UGEE CHEMICALS	UGEE CHEMICALS Plant General SOP	SOP Standard Operating Procedure

RECORD KEEPING

SOP #: UCL/IBDSITE/CD/Q/22.0	Issuance Date:	As of Last Signature	Reference: P&G Internet; https://pg.myretentionschedule.com/, LDR-P-04 https://pgsecurity.pg.com https://privacy.pg.com
	Revision Date:	Maximum 2 years from issuance date	
	Effective Date:	20 working days from the issuance date	Page 1 of 13

PURPOSE

- Provide guidelines for good record-keeping, as they relate to designing forms and attachments, completing Records, storing and archiving.
- Assures data and records supporting the quality of Ugee Chemicals product complies with ALCOA+ (accurate, legible, contemporaneous, original, attributable +: complete, consistent, Enduring and Available) principlesthroughout the data lifecycle.

SCOPE

- This SOP is applicable in Ibadan plant.

RESPONSIBILITY

- Quality Assurance (QA) is responsible for checking for compliance to this quality program health assessments.
- Employees are responsible for adhering to this SOP. They will ensure they are qualified and have the materials necessary to comply with this SOP.

POTENTIAL RISKS

- Internal control issues: The company can be exposed to significant legal or tax liabilities if not fully complied with.

PPE REQUIRED

- Compliance to control requirements and objectives.

PROCEDURE

RECORD-KEEPING

1. **Designing Forms & Attachments**

   1.1 All forms and attachments must be traceable to its parent document, easy to distinguish current issue from previous one (i.e. no outdated documents) and unambiguous to follow or fill.

   1.2 When designing a form, an attachment, or a label, follow the guidelines given below:

1.2.1 Include a reference number or name of parent document (e.g. SOP #, Technical Standard)

1.2.2 Include an Issue number on Attachment/Form/Label.

1.2.3 Include an Issue date on Attachment/Form/Label.

1.2.4 Include some simple instructions, if required

1.2.5 Add page numbers for multiple-paged documents (e.g. Page 1 of 2)

1.2.6 If information must be filled in, space should be provided for (at a minimum):

- Reference data
- Date
- Signature or initial

1.3 If information must be filled in, the person making the form/attachment must ensure (via dry run) that there is enough space for the information required. Dry run involves the use of a draft of the form/attachment for verification.

1.4 The print of attachments/labels/forms must be large enough to be legible even if photocopied. Documents with illegible print must not be used for product related documentation. An original copy should be re-approved in such scenarios.

1.5 Forms and Attachments used in product related documentation will be peer reviewed before use. The reviewer will be knowledgeable in the task and intent of the form.

1.6 Paper copies of forms/attachments will be signed, dated by the originator and reviewer(s) for tracking purposes.

1.7 Forms/Attachments used in product related documentation will have unique issue numbers assigned to each version for tracking purposes.

1.8 The issue number will include reference numbers to parent documents (e.g. SOPs, Technical Standard) where applicable.

2 Good Practices for Completing Records

2.1 Records must be accurate, legible, contemporaneous, original, attributable +: complete, consistent, Enduring and Available. (ALCOA+)

2.2 Good record keeping can be achieved by:

2.2.1 Perform data entry on time

2,2,2 Do not use scraps of paper

2.2.3 Do not use ditto marks

2.2.4 Do not leave blanks

2.3 Put Dates & Time proper format

- *Always include the year and distinguish the month from the day.*
- *Either use am/pm or use military timings (e.g. 2100 for 9:00pm).*

2.4 Use only permanent ink, no pencil

2.5 Always double-check records for completeness before filing or archiving.

2.6 Follow the steps under "Do" for error correction

DO's	DON'T's
• Put a single line across error.	• Scratch-out.
• Put Correction as close as possible to the error.	• Over-write.
• Write Brief Explanation for correction.	• Use liquid paper ("Tipp-Ex").
• Initial & Date the correction.	

3 Classification of Data:

All employee and organizational data are categorized into two classes:

- Information for public use/consumption
- Information which is not meant to be shared publicly. This includes information, which because of adverse consequences of unauthorized disclosure, alteration, unavailability, or destruction, requires appropriate controls for its protection. **(i.e Business use, highly restricted or secret)**

Information assets whose classification cannot be readily determined must be, in default, classified as "Business Use" information. Appropriate controls with regards to the classification must also be implemented and observed.

