a deviation and/or exception is required, the line manager will conduct a thorough investigation following the attached format. One or two sentence explaining what variance was noticed is indicated.
4. The process owner will initiate the deviation using the attached deviation checklist
5. Process Owner/initiator must describe what happened, outline the sequence of events and how deviation was found. Review against validation data and state what causes were found related to raw materials and/or packaging material, or related to procedure, or to the equipment performance or due to overall system capability when raising steam deviation approval.
6. Initiator must include in the deviation:

   (i)ODMs/Line manager as 'Signature approval' and QA manager as 'Approver' at a minimum.
   (ii)The site deviation system owner in the distribution alignment list.
7. The Lab will provide all the required test results (chemistry, micro, physical evaluation, reconciliation) as compared to specifications (where necessary) for all deviation both requiring local/regional approvals.
8. Process owner reviews all previous data to find out if this problem relates or does not relate to other lots. e.g., Raw materials, packaging materials and other batches of product made with the same materials and where they were used,

1 1. Outline a conclusion summary supported by rationale and data from investigation listing all the entire root causes(s), the status of the product (reject, reworked, release) & the status of the materials and facilities.

9. Deviations must be reported, investigated and corrective action plans reviewed by the appropriate stakeholders as needed to properly evaluate each specific Deviation (i) any affected Materials or intermediates to the next stage of operation (ii). Finished product to the market (iii). Finished product for investigational use or any alternative disposition.
10. For any finished product lots, single lot or portion of a lot confirmed to be out of specification after proper investigation, refer to MAT-S-14 (Managing finished product associated with deviations).
11. Finally a follow-up action will be initiated to eliminate the condition that led to the deviation or exception with clear responsibility & time to finalize the action in order to avoid reoccurrences.
12. If the deviation or exception is recurring, the process must be evaluated and, if necessary, requirements be changed and process re-validated.
13. Document the deviation exception form in the batch records or packaging records where applicable, or in the Master Deviation File.
14. Exceptions of any form must be formally requested, evaluated, documented and approved by QA at management levels at or above the approval level for the original requirements as applicable. This must be complete prior to implementation.

    Any Deviation or Exception to be used and /or sustained permanently must be adopted via the approved Change Control System (see Change Control SOP UCL/IBDSITE/CD/Q/18.0

CONCURRENCES/APPROVALS FOR DEVIATIONS/EXCEPTIONS:

15. The following can give approvals to deviation/exception based on the nature of the issue:

Plant Manager
Site QA

DEFINITIONS:

16. Deviation: is any unplanned event/condition which constitutes a departure from requirement identified in Technical
17. Standards or in Written Procedures for:
18. Normal operating conditions
19. Specified Production processes
20. Testing and Monitoring
21. Storage and Distribution
22. Exception: is any pre-planned and pre-approved departure of limited duration from normal operating conditions, specified production processes, testing and monitoring or any other production, storage and distribution requirements contained in Technical Standards and Specifications (TS&S) or in Written Procedures.

REASON FOR UPDATE

New SOP

End Of Procedure

SOP RELATED ATTACHMENTS

Attachment 1 — SOP Qualification Sheet
Attachment 2 Managing Deviation & Exception Form
Attachment 3 Model Answers
Attachment 4 — Step Up Card

MANAGING DEVIATION & EXCEPTION REQUEST FORM

No.:

Department _____Date_____

Product/Procedure/System Affected: _____Area_____

DESCRIPTION/REASON FOR DEVIATION/EXCEPTION REQUEST (one or two sentences explaining the need)**:**

BACKGROUND INFORMATION/INVESTIGATION DETAILS (Clearly describe what was happened, sequence of events leading to deviation). For materials, indicate RMS & GRN Nos. For Finished Products, indicate Batch Nos.

Batch No:		**GRN No:**		**IRMS/IPMS:**		(Fill as applicable)

Potential Cost:

RATIONALE FOR DEVIATION APPROVAL: (to be filled ONLY by QA)

DEVIATION EXPIRATION DATE :

CONCLUSIONS: (Supported by rationale and data from the above investigation)

Root Cause(s)	Status of all FP/Raw/Pack Material (Chose one)	Status of process, materials & facilities (Chose one)
1.	Rejected ☐	Continue to use as they are ☐
2.	To be reworked ☐	Use after specific change or action ☐
3.	Held pending further testing ☐	Discontinue use ☐
4.	Release ☐	Revalidate ☐
5.	Any other: NA	Any other:

AGREEMENT & APPROVAL

Originator/Initiator	**Dept./Area Leader Agreement**	**Plant Mgr. Concurrence (if appl.)** Approval ☐ Disapproval ☐
Name/Sign	Name/Sign	Name/Sign
Process Leader Concurrence(if appl.) Approval ☐ Disapproval☐	**QA Concurrence** Approval ☐ Disapproval ☐	
Name/Sign	Name/Sign	

NEXT STEPS/ RESPONSIBILITY (What is to be done to eliminate root cause?)

#	Actions	Responsibility	Date to finalize	Status
1				
2				
3				
4				

SOP OWNER	QA APPROVAL	HS&E APPROVAL	AUTHORISATION
Adio Sakiru	NA	NA	Alawode Olujide
Date: 14th Aug. 2022	Date:	Date:	Site QA: Date: 11-08-2022

STEP UP CARD FOR VALIDATION OF MANAGING DEVIATION AND EXCEPTIONS

Trainee: _____ Skill Owner_____

Role: _____ Qualifier: _____

S/N	Skill Block/Skill		Knowledge/Task/Skill	Target Profic.	Self Evaluation Date	Self Evaluation Evaluation	First Evaluation Final Evaluation Date	First Evaluation Final Evaluation Evaluation	Date	Evaluation
1	Shelf Quality Measures	1	Understand the purpose of the SOP	3		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5
		2	Can explain the system requirements and measure of the system according to this SOP	3		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5
		3	Can explain the process identified in this SOP	3		1 2 3 4 5		1 2 3 4 5		1 2 3 4 5
		4	Can explain end to end initiation and approval of deviation system	3		1 2 3 4 5		2 2 3 4 5		2 2 3 4 5
		5	Understands the content and what to fill in deviation forms	3		1 2 3 4 5		3 2 3 4 5		3 2 3 4 5
		6	Knows how to update deviation tracking system	3		1 2 3 4 5		4 2 3 4 5		4 2 3 4 5
		7	Understands document filling and storage systems for approved deviations	3		1 2 3 4 5		5 2 3 4 5		5 2 3 4 5
		8	Knows the process involved when permanently sustaining	3		1 2 3 4 5		6 2 3 4 5		6 2 3 4 5
		9	Can explain the diffrence beween deviation and exception	3		1 2 3 4 5		5 2 3 4 5		7 2 3 4 5
		10	Can explain the diffrence beween the different types of validation and when each is needed	3		1 2 3 4 5		1 2 3 4 5		8 2 3 4 5
				3						

Signature of Trainee _____ Signature of Qualifier _____

Date of Qualification _____ Date of Qualification _____

SOP OWNER	QA APPROVAL	HS&E APPROVAL	AUTHORISATION
Adio Sakiru	----------NA----------	----------NA----------	Alawode Olujide
Date: 11th Aug. 2022	Date:	Date:	Site QA: Date: 11-08-2022