3.1 Public information:

Public information are information assets that have been explicitly authorized by the information asset owner for public access. This information is willingly share externally.

3.2 Business Use:

Business use- Data that is shared internally and externally on a limited basis. This is data that has the potential for little to no risk to the financial or reputational health of the total Company if disclosed, made unavailable, or modified without authorization. This is a subset of information and does not provide a complete picture of one element of a brand, region, or the Company.

I. Little to no impact
II. Likely to not impact OTSR or NOS
III. Expected to represent approximately ~80% of the total Company's data by volume
IV. Certain types of Personal information (PII) as defined by Legal experts or privacy.pg.com.

3.3 Highly Restricted:

Data that is shared on a very restrictive basis internally and externally and has the potential for moderate, short-term risk to the financial or reputational health of the total Company if disclosed, made unavailable, or modified without authorization. This includes information that provides a complete picture of one element of a brand, region, or the Company that could significantly impact Company's local competitive advantage (i.e., technical information on product or processing, global brand marketing plan, total region initiatives, customer team trade fund plans, and global financials by total Company, total GBU, or total brand)

- Recoverable impact
- May impact OTSR or NOS
- Expected to be <20% of the total Company's data
- Certain types of Personal Information (also known as PII) as defined by Legal experts or privacy.pg.com

Any information that has an external mandate for protection either from contractual or regulatory requirement is Highly Restricted information.

3.4 Secret:

Data that involves the most restricted access (very few individuals) and requires a high degree of Confidentiality, Integrity, and Availability. This is data that has the potential for significant, long-term risk to the financial or reputational health of the total Company if disclosed, made unavailable, or modified without authorization. (This represents confidential financial or business data or material business operations which, if disclosed or compromised, could require SEC disclosure.) This is also data on intellectual property which would create a significant competitive disadvantage to the total Company if shared externally (i.e., upstream innovation that will disrupt the industry).

- Potentially unrecoverable impact
- Would impact OTSR or NOS
- Cannot be shared externally in totality - a subset of the Secret may be shared with a 3rd party using the handling and protection standards for Highly Restricted
- Expected to be <1% of the total company's data by volume.

4. Personal data:

Personal data (also known as PII) is classified based on the types of data processed (name, credit card #, etc.) and volumes of personal data processed or handled by the end user. Employees handling or processing personal data should consult with a Legal expert to determine the proper classification of their personal data. The personal data classification will match with the other classifications in this document (e.g., Business Use, Highly Restricted, etc.) and therefore involve similar handling requirements. The processing, handling and storage of personal data (PII) records must be conducted according to work processes, applications, database, tools, or systems designed and approved to handle this information. Do not process personal data records outside of these approved work processes. If you arehandling or storing any personal data in electronic or hardcopy/offline format beyond your own career data *(e.g.,* 5 Rocks) or data about your organizational team, please consult privacy.pg.com to understand whetheryou should continue to store or process this data or whether it should be handled in an approved and qualified data processing application.

5. Storage, Security & Retrieval

5.1 Good storage area must be a clean pest-free environment, moderate conditions of temperature and humidity, easy to retrieve, authorized access and removal of documents.

5.2 Highly restricted and secret records must be kept in a locked cabinet and labelled with document classification to prevent unauthorized access and removal. Technical standards which are used directly on the line/lab could be kept in close cabinets if access to storage area is controlled.

5.3 Records that are old but still within the retention limits should be kept in the archive.

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5.4 Records should be kept in a clean location and access limited using administrative control

5.5 Computer Records:

5.5.1 Regular backups of all computer-based records will be made on one-drive to maintain the integrity and security of electronic records.

5.5.2 Magnetic media (computer disks, computer backup) will be stored in a clean, secure environment free from electromagnetic interference (EMI), vibrations, and extremes of temperature and humidity. Consult with the site Information Technology group to select a suitable place.

6 Records Retention

6.1 Where necessary/applicable, an index will be kept of records to allow **easy and prompt** retrieval.

6.1.1 The index will be reviewed at on timely basis as applicable to ensure accuracy.

6.1.2 At every change (e.g. addition), the index will be updated.

6.1.3 For records with index, there will be a SIGN-OUT page to ensure tracking of temporarily removed records.

6.2 Records review shall be done annually following on-line roll out from the company.

6.3 Retain records as follows, unless local regulations dictate otherwise:

Company's requirement on Retention limit can be found in http://retentionschedule.pg.com.

RECORD	DESCRIPTION	' RETENTION PERIOD (YEARS)
Assessments - Acquisitions, Divestitures and Licensee	Records and supporting data for external quality assurance assessments, including resulting fellow- up. CAPA's, risk assessment, mitigation plans, transition plans and continuous improvement.	10 years
Assessments - CQA	Records and supporting data for periodic Internal and External Business Partner (contractor, vendor or supplier) quality assurance assessments. Includes resulting follow- up, CAPA's, risk assessment and mitigation plans. Also includes IT Vendors and Data Centers.	10 years
Batch Production Records	Batch production records involving production, packing and labeling of products sold to the consumer or for preclinical/clinical trials. Includes line clearance/start-up, starting material usage/traceability, production, process control, inspection, quality records, QA review/release, test market records, chemical development records, experimental orders, certification /characterization lot, use and risk assessment test	6 years
Certifications, Registrations, Licenses and Permits	ISO	Term of permit/license + 3 years

Cleaning and Sanitization	Equipment cleaning and sanitization, verify compliance with written procedures.	6 years

Computer System - User account reviews	Records documenting the periodic review of computer system access and user access/authority. Documentation outlining the qualifications and authorization of a user to have access to a defined area, process, information or software application affected by GMP, GLP, GCP for the FDA (Food & Drug Admin or equivalent).	Date superseded + 6 years Date superseded + 3 years (non-GMP)
Consumer & Customer Comments/Complaints	Non-Adverse Event comments, complaints and inquires on distributed, marketed products and those used in Clinical & Consumer Studies. Includes summary reports, comment files, investigation records, communications and supporting literature searches.	6 years
Contracts and Quality Agreements	Documents the obligations between Company and outside parties. Includes contracts, banking agreements and memorandum of agreement (MOA) for products, services, sales, service level agreements (SLA), Quality (QATA), confidentiality (CDA's), and guarantees/warranties. Some contracts are kept within SAP as a price master list to a purchase order (PO)	Life of contract + 6 years
Destruction and Disposal	Material status and traceability, FIFO inventory, site inventory adjustments (including scrapping). Review Country Hold List before disposal,	8-28 years (per country hold list)
Distribution Records	Recording detailing the finished product and raw material lot numbers corresponding to shipment records for recall purposes affected by Food Drug & Cosmetic Acts or international equivalent. Truck inspection, BOL, product status and lot traceability.	6 years
Equipment Records - Validation	Manuals, warranties, vendor verification, drawings, and validation records for GMP product making, packing, laboratory or utility equipment and instruments.	Life of equipment + 6 years (GMP)
Equipment Records - Usage Logs	Equipment usage records for product making, packing, laboratory instruments and utilities.	Life of equipment + 6 years

Inventory Record Accuracy (IRA)	Records relating to the physical accounting of inventory in a Plant by item code (e.g. GCAS#) on warehouse and production floors. Information used to maintain system accuracy between the company inventory system (e.g. SAP) and the manufacturing (or floor) inventory system (e.g. RTCIS, WAP)	1 year
Maintenance, Calibration, Process Control Records	Equipment usage, maintenance, settings and centerline records for production, packing, laboratory, utility equipment or instruments. Includes but not limited to repairs, preventative maintenance, cleaning, calibration, water and waste removal.	Life of Equipment + 6 years (GMP) Life of Equipment + 3 years (non-GMP)
Materials - Receipt and Inventory	Material receipt, Bill of Lading (BOL), Certificate of Analysis (COA), incoming sampling, inspection, status, FIFO and traceability.	6 years
Mock Retrieval Assessments	Annual Mock Retrieval report, supporting data and reconciliation	3 years
Out of Specification and Deviation Records	Investigation reports and disposition. Quality test results and lot information for raw material, packaging, finished product and returns. Includes deviation reports, off quality production; hold notices, variation reports, rejection reports and disposition notices and may include physical materials/product samples	6 years
Pest Control	Routine inspection and maintenance of facility, devices and use of chemicals	6 years
Policies & Procedures	Procedures, manuals and guides that document approved methods, processes or directives for performing activities to ensure uniformity (supporting GMP, GLP or GCP or international equivalent). Includes functional area or department level Policies, Procedures, Work Instructions, Current Best Approach, FAQ, Reference Documents, Guidance Documents, etc.	Date superseded + 3 years

Process Development - Make & Pack	Documents the development of a manufacturing / packaging process (Knowledge Package) which is given to Product Supply when finalized. Includes transformation and process flow sheets & diagrams that show the process, ingredients and systems to make and pack, centerline worksheet, process development records, capability data, reports, etc.	10 years
Quality Alerts, Incidents, Deviations and Investigations	Notification, investigation, follow-up records and CAPA's for quality system failures	6 years
Quality Testing- In process and finished product (includes analytical)	Quality test results and lot information for raw material, packaging, in-process, finished product and returns. Includes COA, deviation reports, off quality, hold notices, variation reports, rejection reports and disposition notices. (Lab notebooks, reagents and solutions prep, instrument logbooks, reference standards data, raw data, calculations, results and QA release)	6 years
Regulatory Inspections, Commitments and Evidence of Completion	Records documenting results from inspection or investigation by a regulatory agency (i.e. Food & Drug Admin, FDA or other international equivalent). Including violation notice, settlement/agreement and actions taken to resolve any outages.	Closed+6 years
Returns - Customer	Product return documentation, traceability, evaluation, status and disposition.	Date of Return + 4 years or (Exp Date +1)
Specifications and Standards - Artwork & Copy	Approved artwork & copy for material release and regulatory claims. Illustrations, technical specifications and drawings of product containers, labels and packaging materials artwork	Date superseded + 20 years
Specifications and Standards — Formula Cards	Product formula and sampling information, testing requirements, limits, etc.	75 years
Specifications and Standards - Making & Packing Instructions	Contains all package elements for a given Finished Product (SKU). Lists pack materials, assembly instructions, trade weights & dimensions and approved countries for sale.	Date superseded + 6 years Date superseded + 3 years (non- GMP)

Temperature and Humidity Monitoring	Records of warehouse and transportation storage conditions. May include mapping studies. Environment monitoring and equipment maintenance records for GMP (Good Manufacturing Practice) product making, packing, laboratory, utility equipment or instruments. Includes but not limited to repairs, preventative maintenance, cleaning, calibration, temperature / humidity charts.	6 years
Training Materials	Documentation of each course's content including any material, manuals, job aids for training that support product work under GMP, GLP, GCP (or international equivalent).	Date superseded + 6 years Date superseded + 3 years (non GMP
Training Records	Training records for each employee that supports product work requiring training under GMP, GLP, GCP regulations (or international equivalent). May include training materials, training plans, curriculum vitae (CV's), completion certificates, and knowledge checks.	Period of employment + 6 years Period of Employment + 3 years (non GMP)
Validation - Computer Systems	Computer system validation protocols, reports and supporting data. Includes Corporate Enterprise-Wide IT systems. Qualification, verification, risk assessment and mitigation plans of computer systems equipment and software including change control.	Life of system + 8 years
Validation - Control Systems	Control system validation protocols, reports and supporting data. Records and documentation relating to the Qualification (Input, Output and Process Qualification) of the operation and performance of equipment, software or process components and change control.	Life of system + 8 years
Validation- Equipment	Equipment IQ/OQ validation protocols, reports, drawings, supporting data and documentation.	Life of equipment + 6 years
Validation - Utilities	Utilities (HVAC, Water, Compressed Air, etc.) validation protocols, reports and supporting data.	Life of equipment / process + 6 years

REASON FOR UPDATE

Version 0: New SOP

End of Procedure

SOP RELATED ATTACHMENTS

Attachment 1 – Qualification sheet
Attachment 2 -- OPL on Error Correction
Attachment 3 – Model Answers

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